

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**resTORbio, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**2834**  
(Primary Standard Industrial  
Classification Code Number)

**81-3305277**  
(I.R.S. Employer  
Identification No.)

**501 Boylston Street, Suite 6102  
Boston, MA 02116  
(617) 482-2333**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Chen Schor**  
**President and Chief Executive Officer**  
**resTORbio, Inc.**

**501 Boylston Street, Suite 6102  
Boston, MA 02116  
(617) 482-2333**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:**

As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting

company

Emerging growth company

(Do not check if a  
smaller reporting company)

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

**CALCULATION OF REGISTRATION FEE**

Class of Securities To Be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)
Common Stock, \$0.0001 par value per share	\$	\$

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion  
Preliminary Prospectus dated \_\_\_\_\_, 2018

**PROSPECTUS**



**Common Stock**

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This is restTORbio, Inc.'s initial public offering. We are selling \_\_\_\_\_ shares of our common stock.

We expect the public offering price to be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share. Currently, no public market exists for the shares. We intend to apply to list our common stock on The Nasdaq Global Market under the symbol "TORC."

**We are an "emerging growth company" under federal securities laws and are subject to reduced public company disclosure standards. See "Summary—Implications of Being an Emerging Growth Company."**

**Investing in the common stock involves risks that are described in the "[Risk Factors](#)" section beginning on page 11 of this prospectus.**

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	<u>Per Share</u>	<u>Total</u>
Public offering price	\$ _____	\$ _____
Underwriting discounts and commissions(1)	\$ _____	\$ _____
Proceeds to us before expenses	\$ _____	\$ _____

(1) We refer you to "Underwriting" beginning on page 172 of this prospectus for additional information regarding underwriting compensation.

The underwriters may also exercise their option to purchase up to an additional \_\_\_\_\_ shares from us, at the public offering price, less underwriting discounts and commissions, for 30 days after the date of this prospectus.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

The shares will be ready for delivery on or about \_\_\_\_\_, 2018.

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**BofA Merrill Lynch**

**Leerink Partners**

**Wedbush PacGrow**

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The date of this prospectus is \_\_\_\_\_, 2018.

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Neither we nor the underwriters have authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus, any amendment or supplement to this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. Neither we nor the underwriters take responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

## SUMMARY

*This summary highlights, and is qualified in its entirety by, the more detailed information and financial statements included elsewhere in this prospectus. This summary does not contain all of the information that may be important to you. You should read and carefully consider the entire prospectus, especially our financial statements and the notes thereto appearing at the end of this prospectus and the “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of this prospectus, before deciding to invest in our common stock. Except as otherwise indicated herein or as the context otherwise requires, references in this prospectus to “resTORbio,” “the Company,” “we,” “us” and “our” refer to resTORbio, Inc.*

### Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapeutics for the treatment of aging-related diseases. Our lead program has demonstrated in several clinical trials, including a randomized, placebo-controlled trial, the potential to treat multiple diseases of aging for which there are no approved therapies. The decline in immune function that occurs during aging, or immunosenescence, increases susceptibility to a variety of diseases, including respiratory tract infections, or RTIs, that significantly contribute to morbidity and mortality in the elderly. Our approach focuses on the mechanistic target of rapamycin, or mTOR, pathway, an evolutionarily conserved pathway that regulates aging, and specifically on selective inhibition of the target of rapamycin complex 1, or TORC1. Our initial focus is on the development of RTB101, an orally administered, small molecule, potent TORC1 inhibitor, alone and in combination with other mTOR inhibitors such as everolimus—as a first-in-class immunotherapy program designed to improve immune function and thereby reduce the incidence of RTIs in the elderly regardless of the causative pathogen. We licensed the worldwide rights to our TORC1 program, including RTB101 alone or in combination with everolimus or other mTOR inhibitors, from Novartis International Pharmaceutical Ltd., or Novartis, in March 2017.

Our TORC1 immunotherapy approach is supported by a randomized, placebo-controlled Phase 2a clinical trial in 264 elderly subjects that provided statistically significant and clinically meaningful results. This trial demonstrated that treatment with RTB101 alone and in combination with everolimus can enhance the ability of the aging immune system to fight infectious pathogens and consequently reduce the incidence of all infections, including RTIs in elderly subjects. Six weeks of treatment with RTB101 alone and in combination with everolimus met a prespecified endpoint of reducing the incidence of infections by 33% and 38%, respectively, during a period of one year following initiation of therapy. We are evaluating RTB101 alone and in combination with everolimus in a Phase 2b clinical trial for the reduction in the incidence of RTIs in the elderly and expect to report top-line data from this trial in the second half of 2018.

**Our Product Pipeline**

The following table summarizes key information about our product candidates.

Program	Indication	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones
TORC1 Program: RTB101 and RTB101+ Everolimus	Respiratory Tract Infections	[Progress bar from Discovery to Phase 2]					Phase 2b top-line data in 2H 2018
	Other Infections*	[Progress bar from Discovery to Phase 1]					
	Heart Failure with Preserved Ejection Fraction	[Progress bar from Discovery to Phase 1]					Initiation of at least one Phase 2 trial in 2018**
	Autophagy-Related Neurodegenerative Diseases	[Progress bar from Discovery to Phase 1]					

\* Other infections include those that the elderly are at increased risk of contracting, such as urinary tract infections.

\*\* For heart failure with preserved ejection fraction, autophagy-related neurodegenerative diseases and certain other infections, we may be required to file an investigational new drug application, or IND, prior to initiating Phase 2 clinical trials. We expect to have the ability to initiate these Phase 2 clinical trials without the need to conduct prior Phase 1 clinical trials.

We also have a follow-on TORC1 inhibitor program at discovery stage.

We expect market exclusivity for RTB101 alone and in combination with everolimus until at least 2031 in the United States, 2032 in major European markets, and 2030 in Japan, and additional pending patent applications may prolong the exclusivity of these product candidates up to 2036.

**TORC1 Inhibition for Improving Immune Function in the Elderly**

Recent scientific findings, including those published in the scientific journals Cell, Nature and Science suggest that aging and aging-related conditions, such as immunosenescence, are attributable not only to random cellular wear and tear, but also to specific intra-cellular signaling pathways, including the mTOR pathway. mTOR is a protein kinase that signals via two multiprotein complexes, known as TORC1 and TORC2. TORC1 inhibition has been observed to prolong lifespan, enhance immune function, ameliorate heart failure, enhance memory and mobility and delay the onset of aging-related diseases in multiple animal studies. Specifically with respect to enhanced immune function, TORC1 inhibition was observed in preclinical studies to rejuvenate blood, or hematopoietic, stem cell function, increase infection-fighting white blood cell production and enhance antibody-mediated, or adaptive, immunity. On the other hand, TORC2 inhibition has been observed to decrease lifespan in preclinical studies and cause unwanted side effects of hyperlipidemia and hyperglycemia in certain animals and humans. Therefore, based on these observations and data from the Phase 2a clinical trial, we believe our TORC1 program is well-suited to improve immune function and counteract immunosenescence in the elderly.

**High Unmet Need for Addressing Respiratory Tract Infections in the Elderly**

The reduced ability of elderly patients to effectively detect and fight infections is most commonly manifested in their susceptibility to RTIs and the negative effects such infections have on their overall health. According to the U.S. Census Bureau, RTIs are the fifth leading cause of death in people age 85 and over and the

seventh leading cause of death in people age 65 and over, and result in high healthcare burdens and costs for the elderly population and the healthcare system. The majority of RTIs are caused by viruses for which there are no approved therapies. Despite this, antibiotics, which are ineffective against viruses, are often prescribed indiscriminately to treat RTIs, which may cause side effects related to antibiotic use and contribute to the growing global problem of antibiotic resistance. As the elderly represent the fastest growing population in all regions of the world, we believe there is significant unmet medical need for innovative therapeutic options for reducing the incidence of RTIs by enhancing the function of the aging immune system.

***Our TORC1 Program for Addressing Respiratory Tract Infections in the Elderly***

We believe our approach to addressing RTIs in the elderly possesses several clinical and commercial advantages. Our TORC1 program offers an immunotherapy approach that has the potential to address a broad range of viral, and potentially bacterial, pathogens. Statistically significant and clinically meaningful reductions in RTI incidence were observed in the Phase 2a clinical trial that evaluated RTB101 alone and in combination with everolimus. We believe the risk-to-benefit ratio of our program is well-suited to the elderly due to the following observations: our oral product candidates were well-tolerated in elderly subjects and were associated with no study drug-related serious adverse events in the Phase 2a clinical trial, and the doses being investigated in our ongoing Phase 2b clinical trial are 60 to 240 times lower than maximum tolerated doses established in prior clinical trials for other indications. Based on communications, including those during a high-level policy meeting, with the U.S. Food and Drug Administration, or FDA, to date, we believe a reduction in the incidence of RTIs has the potential to be a clinically relevant endpoint.

We are conducting a randomized, double-blinded, placebo-controlled Phase 2b clinical trial to assess the safety, tolerability and efficacy of 16 weeks of treatment with RTB101 alone or in combination with everolimus as compared to placebo in elderly patients without unstable medical conditions but who are at increased risk of RTI-related morbidity or mortality. Elderly patients at increased risk of RTI-associated morbidity and mortality are defined as subjects who are 85 years of age or older or subjects 65 years of age or older with asthma, chronic obstructive pulmonary disease, chronic bronchitis, Type 2 diabetes mellitus, congestive heart failure, an emergency room visit or hospitalization for an RTI within the past 12 months, or who are current smokers. We are conducting the trial in two parts across two hemispheres. The first part was conducted during the winter cold and flu season in the southern hemisphere. Following an interim analysis that we conducted in October 2017, we commenced the second part during the winter cold and flu season in the United States in the fourth quarter of 2017. We expect to report top-line data from this trial in the second half of 2018. The primary endpoint of the trial is to assess the potential of RTB101 alone or in combination with everolimus to decrease the percentage of subjects with RTIs compared to placebo during the 16-week administration period.

If the results from the ongoing Phase 2b clinical trial are positive, we intend to conduct two Phase 3 pivotal clinical trials across two hemispheres. The Phase 3 clinical program is expected to start in the southern hemisphere in the first half of 2019 at the beginning of the winter cold and flu season and run through the second quarter of 2020. If our Phase 3 clinical trials are successful, we anticipate filing a New Drug Application, or NDA, with the FDA in 2020, and a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, in 2021.

***Other Potential Indications for Our TORC1 Program***

We may evaluate RTB101 alone or in combination with everolimus or other drugs for the treatment of additional indications, such as heart failure with preserved ejection fraction, urinary tract infections, Huntington's disease and Parkinson's disease. We plan to initiate at least one Phase 2 proof of concept study in 2018. We expect to select indications based on strong scientific rationale, preclinical or clinical data, unmet medical need and other relevant considerations.

### ***Company Management and Investors***

We were founded by Chen Schor, who serves as our President and Chief Executive Officer, Joan Mannick, M.D., who serves as our Chief Medical Officer, and PureTech Health LLC, or PureTech Health, an advanced clinical-stage biopharma company. Dr. Mannick led the TORC1 clinical program at Novartis Institutes for Biomedical Research, or NIBR, prior to our in-licensing of the program. Our management team includes veterans in drug development and discovery, with executive experience in leading global pharmaceutical companies. We are supported by investors that include both private equity venture capital funds and public healthcare investment funds. Our investors include OrbiMed Advisors, Fidelity Management & Research Company, Rock Springs Capital, Quan Capital and Nest Bio.

### **Our Strategy**

Our goal is to be a leading biopharmaceutical company focused on treating aging-related diseases. We strive to maintain a leadership position in the TORC1 inhibitor class of pharmaceutical products. The key elements of our strategy to achieve this goal include:

- Rapidly advance our TORC1 program as immunotherapy for reducing the incidence of RTIs in elderly subjects;
- Develop our TORC1 program for additional indications;
- Commercialize our product candidates in the United States and potentially collaborate with others globally to maximize their commercial value;
- Maintain and grow a robust intellectual property portfolio in the field of TORC1 inhibition for aging-related diseases; and
- Develop, acquire or in-license product candidates that enhance our global leadership position.

### **Risks Associated with Our Business**

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the “Risk Factors” section of this prospectus immediately following this prospectus summary. These risks include the following:

- We have a limited operating history, have incurred significant operating losses since inception, expect to incur significant and increasing losses for the foreseeable future, will need substantial additional funding and may never achieve or maintain profitability; investors may lose their entire investment;
- Our business has no history of commercialization and depends virtually entirely upon the success of RTB101 alone or in combination with everolimus, which is still under clinical development. If we are unable to obtain regulatory approval for or successfully commercialize RTB101, our business would be materially harmed. Even if we receive regulatory approval to market product candidates, the market may not be receptive to our product candidates upon their commercial introduction, which will prevent us from becoming profitable;
- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if any;

- We may be subject to additional risks because we are administering RTB101 in combination with other mTOR inhibitors, such as everolimus;
- If we fail to develop RTB101 alone or in combination with an mTOR inhibitor for additional therapies or develop other product candidates, we may be unable to grow our business;
- Use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates or products, or necessary quantities at an acceptable cost;
- Our commercial success depends on our ability to protect our intellectual property and proprietary technology;
- We depend heavily on our executive officers and principal consultants and the loss of their services could materially harm our business; and
- Immediately after the closing of this offering, % of our outstanding common stock will be held by our directors, executive officers and 5% stockholders and % will be held by our public stockholders. Concentration of ownership of our common stock may prevent new investors in this offering from influencing significant corporate decisions.

### **Our Corporate Information**

We were incorporated under the laws of the State of Delaware on July 5, 2016 under the name resTORbio, Inc. Our executive offices are located at 501 Boylston Street, Suite 6102, Boston, Massachusetts 02116, and our telephone number is (617) 482-2333. Our website address is [www.restorbio.com](http://www.restorbio.com). The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

In this prospectus, unless otherwise stated or the context otherwise requires, references to “resTORbio,” “the Company,” “we,” “us,” “our” and similar references refer to resTORbio, Inc. resTORbio and other trademarks or service marks of resTORbio appearing in this prospectus are the property of resTORbio. The other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

### **Implications of Being an Emerging Growth Company**

As a company with less than \$1.07 billion of revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We may remain an emerging growth company for up to five years, or until such earlier time as we have more than \$1.07 billion in annual revenue, the market value of our stock held by non-affiliates is more than \$700.0 million or we issue more than \$1.0 billion of non-convertible debt over a three-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure and other requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;



- reduced disclosure about our executive compensation arrangements;
- no non-binding advisory votes on executive compensation or golden parachute arrangements;
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting; and
- an exemption from new or revised financial accounting standards until they would apply to private companies and from compliance with any new requirements adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation.

In particular, in this prospectus, we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. We are considering whether to “opt out” of the exemption for the delayed adoption of certain accounting standards and thereby be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. If we do elect to “opt out” of this exemption, such election is irrevocable.

**THE OFFERING**

Common stock offered by us	shares
Common stock to be outstanding immediately following this offering	shares ( shares if the underwriters exercise their option to purchase additional shares of common stock in full)
Option to purchase additional shares	The underwriters have the option to purchase an additional shares of common stock. The underwriters may exercise this option at any time within 30 days from the date of this prospectus.
Use of proceeds	<p>We estimate that the net proceeds to us from this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately \$ million, or approximately \$ million if the underwriters exercise their option to purchase additional shares from us in full, assuming an initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus.</p> <p>We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund the development of RTB101, alone and in combination with everolimus, for RTIs and other indications, and our TORC1 follow-on candidate and other pipeline candidates, and the remainder, if any, for working capital and general corporate purposes. See the “Use of Proceeds” section in this prospectus for a more complete description of the intended use of proceeds from this offering.</p>
Risk factors	You should read the “Risk Factors” section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Proposed Nasdaq Global Market symbol	“TORC”
<p>The number of shares of our common stock to be outstanding after this offering is based on shares of our common stock outstanding as of and additional shares of our common stock issuable upon the automatic conversion of all outstanding shares of our preferred stock upon the closing of this offering.</p> <p>The number of shares of our common stock to be outstanding after this offering excludes:</p> <ul style="list-style-type: none"><li>• shares of our common stock issuable upon the exercise of stock options outstanding as of , 2017, at a weighted average exercise price of \$ per share;</li><li>• additional shares of our common stock available for future issuance as of , 2017 under our 2017 stock incentive plan; and</li></ul>	

- additional shares of our common stock that will become available for future issuance under our 2018 stock incentive plan and our 2018 employee stock purchase plan that we intend to adopt in connection with this offering.

Unless otherwise indicated, all information in this prospectus assumes or gives effect to:

- no exercise of the outstanding options described above;
- no exercise by the underwriters of their option to purchase up to additional shares of our common stock;
- the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 20,320,667 shares of our common stock upon the closing of this offering;
- a 1-for- reverse split of our common stock effected on ; and
- the amendment and restatement of our certificate of incorporation and the amendment and restatement of our bylaws upon the closing of this offering.

## SUMMARY FINANCIAL DATA

The following tables summarize our financial data as of the dates and for the periods indicated. The statements of operations data for the period from July 5, 2016 (inception) through December 31, 2016 and the nine months ended September 30, 2017 and the balance sheet data as of September 30, 2017 have been derived from our audited financial statements included elsewhere in this prospectus. The statement of operations data for the period from July 5, 2016 (inception) through September 30, 2016 have been derived from our unaudited financial statements included elsewhere in this prospectus and have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal, recurring adjustments, necessary for a fair statement of the financial information in those statements. Our historical results from any prior period are not necessarily indicative of results to be expected in any future period, and our interim period results are not necessarily indicative of results to be expected for a full year or any other interim period. The summary financial data below should be read in conjunction with the sections entitled “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes included elsewhere in this prospectus.

	July 5, 2016 (inception) through December 31, 2016	July 5, 2016 (inception) through September 30, 2016	Nine Months Ended September 30, 2017
(In thousands, except share and per share data)			
<b>Statements of Operations Data:</b>			
Operating expenses:			
Research and development	\$ —	\$ —	\$ 10,047
General and administrative	1	1	1,312
Total operating expenses	<u>1</u>	<u>1</u>	<u>11,359</u>
Loss from operations	(1)	(1)	(11,359)
Other income, net	—	—	635
Net loss	<u>\$ (1)</u>	<u>\$ (1)</u>	<u>\$ (10,724)</u>
Net loss per share, basic and diluted <sup>(1)</sup>	<u>\$ (0.00)</u>	<u>\$ (0.00)</u>	<u>\$ (2.18)</u>
Weighted-average common shares used in computing net loss per share, basic and diluted <sup>(1)</sup>	<u>2,532,807</u>	<u>2,458,164</u>	<u>4,915,847</u>
Pro forma net loss per share, basic and diluted <sup>(1)</sup>			<u>\$ (1.02)</u>
Weighted-average common shares used in computing pro forma net loss per share, basic and diluted <sup>(1)</sup>			<u>10,538,278</u>

- (1) See Notes 2 and 12 in the notes to our financial statements included elsewhere in this prospectus for an explanation of the calculation of our basic and diluted net loss per share, the weighted-average common shares used in computing basic and diluted net loss per share, basic and diluted pro forma net loss per share and the weighted-average common shares used in computing basic and diluted pro forma net loss per share. The information presented in this table does not give effect to the sale and issuance of our Series A preferred stock in October 2017 and Series B preferred stock in November 2017.

	As of September 30, 2017		
	Actual	Pro Forma(2)	Pro Forma As Adjusted(3)
(In thousands)			
<b>Balance Sheet Data:</b>			
Cash	\$ 3,965	\$58,895	\$
Working capital(1)	684	56,993	
Total assets	4,215	59,145	
Total liabilities	3,495	2,116	
Redeemable convertible preferred stock	9,764	—	
Total stockholders' (deficit) equity	(9,044)	57,029	

(1) We define working capital as current assets less current liabilities.

(2) Pro forma amounts give effect to (i) the sale and issuance of 7,763,975 shares of our Series A preferred stock in October 2017 for aggregate net proceeds of \$15.0 million, (ii) the sale and issuance of 4,792,716 shares of our Series B preferred stock in November 2017 for aggregate net proceeds of \$39.9 million and (iii) the automatic conversion of all of our outstanding shares of preferred stock into an aggregate of 20,320,667 shares of common stock upon the closing of this offering.

(3) Pro forma as adjusted amounts reflect pro forma adjustments described in footnote (2) as well as the sale of \_\_\_\_\_ shares of our common stock in this offering at the assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total stockholders' equity by approximately \$ \_\_\_\_\_ million, assuming that the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total stockholders' equity by approximately \$ \_\_\_\_\_ million, assuming the assumed initial public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all other information in this prospectus, including our financial statements and related notes and “Management’s Discussion and Analysis of Results of Operations and Financial Condition,” before investing in our common stock. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations. The market price of our common stock could decline if one or more of these risks or uncertainties actually occur, causing you to lose all or part of your investment in our common stock. The risks and uncertainties we describe below are not the only ones we face. Additional risks and uncertainties that we currently do not know about or that we currently believe to be immaterial may also impair our business. Certain statements below are forward-looking statements. See “Special Note Regarding Forward-Looking Statements and Industry Data” in this prospectus.*

### **Risks Related to Our Financial Position and Need for Capital**

***We have incurred significant losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability.***

We are a clinical-stage biopharmaceutical company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we will continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in July 2016. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and our clinical trials. Our financial condition and operating results, including net losses, may fluctuate significantly from quarter to quarter and year to year. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. Additionally, net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders’ equity and working capital. For the period from July 5, 2016 (inception) to December 31, 2016, we reported a net loss of \$1,000. For the nine months ended September 30, 2017, we reported a net loss of \$10.7 million. As of September 30, 2017, we had an accumulated deficit of \$10.7 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, RTB101, alone or in combination with everolimus, and other product candidates.

We anticipate that our expenses will increase substantially if and as we:

- continue to develop and conduct clinical trials for our lead product candidate, RTB101, alone and in combination with everolimus;
- initiate and continue research, preclinical and clinical development efforts for any current or future product candidates;
- seek to identify additional product candidates;
- seek regulatory approvals for RTB101, alone or in combination with everolimus, or any other product candidates that successfully complete clinical development, if any;
- establish sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure in the future to commercialize various products for which we may obtain regulatory approval, if any;

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- require the manufacture of larger quantities of RTB101 alone or in fixed dose combination with everolimus for clinical development and, potentially, commercialization;
- maintain, expand and protect our intellectual property portfolio;
- hire and retain additional personnel, such as clinical, quality control, scientific and commercial personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and help us comply with our obligations as a public company;
- add equipment and physical infrastructure to support our research and development; and
- acquire or in-license other product candidates and technologies.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we are, or any future collaborator is, able to obtain regulatory approval for, and successfully commercialize, RTB101, alone or in combination with everolimus, or any other product candidates. Successful commercialization will require achievement of key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory, including marketing, approval for these product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we do, or any future collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Additionally, our expenses could increase if we are required by the U.S. Food and Drug Administration, or FDA, or any comparable foreign regulatory authority to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates.

Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment.

***Our company has a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.***

We were formed in July 2016 and commenced research and development operations in March 2017. Our operations to date have been limited to organizing, staffing and financing our company, raising capital, in-licensing our technology and conducting research and development activities for our product candidates. We have not yet demonstrated an ability to obtain regulatory approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will eventually need to transition from a company with

a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

***We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product discovery and development programs or commercialization efforts.***

Our operations have required substantial amounts of cash since inception. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. For the foreseeable future, we expect to continue to rely on additional financing to achieve our business objectives.

From July 5, 2016 (inception) to December 31, 2016, we did not use any cash for our operating activities, and in the nine months ended September 30, 2017, we used \$6.0 million in net cash for our operating activities, substantially all of which related to research and development activities. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we initiate new clinical trials of, initiate new research and preclinical development efforts for and seek regulatory approval for, RTB101, alone or in combination with everolimus, or any product candidates that we develop or acquire, if any. In addition, if we obtain regulatory approval for RTB101, alone or in combination with everolimus, or any other product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Some of these expenses may be incurred in advance of regulatory approval, and could be substantial. Furthermore, following the completion of this offering, we expect to incur significant additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We intend to use the net proceeds from this offering, together with our existing cash, to fund the development of RTB101, alone and in combination with everolimus, for RTIs and other indications, and of our TORC1 follow-on candidate and other pipeline candidates, and the remainder, if any, for working capital and general corporate purposes. We will be required to expend significant funds in order to advance the development of RTB101 alone and in combination with everolimus, as well as other product candidates we may seek to develop or acquire. In addition, while we may seek one or more collaborators for future development of RTB101 alone and in combination with everolimus for one or more additional indications beyond immunosenescence or in geographies outside of the United States, Europe and key territories, we may not be able to enter into a collaboration for RTB101 or any other product candidates for such indications or in such geographies on suitable terms, on a timely basis or at all. In any event, the net proceeds of this offering and our existing cash will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development of RTB101 alone or in combination with everolimus, including activities related to the development of RTB101, alone and in combination with everolimus, for RTIs and other indications, and the development of our TORC1 follow-on candidate and other pipeline candidates. Accordingly, we will be required to obtain substantial additional funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources.

We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Any of our current or future license agreements may also be terminated if we are unable to meet the payment or other obligations under the agreements. We could be required to seek collaborators for product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.



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We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through . Our estimate may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements, both short- and long-term, will depend on many factors, including:

- the scope, progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for, RTB101, alone or in combination with everolimus, and any future product candidates;
- our ability to enter into, and the terms and timing of, any collaborations, licensing or other arrangements on favorable terms, if at all;
- the number of future product candidates that we pursue and their development requirements;
- the outcome, timing and costs of seeking regulatory approvals;
- if approved, the costs of commercialization activities for RTB101, alone or in combination with everolimus, or any other product candidate that receives regulatory approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of RTB101, alone or in combination with everolimus, or any future product candidates;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay pursuant to our license agreement;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

***Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, your ownership interest may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

If we raise additional funds through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***Our ability to use net operating losses and research and development credits to offset future taxable income may be subject to certain limitations.***

As of September 30, 2017, we had federal and state net operating loss carryforwards of \$7.5 million and \$7.4 million, respectively, which begin to expire in various amounts in 2036. As of September 30, 2017, we also had federal research and development tax credit carryforwards of \$0.1 million, which begin to expire in 2037. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after this offering, our ability to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. If we determine that an ownership change has occurred and our ability to use our historical NOLs or credits is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U. S. federal and state taxable income. As described above under "Risk Factors—Risks Related to our Financial Position and Need for Additional Capital," we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOL or credit carryforwards that are subject to limitation by Sections 382 and 383 of the Code.

## Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

***Our business depends virtually entirely upon the success of RTB101 alone or in combination with everolimus. If we are unable to obtain regulatory approval for or successfully commercialize RTB101, alone or in combination with everolimus, our business may be materially harmed.***

We currently have no products approved for sale and are investing the majority of our efforts and financial resources in the development of our lead product candidate, RTB101, either alone or in combination with everolimus. Successful continued development and ultimate regulatory approval of RTB101, alone or in combination with everolimus, for the treatment of aging-related diseases, including our lead indication, reducing the incidence of respiratory tract infections, or RTIs, is critical to the future success of our business. We will need to raise sufficient funds for, and successfully enroll and complete, our clinical development program for RTB101, alone or in combination with everolimus, to treat RTIs and possibly other aging-related diseases. The future regulatory and commercial success of this product candidate is subject to a number of risks, including the following:

- we may not have sufficient financial and other resources to initiate or complete the necessary clinical trials for RTB101, alone or in combination with everolimus;
- we may not be able to obtain adequate evidence of clinical efficacy and safety for RTB101, alone or in combination with everolimus, or to obtain regulatory approval of RTB101, alone or in combination with everolimus, for reducing the incidence of RTIs or other indications;
- even if RTB101 monotherapy succeeds in its clinical development and is approved for one or more targeted indications, there can be no assurance that the RTB101+everolimus combination therapy would be developed successfully and approved, and vice versa;
- we may not be able to maintain an acceptable safety profile for RTB101 alone or in combination with everolimus, even if approved;
- we do not know the degree to which RTB101 alone or in combination with everolimus will have market uptake as a therapy by patients, the medical community or third-party payors, among others, if approved;
- in our clinical programs, we may experience variability in the response of subjects to treatment, the need to adjust clinical trial procedures and the need for additional clinical trial sites, which could delay our clinical trial progress;
- the results of our clinical trials may not meet the level of statistical significance required by the FDA, the European Medicines Agency, or EMA, or comparable foreign regulatory bodies for regulatory approval for reducing the incidence of RTIs or for other indications;
- we may have difficulty enrolling subjects in trials if, for instance, a current or future effective standard of care limits the desire of patients, physicians, or regulatory agencies to participate in or support clinical trials, or if patients choose to participate in the trials of other sponsors' product candidates;
- patients in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to RTB101, which could delay or prevent further clinical development;
- the requirements implemented by regulatory agencies may change at any time;

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- the FDA, EMA or foreign regulatory agencies may require efficacy endpoints for a future clinical trial for reducing the incidence of RTIs that differ from the endpoints of our current or future trials, which may require us to conduct additional clinical trials;
- the mechanism of action of RTB101, alone or in combination with everolimus, is complex and we cannot guarantee the degree to which it will translate into a medical benefit in any indications;
- competitor products including generic products may be developed to reduce the incidence of RTIs that may have similar or better safety and efficacy or lower costs than RTB101 alone or in combination with everolimus;
- we may not be able to establish sales, marketing, distribution and other commercial infrastructure in the future to commercialize various products for which we may obtain regulatory approval;
- we or our contract manufacturers may not be able to manufacture RTB101, everolimus, the fixed dose combination of RTB101 with everolimus or other future product candidates at the appropriate quality or sufficient quantities to support further clinical development and/or commercialization;
- our investigational drug products or manufacturing processes may be considered by regulatory authorities, such as the FDA or EMA, to be unsuitable for continued development and/or commercialization;
- we may observe unexpected toxicities in preclinical safety or efficacy animal studies that delay, limit or prevent further clinical development;
- our intellectual property may not be patentable, valid or enforceable; and
- we may not be able to obtain, maintain, defend, protect or enforce our patents, our trade secrets, regulatory exclusivities and other intellectual property rights, both in the United States and internationally, including those that we have licensed under our license agreement with Novartis.

Many of these risks are beyond our control, including the risks related to clinical development, the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we are unable to develop, receive regulatory approval for, or successfully commercialize RTB101 alone or in combination with everolimus, or if we experience delays as a result of any of these risks or otherwise, our business could be materially harmed.

In addition, of the large number of drugs in development in the pharmaceutical industry, only a small percentage result in the submission of a new drug application, or NDA, to the FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval for RTB101, alone or in combination with everolimus, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure you that we will successfully develop or commercialize RTB101, alone or in combination with everolimus, for RTIs or any other indications. If we or any of our future collaborators are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize RTB101, alone or in combination with everolimus, for RTIs or any other indications, we may not be able to generate sufficient revenue to continue our business.

***We have no experience as a company in obtaining regulatory approval for a drug.***

As a company, we have never obtained regulatory approval for, or commercialized, a drug. It is possible that the FDA may refuse to accept any or all of our planned NDAs for substantive review or may conclude after

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review of our data that our application is insufficient to obtain regulatory approval for any current or future product candidates. If the FDA does not approve any of our planned NDAs, it may require that we conduct additional costly clinical, nonclinical or manufacturing validation studies before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA or other application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any failure or delay in obtaining regulatory approvals would prevent us from commercializing RTB101 alone or in combination with everolimus or any other product candidate, generating revenues and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any NDA or other application that we submit. If any of these outcomes occur, we may be forced to abandon the development of our product candidates, which would materially adversely affect our business and could potentially cause us to cease operations. We face similar risks for our applications in foreign jurisdictions.

***We depend on the successful initiation and completion of clinical trials for RTB101 alone or in combination with everolimus. The positive clinical results, if any, obtained in prior or ongoing clinical trials may not be predictive of future results or repeated in later-stage clinical trials.***

Before obtaining regulatory approval for the sale of RTB101, alone or in combination with everolimus, or any other potential product candidate, we must conduct additional clinical trials to demonstrate safety and efficacy in humans. The regulatory requirements for demonstrating efficacy and safety for obtaining approval for reducing the incidence of RTIs or other indications with RTB101 alone or in combination with everolimus may differ. We have not completed the clinical trials necessary to support an application for approval to market RTB101 alone or in combination with everolimus. Successful completion of such clinical trials is a prerequisite to submitting an NDA to the FDA and, consequently, the ultimate approval and commercial marketing of RTB101 alone or in combination with everolimus or any other potential product candidate. A failure of one or more clinical trials can occur at any stage of testing. We need to complete our ongoing Phase 2b clinical trial of RTB101 alone and in combination with everolimus, and subsequently the requisite Phase 3 clinical trials prior to a submission for regulatory approval. We have conducted limited safety studies in humans to date and have only recently commenced our Phase 2b clinical program to assess the safety, tolerability and efficacy of RTB101, alone or in combination with everolimus, in elderly patients. Additional toxicity and metabolism studies may be required by the FDA or other regulatory agencies. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in late stage clinical development, even after seeing promising results in earlier clinical trials.

We may experience a number of unforeseen events during, or as a result of, clinical trials for RTB101, alone or in combination with everolimus, or any other potential product candidate that could adversely affect the costs, timing, or successful completion of our clinical trials, including:

- regulators or other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators, and/or institutional review boards or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of RTB101, alone or in combination with everolimus, or any other potential product candidate may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

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- the number of subjects or patients required for clinical trials of RTB101, alone or in combination with everolimus, or any other potential product candidate may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of RTB101, alone or in combination with everolimus, or any other potential product candidate for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical trial protocol submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to resubmit to an Institutional Review Board, or IRB, and regulatory authorities for re-examination;
- regulators, institutional review boards or data monitoring committees may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical trials of RTB101, alone or in combination with everolimus, or any other potential product candidate may be greater than we anticipate;
- regulators, institutional review boards or other reviewing bodies may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, or the supply or quality of RTB101, everolimus or the fixed dose combination of RTB101 and everolimus or any other potential product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval; and
- RTB101, alone or in combination with everolimus, or any other potential product candidate may have undesirable side effects or other unexpected characteristics.

Regulators, institutional review boards of the institutions in which clinical trials are being conducted or data monitoring committees may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Negative or inconclusive results from our ongoing clinical trial of RTB101 alone and in combination with everolimus, or any other clinical trial or preclinical studies in animals that we conduct, could mandate

repeated or additional clinical trials. We do not know whether any clinical trials that we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market RTB101, alone or in combination with everolimus, or any other potential product candidate. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for RTB101, alone or in combination with everolimus, or any other potential product candidate may be adversely impacted.

Clinical trials must be conducted in accordance with the laws and regulations of the FDA, EMA and regulations and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under current good manufacturing practice, or cGMP, requirements and other regulations. Furthermore, we rely on CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the United States and EU may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. and non-EU CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA or the EMA, and different standards of diagnosis, screening and medical care.

***We may be subject to additional risks because we are administering RTB101 in combination with other mTOR inhibitors, such as everolimus.***

We are evaluating RTB101 in combination with other mTOR inhibitors. For example, in our ongoing Phase 2b clinical trial, we are assessing the safety, tolerability and efficacy of RTB101 alone and in combination with everolimus. The use of RTB101 in combination with other compounds may subject us to risks that we would not face if RTB101 were being administered as a monotherapy. For example, the other mTOR inhibitors, including everolimus, may have safety issues that are improperly attributed to RTB101 or the administration of RTB101 with such other therapies may result in safety issues that such other therapies or RTB101 would not have when used alone. In addition, other mTOR inhibitors with which we may administer RTB101, such as everolimus, could be removed from the market and thus be unavailable for testing or commercial use concomitantly with RTB101. The outcome and cost of developing a product candidate to be used with other compounds is difficult to predict and dependent on a number of factors that are outside our reasonable control. If we experience efficacy or safety issues in our clinical trials in which RTB101 is being administered with everolimus, we may not receive regulatory approval for RTB101, which could prevent us from ever generating revenue or achieving profitability.

***Competitive products may reduce or eliminate the commercial opportunity for RTB101, alone or in combination with everolimus. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies are more effective or safer than ours, our ability to develop and successfully commercialize RTB101 alone or in combination with everolimus may be adversely affected.***

The clinical and commercial landscape for aging-related diseases is highly competitive and subject to rapid and significant technological change. New data from competitors' product candidates continue to emerge. It is possible that these data may alter the current standard of care, completely precluding us from further developing RTB101, alone or in combination with everolimus, for RTIs or other aging-related diseases. Further, it is possible that we may initiate a clinical trial or trials for RTB101, alone or in combination with everolimus, or any other potential product candidate only to find that data from competing products make it impossible for us to complete enrollment in clinical trials, resulting in our inability to submit applications for regulatory approval

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with regulatory agencies. Even if RTB101 were approved, alone or in combination with everolimus, it may have limited sales due to competition in the specific indications approved.

Competitive therapeutic treatments for aging-related diseases, including RTIs, include those that are currently in development and any new treatments that enter the market. We believe that a significant number of product candidates are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may try to develop product candidates. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. We consider Navitor Pharma to be our most direct competitor in developing novel therapeutics targeting the TORC1 mechanism of action. Additionally, we are also aware of other companies, including Calico and Unity, which are seeking to develop treatments to prevent or treat aging-related diseases through biological pathways that may be unrelated to mTOR inhibition. Similarly, there are several other companies, such as PrEP BioPharm, Virion Health and Innovac, which are pursuing broad-spectrum prophylactic and therapeutic treatments in RTIs.

Many of our competitors have greater financial, technical, manufacturing, marketing, sales and supply resources, and human resources or experience than us and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for therapies and achieving widespread market acceptance. Our competitors' products may be more effective, or more effectively marketed and sold, than any product candidate we may commercialize and may render our therapies obsolete or non-competitive before we can recover development and commercialization expenses. If RTB101, alone or in combination with everolimus, is approved for the indications we are currently pursuing, it could compete with a range of therapeutic treatments that are in development. In addition, our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than RTB101 alone or in combination with everolimus or any other product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete and noncompetitive.

If we obtain approval for RTB101, alone or in combination with everolimus, or any other future product candidate, we may face competition based on many different factors, including the efficacy, safety and tolerability of our products, the ease with which our products can be administered, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Existing and future competing products could present superior treatment alternatives, including being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a small number of competitors.

We also compete with other clinical stage companies and institutions for clinical trial participants, which could reduce our ability to recruit participants for our clinical trials. Delay in recruiting clinical trial participants could adversely affect our ability to bring a product to market prior to our competitors. Further, research and discoveries by others may result in breakthroughs that render our product candidates obsolete even before they begin to generate any revenue.

In addition, our competitors may obtain patent protection, regulatory exclusivities, or FDA approval and commercialize products more rapidly than we do, which may impact future approvals or sales of any of our product candidates that receive regulatory approval. If the FDA approves the commercial sale of RTB101, alone or in combination with everolimus, or any other product candidate, we will also be competing with respect to



marketing capabilities and manufacturing efficiency. We expect competition among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payers, regulatory exclusivities and patent position. Our profitability and financial position will suffer if our product candidates receive regulatory approval, but cannot compete effectively in the marketplace.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, our programs.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for regulatory approval applications can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

***The regulatory approval processes of the FDA, EMA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If clinical trials of RTB101, alone or in combination with everolimus, fail to satisfactorily demonstrate safety and efficacy to the FDA or other regulators, or do not otherwise produce favorable results, we, or any future collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of RTB101 alone or in combination with everolimus.***

We, and any future collaborators, are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. Foreign regulatory authorities, such as the EMA, impose similar requirements. The time required to obtain approval by the FDA, EMA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date, we have not submitted an NDA to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for RTB101, alone or in combination with everolimus, or any other product candidate. We, and any future collaborators, must complete additional preclinical or nonclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of RTB101 alone or in combination with everolimus or other drugs is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements, and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if RTB101, alone or in combination with everolimus, or any other product candidate has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the seasonal and

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geographical RTI rates and size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of RTB101, alone or in combination with everolimus, or any other product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of or intolerability caused by RTB101, everolimus or any other product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us, or any future collaborators. Moreover, if we, or any future collaborators, are required to conduct additional clinical trials or other testing of RTB101, alone or in combination with everolimus, or any other product candidate beyond the trials and testing that we or they contemplate, if we or they are unable to successfully complete clinical trials of our product candidates or other testing or the results of these trials or tests are unfavorable, uncertain or are only modestly favorable, or there are unacceptable safety concerns associated with our product candidates, we, or any future collaborators may:

- incur additional unplanned costs;
- be delayed in obtaining regulatory approval for our product candidates;
- not obtain regulatory approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements; or
- be required to remove the product from the market after obtaining regulatory approval.

Our failure to successfully initiate and complete clinical trials of RTB101, alone or in combination with everolimus, or any other product candidate and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market RTB101, alone or in combination with everolimus, or any other product candidate would significantly harm our business. Our product candidate development costs will also increase if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete clinical trials. We cannot assure you that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of RTB101 alone or in combination with everolimus or any other product candidate.

***Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.***

Undesirable side effects caused by RTB101, alone or in combination with everolimus, or any other product candidate could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In clinical trials of RTB101, alone or in combination with

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everolimus, to date, there were no observed study drug-related serious adverse events in the Phase 2a clinical trial except in the placebo arm. The majority of observed study-drug related adverse events were mild or moderate in severity, transient and resolved without stopping the study drug. However, there can be no guarantee that we would observe a similar tolerability profile of RTB101, alone or in combination with everolimus, in our ongoing Phase 2b clinical trial or in future clinical trials. Many compounds that initially showed promise in clinical or earlier stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound.

If unacceptable side effects arise in the development of our product candidates, we, the FDA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our trials are conducted, or the Data Safety Monitoring Board, or DSMB, could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-emergent side effects that are deemed to be treatment-related could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse consequences could occur:

- regulatory authorities may withdraw their approval of the product, seize the product, or seek an injunction against its manufacture or distribution;
- we, or any future collaborators, may need to recall the product, or be required to change the way the product is administered or conduct additional clinical trials, develop a surveillance program;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- regulatory authorities may require one or more post-market studies;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

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Any of these events could harm our business and operations, and could negatively impact our stock price.

***If we fail to develop and commercialize RTB101, alone or in combination with everolimus, for additional indications or fail to discover, develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.***

Although the development and commercialization of RTB101 alone or in combination with everolimus for RTIs is our primary focus, as part of our longer-term growth strategy, we may evaluate RTB101, alone or in combination with everolimus, in other indications and develop other product candidates. We intend to evaluate internal opportunities from RTB101, alone or in combination with everolimus, or other product candidates from our TORC1 program, and also may choose to in-license or acquire other product candidates as well as commercial products to treat patients suffering from other disorders with significant unmet medical needs and limited treatment options. These other product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and/or applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates that we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If we are unsuccessful in identifying and developing additional product candidates, our potential for growth and achieving our strategic objectives may be impaired.

***Our preclinical programs may not produce new product candidates that are suitable for clinical trials or that can be successfully commercialized or generate revenue through collaborations.***

We must successfully complete preclinical testing for our preclinical programs, including our TORC1 follow-on program, which may include demonstrating activity and comprehensive studies to show the lack of

toxicity and other adverse effects in established animal models, before commencing clinical trials for any product candidate. Many pharmaceutical products do not successfully complete preclinical testing and, even if preclinical testing is successfully completed, may fail in clinical trials. In addition, there can be no assurance that positive results from preclinical studies will be predictive of results obtained from subsequent preclinical studies or clinical trials. Many pharmaceutical candidates are not suitable for manufacture on the scale or of the quality required for clinical trials or commercialization. Some pharmaceutical candidates that initially seem suitable may later be found to be insufficiently stable or may generate toxic impurities over time. We also cannot be certain that any product candidates that do advance into clinical trials will successfully demonstrate safety and efficacy in clinical trials. Even if we achieve positive results in early preclinical studies or clinical trials, they may not be predictive of the results in later trials.

***We may expend our resources to pursue a particular product candidate or indication and forgo the opportunity to capitalize on product candidates or indications that may ultimately be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we intend to focus on developing product candidates for specific indications that we identify as most likely to succeed, in terms of both their potential for regulatory approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

***If the FDA or comparable foreign regulatory authorities approve generic versions of RTB101, alone or in combination with everolimus, or any other product candidate of ours that receives regulatory approval, or such authorities do not grant our products appropriate periods of non-patent exclusivity before approving generic versions of such products, the sales of such products could be adversely affected.***

Once an NDA is approved, the product covered thereby becomes a “listed drug” in the FDA’s publication, “Approved Drug Products with Therapeutic Equivalence Evaluations,” or the Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States. In support of an ANDA, a generic manufacturer generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration, conditions of use and labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning, in part, that it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Moreover, many states allow or require substitution of therapeutically equivalent generic drugs at the pharmacy level even if the branded drug is prescribed. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug may be lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference listed drug has expired. The Federal Food, Drug, and Cosmetic Act, or FDCA, provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity, or NCE. Specifically, in cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the listed drug is invalid, unenforceable or will not be infringed by the generic product, in which

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case the applicant may submit its application four years following approval of the listed drug. It is unclear whether the FDA will treat the active ingredients in our product candidates as NCEs and, therefore, afford them five years of NCE data exclusivity if they are approved. If any product we develop does not receive five years of NCE exclusivity, the FDA may approve generic versions of such product three years after its date of approval, subject to the requirement that the ANDA applicant certifies to any patents listed for our products in the Orange Book. Three year exclusivity is given to a drug if it contains an active moiety that has previously been approved, and the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the NDA. If approved, manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if we still have patent protection for our product.

Competition that our products, if approved, may face from generic versions of our products could negatively impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on our investments in those product candidates.

***If we encounter difficulties enrolling patients in our future clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion.

Patient enrollment is affected by many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. In addition, because we intend to investigate our product candidates during the winter cold and flu season, this timing requirement may further limit the available pool of clinical trial subjects.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials altogether. Delays in patient enrollment may

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result in increased costs, affect the timing or outcome of the planned clinical trials, product candidate development and approval process and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could prevent completion of these trials, adversely affect our ability to advance the development of our product candidates, cause the value of our company to decline and limit our ability to obtain additional financing if needed.

***Ingredients, excipients and other materials necessary to manufacture RTB101 or everolimus may not be available on commercially reasonable terms, or at all, which may adversely affect the development and commercialization of RTB101, alone or in combination with everolimus.***

We and our third-party manufacturers must obtain from other third-party suppliers the active pharmaceutical ingredients, excipients and primary and secondary packaging materials necessary for our contract manufacturers to produce RTB101 or everolimus for our clinical trials and, to the extent approved or commercialized, for commercial distribution. There is no guarantee that we would be able to enter into all the necessary agreements with third-party suppliers that we require for the supply of such materials on commercially reasonable terms or at all. Even if we were able to secure such agreements or guarantees, our suppliers may be unable or choose not to provide us the ingredients, excipients or materials in a timely manner or in the quantities required. If we or our third-party manufacturers are unable to obtain the quantities of these ingredients, excipients or materials that are necessary for the manufacture of commercial supplies of RTB101 or everolimus, our ability to generate revenue from the sale of RTB101 alone or in combination with everolimus would be materially and adversely affected. Further, if we or our third-party manufacturers are unable to obtain active pharmaceutical ingredients, excipients and materials as necessary for our clinical trials or for the manufacture of commercial supplies of our product candidates, if approved, potential regulatory approval or commercialization would be delayed, which would materially and adversely affect our ability to generate revenue from the sale of our product candidates. As a result of these and other factors, the cost of manufacturing drug material may not support continued development or commercialization or may materially reduce revenue.

***Even if RTB101, alone or in combination with everolimus, or any other product candidate of ours receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.***

We have never commercialized a product, and even if RTB101, alone or in combination with everolimus, or any other product candidate of ours is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. The market for therapies targeting aging-related diseases with an immunotherapy is novel, and physicians may be reluctant to adopt novel therapies. In addition, patients and their physicians may not desire to add RTB101, alone or in combination with everolimus, even if approved, to their existing prophylactic treatment regime. For example, physicians are often reluctant to switch their patients from existing prophylactics for RTIs even when new and potentially more effective or convenient alternatives enter the market. Further, patients often acclimate to the treatment regime that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch due to lack of coverage and reimbursement. In addition, even if we are able to demonstrate our product candidates' safety and efficacy to the FDA and other regulators, safety or efficacy concerns in the medical community may hinder market acceptance.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including management time and financial resources, and may not be successful. If RTB101, alone or in combination with everolimus, or any other product candidate is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we

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may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies;
- the prevalence and severity of any side effects;
- whether the product is recommended under physician prophylactic guidelines;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product; and
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors.

Any failure by RTB101 alone or in combination with everolimus or any other product candidate of ours that obtains regulatory approval to achieve market acceptance or commercial success would adversely affect our business prospects.

***Even if we, or any future collaborators, are able to commercialize any product candidate that we, or they, develop, the product may become subject to unfavorable pricing regulations or third-party payor coverage and reimbursement policies, any of which could harm our business.***

Patients who are provided medical treatment for their conditions generally rely on third party payors to reimburse all or part of the costs associated with their treatment. Therefore, our ability, and the ability of any future collaborators to commercialize any of our product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors including government health administration authorities and private health coverage insurers. Third-party payors decide which medications they will cover and establish reimbursement levels. We cannot be certain that coverage will be available and reimbursement will be adequate for RTB101, alone or in combination with everolimus, or any of our other product candidates. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products.

If coverage and reimbursement are not available, or reimbursement is available only to limited levels, we, or any future collaborators, may be limited in our ability to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow



us, or any future collaborators, to establish or maintain pricing sufficient to realize a sufficient return on our or their investment. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Regulatory approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we, or any future collaborators, might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability or the ability of any future collaborators to recoup our or their investment in one or more product candidates, even if our product candidates obtain regulatory approval.

The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for certain medications, which could affect our ability or that of any future collaborators to sell our product candidates profitably. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or those of any future collaborators, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost-control initiatives could cause us, or any future collaborators, to decrease the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the prices for our products, if any, decrease or if governmental and other third-party payors do not provide coverage or adequate reimbursement, our prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

In addition, increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging prices. We cannot be sure that coverage will be available for any product candidate that we, or any future collaborator, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from one country to another. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we, or any future collaborator, obtain regulatory approval could significantly harm our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

***Product liability lawsuits against us or any of our future collaborators could divert our resources and attention, cause us incur substantial liabilities and limit commercialization of our product candidates.***

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently, we have no

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products that have been approved for commercial sale; however, the current and future use of our product candidates by us and any collaborators in clinical trials, and the sale of these product candidates, if approved, in the future, may expose us to liability claims. We face an inherent risk of product liability lawsuits related to the use of our product candidates in elderly patients and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us or our partners by participants enrolled in our clinical trials, patients, health care providers, pharmaceutical companies, our collaborators or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any of our future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs;
- substantial monetary awards to, or costly settlements with, patients or other claimants;
- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies.

Although we maintain product liability insurance coverage in the amount of up to \$10.0 million in the aggregate, including clinical trial liability, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives regulatory approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could harm our business, financial condition, results of operations and prospects.

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***We currently have no marketing, sales or distribution infrastructure. If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates.***

We currently have no marketing, sales or distribution capabilities. If RTB101, alone or in combination with everolimus, is approved for RTIs, we intend to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize the approved product in key territories, which will require substantial additional resources. Some or all of these costs may be incurred in advance of any approval of RTB101, alone or in combination with everolimus. Any failure or delay in the development of our or third parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of RTB101, alone or in combination with everolimus, and other future product candidates.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems to serve as an alternative to our own sales force and distribution systems. Our product revenue may be lower than if we directly marketed or sold our products, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

***If we, or any future collaborators, experience any of a number of possible unforeseen events in connection with clinical trials of RTB101, alone or in combination with everolimus, or any other product candidate, potential clinical development, regulatory approval or commercialization of our product candidates could be delayed or prevented.***

We, or any future collaborators, may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent clinical development, regulatory approval or commercialization of our product candidates, including:

- our product candidates may produce unfavorable or inconclusive results;
- regulators may require us or any future collaborators, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we, or any future collaborators anticipate, patient enrollment in these clinical trials may be slower than we, or any future collaborators, may anticipate or participants may drop out of these clinical trials at a higher rate than we, or any future collaborators, anticipate;

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- the cost of planned clinical trials of our product candidates may be greater than we anticipate;
- our third-party contractors or those of any future collaborators, including those manufacturing our product candidates or components or ingredients thereof or conducting clinical trials on our behalf or on behalf of any future collaborators, may fail to comply with regulatory requirements or meet their contractual obligations to us or any future collaborators in a timely manner or at all;
- regulators, IRBs or independent ethics committees may not authorize us, any future collaborators or our or their investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- delays in reaching or failure to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- patients who enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial's duration;
- delay, suspension or termination of clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate; and
- regulators, IRBs or independent ethics committees may require that we, or any future collaborators, or our or their investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their standards of conduct, a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate or findings of undesirable effects caused by a chemically or mechanistically similar product or product candidate.

Further, conducting clinical trials in foreign countries, as we have done and plan to do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Product development costs for us, or any future collaborators, will increase if we, or they, experience delays in testing or pursuing regulatory approvals and we, or they, may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any preclinical studies or clinical trials will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we, or any future collaborators, may have the exclusive right to commercialize our product candidates or allow our competitors, or the competitors of any future collaborators, to bring products to market before we, or any future collaborators, do and impair our ability, or the ability of any future collaborators, to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that lead to clinical trial delays may ultimately lead to the denial of regulatory approval of any of our product candidates.

***Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials, and such results do not guarantee approval of a product candidate by regulatory authorities.***

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in the results of completed

clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for their product candidates. Even if we complete clinical development of RTB101 alone or in combination with everolimus for RTIs or any other indication, there can be no assurance that the FDA, EMA, or other regulatory authorities will approve RTB101 alone or in combination with everolimus for marketing.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial procedures and the rate of dropout among clinical trial participants. If we fail to receive positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidate, and, correspondingly, our business and financial prospects would be negatively impacted.

#### **Risks Related to Regulatory Approval and Marketing of Our Product Candidates and Other Legal Compliance Matters**

***Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process for product candidates is expensive, time consuming and uncertain and may prevent us or any future collaborators from obtaining approvals for the commercialization of RTB101 alone or in combination with everolimus or any other product candidate. As a result, we cannot predict when or if, and in which territories, we, or any future collaborators, will obtain regulatory approval to commercialize a product candidate.***

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. We, and any future collaborators, are not permitted to market RTB101, alone or in combination with everolimus, or any other product candidate in the United States or in other countries until we, or they, receive approval of a NDA from the FDA or regulatory approval from applicable regulatory authorities outside the United States. RTB101 is in clinical development and is subject to the risks of failure inherent in drug development. We have not submitted an application for or received regulatory approval for RTB101, alone or in combination with everolimus, or any other product candidate in the United States or in any other jurisdiction. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including obtaining FDA approval of an NDA.

The process of obtaining regulatory approvals, both in the United States and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA or other regulatory authorities may determine that RTB101, alone or in combination with everolimus, or any other product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining regulatory approval or prevent or limit commercial use. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

In addition, changes in regulatory approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we, or any future collaborators, ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authority. The FDA or other regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or other regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

Any delay in obtaining or failure to obtain required approvals could negatively impact our ability or that of any future collaborators to generate revenue from the particular product candidate, which likely would result in significant harm to our business and adversely impact our stock price.

***Our failure to obtain regulatory approval in foreign jurisdictions would prevent our product candidates from being marketed abroad, and any approval we are granted for RTB101, alone or in combination with everolimus, or any of our other product candidates in the United States would not assure approval of product candidates in foreign jurisdictions.***

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding clinical trial design, safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming and could delay or prevent introduction of RTB101, alone or in combination with everolimus, or any of our other product candidates in those countries. We do not have experience in obtaining regulatory approval in international markets. If we or our partners fail to comply with regulatory requirements or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the referendum could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

***Even if we, or any future collaborators, obtain regulatory approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products, which could impair our ability to generate revenue.***

Once regulatory approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any future collaborators, must therefore comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain regulatory approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we and any future collaborators will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs. Despite our efforts to inspect and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by FDA or other authorities to be not in compliance with cGMP regulations, which may result in shutdown of the third-party vendor or invalidation of drug product lots or processes. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our drug products.

Accordingly, assuming we, or any future collaborators, receive regulatory approval for one or more of our product candidates, we, and any future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If we, and any future collaborators, are not able to comply with post-approval regulatory requirements, we, and any future collaborators, could have the regulatory approvals for our products withdrawn by regulatory authorities and our, or any future collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

***We are subject to extensive government regulation and the failure to comply with these regulations may have a material adverse effect on our operations and business.***

Both before and after approval of any product, we and our suppliers, contract manufacturers and clinical investigators are subject to extensive regulation by governmental authorities in the United States and other countries, covering, among other things, testing, manufacturing, quality control, clinical trials, post-marketing studies, labeling, advertising, promotion, distribution, import and export, governmental pricing, price reporting and rebate requirements. Failure to comply with applicable requirements could result in one or more of the following actions: warning or untitled letters; unanticipated expenditures; delays in approval or refusal to approve a product candidate; voluntary product recall; product seizure; interruption of manufacturing or clinical trials; operating or marketing restrictions; injunctions; criminal prosecution and civil or criminal penalties including fines and other monetary penalties; exclusion from federal health care programs such as Medicare and Medicaid; adverse publicity; and disruptions to our business. Further, government investigations into potential violations of these laws would require us to expend considerable resources and face adverse publicity and the potential disruption of our business even if we are ultimately found not to have committed a violation.

Obtaining FDA approval of our product candidates requires substantial time, effort and financial resources and may be subject to both expected and unforeseen delays, and there can be no assurance that any

approval will be granted for any of our product candidates on a timely basis, if at all. The FDA may decide that our data are insufficient for approval of our product candidates and require additional preclinical, clinical or other studies or additional work related to chemistry, manufacturing and controls. In addition, we, the FDA, IRBs or independent ethics committees may suspend or terminate human clinical trials at any time on various grounds, including a finding that the patients are or would be exposed to an unacceptable health risk or because of the way in which the investigators on which we rely carry out the trials. If we are required to conduct additional trials or to conduct other testing of our product candidates beyond that which we currently contemplate for regulatory approval, if we are unable to complete successfully our clinical trials or other testing, or if the results of these and other trials or tests fail to demonstrate efficacy or raise safety concerns, we may face substantial additional expenses, be delayed in obtaining regulatory approval for our product candidates or may never obtain regulatory approval.

We are also required to comply with extensive governmental regulatory requirements after a product has received marketing authorization. Governing regulatory authorities may require post-marketing studies that may negatively impact the commercial viability of a product. Once on the market, a product may become associated with previously undetected adverse effects and/or may experience manufacturing or other commercial difficulties. As a result of any of these or other problems, a product's regulatory approval could be withdrawn, which could harm our business and operating results.

***Any of our product candidates for which we, or any future collaborators, obtain regulatory approval in the future will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. If approved, our product candidates could be subject to post-marketing restrictions or withdrawal from the market and we, or any future collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products following approval.***

Any of our product candidates for which we, or any future collaborators, obtain regulatory approval, as well as the manufacturing processes, post-approval studies, labeling, advertising and promotional activities for such product, among other things, will be subject to ongoing requirements of and review by the FDA, EMA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. We and our contract manufacturers will also be subject to user fees and periodic inspection by the FDA, EMA and other regulatory authorities to monitor compliance with these requirements and the terms of any product approval we may obtain. Even if regulatory approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS.

The FDA, EMA and other regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or any future collaborators, do not market any of our product candidates for which we, or they, receive regulatory approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing if it is alleged that we are doing so. Violation of the FDCA and other statutes relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws, including the False Claims Act.



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In addition, later discovery of previously unknown adverse events or other problems with our products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on the manufacturing of such products;
- restrictions on the labeling or marketing of such products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenues;
- exclusion from federal health care programs such as Medicare and Medicaid;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

***The efforts of the Administration to pursue regulatory reform may limit FDA's ability to engage in oversight and implementation activities in the normal course, and that could negatively impact our business.***

The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. On January 30, 2017, President Trump issued an executive order, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This executive order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the executive order requires agencies to identify regulations to offset any incremental cost of a new regulation. In interim guidance issued by the Office of Information and

Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the “two-for-one” provisions may apply not only to agency regulations, but also to significant agency guidance documents, and on September 8, 2017, the FDA published notices in the Federal Register soliciting broad public comment to identify regulations that could be modified in compliance with these Executive Orders. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA’s ability to exercise its regulatory authority. If these executive actions impose constraints on FDA’s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

***Our relationships with healthcare providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse, privacy and transparency and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third party payors will play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. Our future arrangements with third party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain regulatory approval. These include the following:

- **Anti-Kickback Statute**—The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity can be found guilty of violating the federal Anti-Kickback Statute without actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute;
- **False Claims Act**—The federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal healthcare program; making a false statement or record material to a false or fraudulent claim or an obligation to pay money to the federal government; or avoiding, decreasing or concealing an obligation to pay money to the federal government. A claim that includes items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim under the False Claims Act.. Potential liability for violating the False Claims Act includes mandatory treble damages and significant per-claim penalties;
- **HIPAA**—The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, HIPAA and, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations on covered entities and their business associates, including mandatory contractual terms and technical safeguards, with respect to maintaining the privacy, security and transmission of individually identifiable health information;
- **Transparency Requirements**—Federal laws require applicable manufacturers of covered drugs to report payments and other transfers of value to physicians, including doctors, dentists, optometrists,

podiatrists and chiropractors, and teaching hospitals, as well as information regarding ownership and investment interests held by the physicians described above and their immediate family members; and

- **Analogous State and Foreign Laws**—Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, can apply to our business practices, including but not limited to research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors and are generally broad and are enforced by many different federal and state agencies as well as through private actions.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is generally not permitted in the countries that form part of the European Union. Some European Union Member States, like the United Kingdom, through the United Kingdom Bribery Act 2010, have enacted laws explicitly prohibiting the provision of these type of benefits and advantages. Infringements of these laws can result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States (e.g., France or Belgium) must be publically disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the European Union Member State national laws, industry codes (e.g. the European Federation of Pharmaceutical Industries and Associations Disclosure and Healthcare Professionals Codes) or professional codes of conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The collection and processing of personal data – including health data – in the European Union is currently governed by the provisions of the Data Protection Directive, as implemented into national laws by the European Union Member States. The new European Union-wide General Data Protection Regulation, or GDPR, entered into force in May 2016 and will become applicable on May 25, 2018, replacing the current data

protection laws of each European Union Member State. The GDPR will implement more stringent operational requirements for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data, mandatory data breach notification requirements and higher standards for controllers to demonstrate that they have obtained valid consent for certain data processing activities. The GDPR provides that European Union Member States may make their own further laws and regulations in relation to the processing of genetic, biometric or health data, which could result in differences between Member States, limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition. We are also subject to evolving and strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with European Union data protection laws may result in fines (for example, of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year (whichever is higher) under the GDPR) and other administrative penalties, which may be onerous and adversely affect our business, financial condition, results of operations and prospects.

***Current and future legislation may increase the difficulty and cost for us and any collaborators to obtain regulatory approval of and commercialize our product candidates and affect the prices we, or they, may obtain.***

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain regulatory approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA. Among the provisions of the ACA of potential importance to our business and our product candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic products;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand products to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient products to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;

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- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report product samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products; and
- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2025 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

With the new Administration and Congress, there will likely be additional administrative or legislative changes, including modification, repeal, or replacement of all, or certain provisions of, the ACA. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law, however, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices.

At the same time, Congress has focused on additional legislative changes, including in particular repeal and replacement of certain provisions of the ACA. It remains to be seen, however, whether new legislation reforming, repealing or replacing the ACA will be enacted and, if so, precisely what the new legislation will provide and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. It is possible that these reform, repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. It is also possible that some ACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with ACA coverage expansion provisions. At this point, healthcare reform and its impacts on us are highly uncertain in many respects.

The costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States, and members of Congress and the Administration have stated that they will address such costs through new legislative and administrative measures. There have been several U.S.

Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

In addition, individual states have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and to encourage importation from other countries and bulk purchasing.

The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of regulatory approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

***Governments outside the United States may impose strict price controls, which may adversely affect our revenues, if any.***

In some countries, including Member States of the European Union, the pricing of prescription drugs is subject to governmental control. Additional countries may adopt similar approaches to the pricing of prescription drugs. In such countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution, or arbitrage between low-priced and high-priced countries, can further reduce prices. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval, which is time-consuming and costly. We cannot be sure that such prices and reimbursement will be acceptable to us or our strategic partners. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of any of our product candidates in those countries would be negatively affected.

***Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.***

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry,

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because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

### **Risks Related to Our Intellectual Property**

***Our commercial success depends on our ability to protect our intellectual property and proprietary technology.***

Our commercial success depends in large part on our ability to obtain and maintain intellectual property rights protection through patents, trademarks, and trade secrets in the United States and other countries with respect to our proprietary product candidates. If we do not adequately protect our intellectual property rights, competitors may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we have patent applications and may file other patent applications in the United States or abroad related to our product candidates that are important to our business; we may also license or purchase patent applications filed by others. The patent application and approval process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

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Agreements through which we license patent rights may not give us control over patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented, how claims are amended, and may not be able to secure, maintain, or successfully enforce necessary or desirable patent protection from those patent rights. We have not had and do not have primary control over patent prosecution and maintenance for certain of the patents and patent applications we license, and therefore cannot guarantee that these patents and applications will be prosecuted or maintained in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents.

If the scope of the patent protection we or our licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our licensed patents have, or that any of our pending owned or licensed patent applications that mature into issued patents will include, claims with a scope sufficient to protect our proprietary platform or otherwise provide any competitive advantage, nor can we assure you that our licenses are or will remain in force. Other parties have developed or may develop technologies that may be related or competitive with our approach, and may have filed or may file patent applications and may have been issued or may be issued patents with claims that overlap or conflict with our patent applications, either by claiming the same compounds, formulations or methods or by claiming subject matter that could dominate our patent position. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to our product candidates. In addition, the patent portfolio licensed to us is, or may be, licensed to third parties, such as outside our field, and such third parties may have certain enforcement rights. Thus, patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against another licensee or in administrative proceedings brought by or against another licensee in response to such litigation or for other reasons.

Even if they are unchallenged, our owned and licensed patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but falls outside the scope of our patent protection or license rights. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. Currently, a significant portion of our patents and patent applications are in-licensed, though similar risks would apply to any patents or patent applications that we now own or may own or in-license in the future.

We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, licensees, or licensors, whether current



or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees, or licensors, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent position of biotechnology and pharmaceutical companies carries uncertainty. In addition, the determination of patent rights with respect to pharmaceutical compounds commonly involves complex legal and factual questions, which are dependent upon the current legal and intellectual property context, extant legal precedent and interpretations of the law by individuals. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are characterized by uncertainty.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, we cannot be certain that parties from whom we do or may license or purchase patent rights were the first to make relevant claimed inventions, or were the first to file for patent protection for them. If third parties have filed prior patent applications on inventions claimed in our patents or applications that were filed on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such prior applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or to other patent offices around the world. Alternately or additionally, we may become involved in post-grant review procedures, oppositions, derivation proceedings, *ex parte* reexaminations, *inter partes* review, supplemental examinations, or interference proceedings or challenges in district court, in the United States or in various foreign patent offices, including both national and regional, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. An adverse determination in any such challenges may result in loss of the patent or in patent or patent application claims being narrowed, invalidated or held unenforceable, in whole or in part, or in denial of the patent application or loss or reduction in the scope of one or more claims of the patent or patent application, any of which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Pending and future patent applications may not result in patents being issued that protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products. Competitors may also be able to design around our patents. Changes in either the patent laws or interpretation of the patent

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laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does. If these developments were to occur, they could have a material adverse effect on our ability to generate revenue.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

Issued patents that we have or may obtain or license may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products by submitting ANDAs to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

In addition, we rely on the protection of our trade secrets and proprietary, unpatented know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and invention assignment agreements with employees, consultants, collaborators, vendors, and advisors, we cannot provide any assurances that all such

agreements have been duly executed, and third parties may still obtain this information or may come upon this or similar information independently. It is possible that technology relevant to our business will be independently developed by a person who is not a party to such a confidentiality or invention assignment agreement. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, collaborators, vendors, advisors, former employees and current employees. Furthermore, if the parties to our confidentiality agreements breach or violate the terms of these agreement, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a consequence of such breaches or violations. Our trade secrets could otherwise become known or be independently discovered by our competitors. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets. If any of these events occurs or if we otherwise lose protection for our trade secrets or proprietary know-how, our business may be harmed.

***We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.***

In March 2017, we entered into a license agreement with Novartis, or the Novartis License, pursuant to which we were granted an exclusive, field-restricted, worldwide license to certain intellectual property rights owned or controlled by Novartis, including patents, patent applications, proprietary information, know-how and other intellectual property, to develop, commercialize and sell one or more therapeutic products comprising RTB101 or RTB101 and everolimus in a fixed dose combination.

We are dependent on these patents, know-how and proprietary technology, licensed from Novartis. Any termination of this license, or a finding that such intellectual property lacks legal effect, could result in the loss of significant rights and could harm our ability to commercialize any product candidates. See the section entitled “Business—Intellectual Property” for additional information regarding our license agreements.

Disputes may also arise between us and our licensor, our licensor and its licensors, or us and third parties that co-own intellectual property with our licensor or its licensors, regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights, if any, granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- whether our licensor or its licensor had the right to grant the license agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property without their authorization;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our obligations with respect to the use of the licensed technology in relation to our development and commercialization of product candidates;
- our involvement in the prosecution of the licensed patents and our licensors’ overall patent enforcement strategy;
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners; and
- the amounts of royalties, milestones or other payments due under the license agreement.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, or are insufficient to provide us the necessary rights to use the intellectual property, we may be unable to successfully develop and commercialize the affected product candidates. If we or any such licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer.

Novartis may partially terminate the license agreement with respect to everolimus if we fail or cease for three years to use commercially reasonable efforts to research, develop and commercialize a product using everolimus, provided that our license related to RTB101 and Novartis's license to our improvements related to everolimus will continue. Additionally, either party may terminate the Novartis License if the other party commits a material breach and fails to cure such breach within 60 days after written notice. If Novartis unilaterally terminates the Novartis License, the research and development of RTB101 or RTB101 and everolimus in a fixed dose combination would be suspended, and we may be unable to research, develop and license future product candidates.

***We may be required to pay certain milestones and royalties under our license agreements with third-party licensors.***

Under our current and future license agreements, we may be required to pay milestones and royalties based on our revenues from sales of our products utilizing the technologies licensed or sublicensed from Novartis or other licensors and these royalty payments could adversely affect the overall profitability for us of any products that we may seek to commercialize. In order to maintain our license rights under current and future license agreements, we may need to meet certain specified milestones, subject to certain cure provisions, in the development of our product candidates and in the raising of funding. In addition, these agreements may contain diligence milestones and we may not be successful in meeting all of the milestones in the future on a timely basis or at all, which could result in termination of our rights under such agreements. We may need to outsource and rely on third parties for many aspects of the clinical development, sales and marketing of our products covered under our current and future license agreements. Delay or failure by these third parties could adversely affect the continuation of our license agreements with their third-party licensors.

***It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.***

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for the use, formulation and structure of our products and product candidates, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment as well as on successfully defending these patents against potential third-party challenges. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Further, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the USPTO or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although we have conducted searches for third-party publications, patents and other information that may affect the patentability of claims in our various patent applications and patents, we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our owned patents or patent applications, in our licensed patents or patent applications or in third-party patents.

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We cannot provide assurances that any of our patent applications will be found to be patentable, including over our own or our licensors' prior art publications or patent literature, or will issue as patents. Neither can we make assurances as to the scope of any claims that may issue from our pending and future patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the United States or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our products and product candidates and/or materially harm our business.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;
- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent(s) claims will have sufficient scope to protect our technology, provide us with a basis for commercially viable products or provide us with any competitive advantages;
- if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under United States or foreign laws;
- if issued, the patents under which we hold rights may not be valid or enforceable;
- we may not successfully commercialize RTB101, alone or in combination with everolimus, if approved, before our relevant patents expire;
- we may not be the first to make the inventions covered by each of our patents and pending patent applications; or
- we may not develop additional proprietary technologies or product candidates that are separately patentable.

In addition, to the extent that we are unable to obtain and maintain patent protection for one of our products or product candidates or in the event that such patent protection expires, it may no longer be cost-effective to extend our portfolio by pursuing additional development of a product or product candidate for follow-on indications.

We also may rely on trade secrets to protect our technologies or products, especially where we do not believe patent protection is appropriate or obtainable. Also, we cannot provide any assurances that any of our licensed patents have claims with a scope sufficient to protect our technology or otherwise provide any competitive advantage, nor can we assure you that our licenses are or will remain in full force or effect, in which case we would similarly rely on trade secrets. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisers may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Notably, proprietary technology protected by a trade secret does not preempt the patenting of independently developed equivalent technology, even if such equivalent technology is invented subsequent to the technology protected by a trade secret.

***Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such a circumstance, competitors may be able to enter the market earlier than otherwise would be the case. Under the terms of some of our current and future licenses, we may not have the ability to maintain patents or prosecute patent applications in the portfolio, and may therefore have to rely on third parties to comply with these requirements.

***Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.***

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). We might not be granted an extension because of, for example, failure to apply within applicable periods, failure to apply prior to the expiration of relevant patents or otherwise failure to satisfy any of the numerous applicable requirements. Moreover, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to obtain approval of competing products following our patent expiration by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have a material adverse effect on our ability to generate revenue.

***Changes to patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.***

As is the case with other biopharmaceutical companies, our commercial success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent wide-ranging patent reform legislation in the United States, including the Leahy-Smith America Invents Act, or the America Invents Act, could increase those uncertainties and costs. The America Invents Act was signed into law on September 16, 2011, and many of the substantive changes became effective on March 16, 2013. The America Invents Act reforms United States patent law in part by changing the U.S. patent system from a “first to invent” system to a “first inventor to file” system, expanding the definition of prior art, and developing a post-grant review system. This legislation changes United States patent law in a way that may weaken our ability to obtain patent protection in the United States for those applications filed after March 16, 2013.

Further, the America Invents Act created new procedures to challenge the validity of issued patents in the United States, including post-grant review and *inter partes* review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with

an effective filing date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine month window from issuance of the patent. A petition for *inter partes* review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for *inter partes* review can be filed after the nine month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas *inter partes* review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or *inter partes* review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we or our licensors or collaborators will be successful in defending the patent, which may result in a loss of the challenged patent right to us.

In addition, recent court rulings in cases such as *Association for Molecular Pathology v. Myriad Genetics, Inc.*, *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation*, and *Promega Corp. v. Life Technologies Corp.* have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

***We may not be able to enforce our intellectual property rights throughout the world.***

Filing, prosecuting, enforcing and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe or from selling or importing products made from our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Agreements through which we license patent rights may not give us sufficient rights to permit us to pursue enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents (or control of such enforcement or defense) of such patent rights in all relevant jurisdictions as requirements may vary.

Proceedings to enforce our patent rights, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products, if approved. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

***Others may challenge inventorship or claim an ownership interest in our intellectual property which could expose it to litigation and have a significant adverse effect on its prospects.***

A third party or former employee or collaborator may claim an ownership interest in one or more of our or our licensors' patents or other proprietary or intellectual property rights. A third party could bring legal actions against us and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. While we are presently unaware of any claims or assertions by third-parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources, and cause a significant diversion of effort by our technical and management personnel.

***If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.***

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may have U.S. and non-U.S. issued patents and pending patent applications relating to compounds, methods of manufacturing compounds and/or methods of use for the treatment of the disease indications for which we are developing our product candidates. If any third-party patents or patent applications are found to cover our product candidates or their methods of use or manufacture, we may not be free to manufacture or market our product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products candidates, including interference and post-grant proceedings before the USPTO. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the composition, use or manufacture of our product candidates. We cannot guarantee that any of our patent searches or analyses including, but not limited to, the identification of relevant patents, the scope of patent claims or the expiration of relevant patents are complete or thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on intellectual property rights that exist now or arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that



our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate or product. If we were required to obtain a license to continue to manufacture or market the affected product, we may be required to pay substantial royalties or grant cross-licenses to our patents. We cannot, however, assure you that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Furthermore, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

***We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.***

Many of our current and former employees and our licensors' current and former employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Some of these employees, including members of our senior management, may have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may sustain damages or lose key personnel, valuable intellectual property rights or the personnel's work product, which could hamper or prevent commercialization of our technology, which could materially affect our commercial development efforts. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such

intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

***We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the trademarks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Additionally, for certain of our existing and future in-licensed patent rights, we may not have the right to bring suit for infringement and may have to rely on third parties to enforce these rights for us. If we cannot or choose not to take action against those we believe infringe our intellectual property rights, we may have difficulty competing in certain markets where such potential infringers conduct their business, and our commercialization efforts may suffer as a result.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our trademarks of interest and our business may be adversely affected.***

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the

USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use for our products in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed product names, we may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

### **Risks Related to Our Dependence on Third Parties**

***We rely on third parties to assist in conducting our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.***

We do not independently conduct clinical trials of any of our product candidates. We have relied upon and plan to continue to rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct these clinical trials and expect to rely on these third parties to conduct clinical trials of any other product candidate that we develop. Any of these third parties may terminate their engagements with us under certain circumstances. We may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

Further, although our reliance on these third parties for clinical development activities limits our control over these activities, we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. For example, notwithstanding the obligations of a CRO for a trial of one of our product candidates, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with requirements, commonly referred to as Good Clinical Practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and IRBs. If we or our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our product candidates, which would delay the regulatory approval process. We cannot be certain that, upon inspection, the FDA will determine that any of our clinical trials comply with GCPs. We are also required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed

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in obtaining, regulatory approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or regulatory approval of our product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue.

***Our use of third parties to manufacture our product candidates and products which we are studying in combination with our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, products, or necessary quantities of such materials on time or at an acceptable cost.***

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely on third parties for the manufacture and supply of the active pharmaceutical ingredients, or API, in our product candidates. Our current strategy is to outsource all manufacturing of our product candidates to third parties.

We currently engage one third-party manufacturer to provide the active pharmaceutical ingredient, or API, and four other third-party manufacturers to provide services for the final drug product formulation of RTB101 that is being used in our clinical trials. Although we believe that there are several potential alternative manufacturers who could manufacture RTB101 and everolimus, we may incur added costs and delays in identifying and qualifying any such replacement. In addition, we typically order raw materials and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements with any commercial manufacturer. There is no assurance that we will be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. We may be unable to conclude agreements for commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of RTB101, alone or in combination with everolimus, and the costs of manufacturing could be prohibitive.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third-party manufacturer to comply with applicable regulatory requirements and reliance on third-parties for manufacturing process development, regulatory compliance and quality assurance;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- limitations on supply availability resulting from capacity and scheduling constraints of third-parties;
- the possible breach of manufacturing agreements by third-parties because of factors beyond our control;
- the possible termination or non-renewal of the manufacturing agreements by the third-party, at a time that is costly or inconvenient to us; and

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- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our products. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities.

If any of our product candidates are approved by any regulatory agency, we intend to utilize arrangements with third-party contract manufacturers for the commercial production of those products. This process is difficult and time consuming and we may face competition for access to manufacturing facilities as there are a limited number of contract manufacturers operating under cGMPs that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could delay our commercialization.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be evaluated by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we may not be able to secure and/or maintain regulatory approval for our product manufactured at these facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA finds deficiencies or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products, if approved.

The FDA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with cGMPs. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

***If any third-party manufacturer of our product candidates is unable to increase the scale of its production of our product candidates, and/or increase the product yield of its manufacturing, then our costs to manufacture the product may increase and commercialization may be delayed.***

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of RTB101, alone or in combination with everolimus, or any other product candidates that we may develop, our third party manufacturer will be required to increase its production and

optimize its manufacturing processes while maintaining the quality of the product. The transition to larger scale production could prove difficult. In addition, if our third party manufacturer is not able to optimize its manufacturing process to increase the product yield for our product candidates, or if it is unable to produce increased amounts of our product candidates while maintaining the quality of the product, then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operation.

***We may need to maintain licenses for active ingredients from third parties to develop and commercialize some of our product candidates, which could increase our development costs and delay our ability to commercialize those product candidates.***

Should we decide to use active pharmaceutical ingredients in any of our product candidates that are proprietary to one or more third parties, we would need to maintain licenses to those active ingredients from those third parties. If we are unable to gain or continue to access rights to these active ingredients prior to conducting preclinical toxicology studies intended to support clinical trials, we may need to develop alternate product candidates from these programs by either accessing or developing alternate active ingredients, resulting in increased development costs and delays in commercialization of these product candidates. If we are unable to gain or maintain continued access rights to the desired active ingredients on commercially reasonable terms or develop suitable alternate active ingredients, we may not be able to commercialize product candidates from these programs.

***Use of third parties to conduct testing of our product candidates in tissues or animals may increase the risk that we will have unsuitable or invalidated data for regulatory submissions and approval.***

We currently do not own or operate laboratory facilities in which to conduct preclinical testing of our product candidates in tissues or animals. Preclinical studies regulated by FDA, EMA and most other health authorities are governed by Good Laboratory Practices, or GLP. Additionally, studies involving animals may be subject to further regulation by institutional, private or government animal welfare authorities that may vary by territory. Studies involving human tissues may also be subject to institutional and government human subject privacy policies that may vary by territory. Third party vendors conducting tissue and/or animal studies on our behalf may be found to be in violation of one or more of these regulations or policies and may be subject to closure, censure or other penalties. In some cases, these penalties could materially impact the performance, availability, or validity of studies conducted on our behalf. Even in the absence of violations resulting in penalties, regulatory and other authorities may refuse to authorize the conduct or to accept the results of studies for regulatory or ethical reasons.

***We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.***

In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our exercise of rights under the agreement. With respect to our commercial agreements, we indemnify our vendors from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance

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coverage or the indemnification obligation exceeds the applicable insurance coverage and does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

***We may seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.***

We may seek one or more collaborators for the development and commercialization of one or more of our product candidates. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In addition, if we are able to obtain regulatory approval for product candidates from foreign regulatory authorities, we may enter into collaborations with international biotechnology or pharmaceutical companies for the commercialization of such product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of our product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA, the EMA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

***If we enter into collaborations with third parties for the development and commercialization of our product candidates, our prospects with respect to those product candidates will depend in significant part on the success of those collaborations.***

We may enter into collaborations for the development and commercialization of certain of our product candidates. If we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any future collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms.

Collaborations involving our product candidates pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, including trade secrets and intellectual property rights, contract interpretation, or the preferred course of development might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours is involved in a business combination, it could decide to delay, diminish or terminate the development or commercialization of any product candidate licensed to it by us.

***We may have to alter our development and commercialization plans if we are not able to establish collaborations.***

We will require additional funds to complete the development and potential commercialization of RTB101 alone or in combination with everolimus and other product candidates. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.



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We face significant competition in seeking and obtaining appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include:

- the design or results of clinical trials;
- the likelihood of approval by the FDA or comparable foreign regulatory authorities;
- the potential market for the subject product candidate;
- the costs and complexities of manufacturing and delivering such product candidate to patients;
- the potential for competing products;
- our patent position protecting the product candidate, including any uncertainty with respect to our ownership of our technology or our licensor's ownership of technology we license from them, which can exist if there is a challenge to such ownership without regard to the merits of the challenge;
- the need to seek licenses or sub-licenses to third-party intellectual property; and
- industry and market conditions generally.

The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market and our business may be materially and adversely affected.

### **Risks Related to Employee Matters and Managing Growth**

***We only have a limited number of employees to manage and operate our business.***

As of \_\_\_\_\_, we had \_\_\_\_\_ full- or part-time employees. Our focus on the development of RTB101, alone or in combination with everolimus, requires us to optimize cash utilization and to manage and operate our business in a highly efficient manner. We cannot assure you that we will be able to hire and/or retain adequate staffing levels to develop RTB101, alone or in combination with everolimus, or run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

***Cyber-attacks or other failures in our telecommunications or information technology systems, or those of our collaborators, contract research organizations, third-party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of our business operations.***

We, our collaborators, our CROs, third-party logistics providers, distributors and other contractors and consultants utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our, our collaborators', our CROs', third-party logistics providers', distributors' and other contractors' and consultants' systems and networks, and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack or destruction or loss of data could have a material adverse effect on our business and prospects. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

***We depend heavily on our executive officers, principal consultants and others and the loss of their services would materially harm our business.***

Our success depends, and will likely continue to depend, upon our ability to hire, retain the services of our current executive officers, principal consultants and others, including Chen Schor, our president and chief executive officer, and Joan Mannick, our chief medical officer. We have entered into employment agreements with Mr. Schor and Dr. Mannick, but they may terminate their employment with us at any time. Although we do not have any reason to believe that we will lose the services of Mr. Schor and Dr. Mannick in the foreseeable future, the loss of their services might impede the achievement of our research, development and commercialization objectives.

Our ability to compete in the biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. Our industry has experienced a high rate of turnover of management personnel in recent years. Replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully.

Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize our product candidates will be limited.

One of our shareholders, PureTech Health, currently provides us with strategic medical, clinical and scientific advice pursuant to a business services, personnel and information management agreement. In addition,

we currently share administrative resources and offices with PureTech Health, including legal, accounting and human resources support, computer and telecommunications systems and other office infrastructure pursuant to the agreement. While we intend to occupy our own office space and hire additional qualified personnel to provide certain of these functions internally in the future, we are currently dependent on PureTech Health for these services. If PureTech Health was unable or unwilling to continue to provide these shared resources, we may be unable to replace in a timely manner or on comparable terms the shared resources or other benefits that PureTech Health currently provides. Also, upon the termination of the shared resources provided under the services agreement, such services will be provided internally or by unaffiliated third parties, and we expect that in some instances, we will incur higher costs to obtain such services than we incurred under the terms of such agreement. If we are unable to transition the shared resources that PureTech Health provides to internal employees or unaffiliated third parties, or to do so in a cost effective and timely manner, we may not be able to operate our business effectively and our business and financial condition could be adversely affected.

***Our employees, independent contractors, consultants, collaborators and contract research organizations may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.***

We are exposed to the risk that our employees, independent contractors, consultants, collaborators and contract research organizations may engage in fraudulent conduct or other illegal activity. Misconduct by those parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates:

- FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities; and
- laws that require the reporting of financial information or data accurately.

Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product materials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations.

***We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of regulatory affairs and sales, marketing and distribution, as well as to

support our public company operations. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of its attention to managing these growth activities. Moreover, our expected growth could require us to relocate to a different geographic area of the country. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion or relocation of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion or relocation of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates.

***Our current operations are concentrated primarily in a single location and any events affecting our headquarters may have material adverse consequences.***

Our current operations are primarily located in our principal office in Boston, Massachusetts. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize the office may have a material adverse effect on our ability to operate our business, and have significant negative consequences on our financial and operating conditions. Loss of access to this office may result in increased costs, delays in the development of our product candidates or interruption of our business operations. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at our office, our insurance coverage may not be sufficient to satisfy all of our damages and losses. If our office is unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed.

***Prior to this offering, we operated as a private company and therefore, have no experience operating as a public company and complying with public company obligations. Complying with these requirements will increase our costs, require additional management resources and qualified accounting and financial personnel, and we may fail to meet all of these obligations.***

We will face increased legal, accounting, administrative and other costs and expenses as a public company. Compliance with the Sarbanes-Oxley Act of 2002, the Dodd-Frank Act of 2010 and the rules promulgated thereunder, as well as rules of the SEC and Nasdaq, for example, will result in significant initial cost to us as well as ongoing increases in our legal, audit and financial compliance costs, particularly after we are no longer an “emerging growth company.” The Securities Exchange Act of 1934, as amended, or the Exchange Act, requires, among other things, that we file certain periodic reports with respect to our business and financial condition. Our executive officers and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and require us to incur substantial costs to maintain the same or similar coverage. We expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404 of the Sarbanes-Oxley Act of 2002 once we lose our status as an “emerging growth company.” We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and it may be difficult to recruit and maintain such personnel. Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any

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failure to maintain that adequacy, or consequent inability to produce accurate financial statements or other reports on a timely basis, could increase our operating costs and could materially impair our ability to operate our business.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an “emerging growth company” under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an “emerging growth company” for up to five years. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.***

Upon completion of this offering, we will become subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

***We have conducted and expect to continue to conduct our operations in jurisdictions outside of the United States, and such foreign operations subject us to additional risks.***

A portion of our operations, including our clinical research and development efforts, have been undertaken outside of the United States, and we expect to continue to conduct a portion of our business in foreign countries. For example, we are conducting our ongoing Phase 2b clinical trial across two hemispheres. In addition, we may utilize third party contract organizations, some of which may be located in foreign jurisdictions, for the conduct of our clinical trials, the manufacturing of our product candidates and the

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commercialization of our product candidates, if approved. Such operations subject us to additional risks related to international business operations, including:

- potentially reduced protection for intellectual property rights;
- price and currency exchange fluctuations;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties in complying with tax, employment, immigration and labor laws for personnel living or traveling abroad;
- production shortages resulting from any events affecting a product candidate and/or finished drug product supply or manufacturing capabilities abroad;
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, hurricanes, typhoons, floods and fires; and
- failure to comply with Office of Foreign Asset Control rules and regulations and the Foreign Corrupt Practices Act.

These and other risks may materially adversely affect our ability to conduct our business in international markets.

***We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.***

In the future, we may enter into transactions to acquire other businesses, products or technologies. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and nondisruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

### **Risks Related to Our Common Stock and this Offering**

***An active trading market for our common stock may not develop or be sustainable. If an active trading market does not develop, investors may not be able to resell their shares at or above the initial public offering price and our ability to raise capital in the future may be impaired.***

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock will be determined through negotiations with the underwriters. This price may not

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reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. Although we intend to list our common stock on The Nasdaq Global Market, an active trading market for our shares may never develop or, if developed, be maintained following this offering. If an active market for our common stock does not develop or is not maintained, it may be difficult for you to sell shares you purchase in this offering without depressing the market price for the shares or at all. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

***If you purchase shares of common stock in this offering, you will suffer immediate dilution in the net tangible book value of your investment.***

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. Based on the assumed initial public offering price of \$      per share, which is the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of \$      per share, representing the difference between our pro forma net tangible book value per share after giving effect to this offering and the assumed initial public offering price. Purchasers of common stock in this offering will have contributed approximately      % of the aggregate price paid by all purchasers of our capital stock and will own approximately      % of our common stock outstanding after this offering, excluding any shares of our common stock that they may have acquired prior to this offering. Furthermore, if the underwriters exercise their over-allotment option or our previously issued options and other rights to acquire common stock at prices below the assumed initial public offering price are exercised, you will experience further dilution. For additional information on the dilution that you will experience immediately after this offering, see the section titled “Dilution.”

***The trading price of our common stock is likely to be highly volatile, which could result in substantial losses for purchasers of our common stock in this offering. Securities class action or other litigation involving our company or members of our management team could also substantially harm our business, financial condition and results of operations.***

Our stock price is likely to be highly volatile. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price and you may lose some or all of your investment. The market price for our common stock may be influenced by many factors, including:

- the success of existing or new competitive products or technologies;
- regulatory actions with respect to our product candidates or our competitors’ products and product candidates;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- the timing and results of clinical trials of RTB101 alone or in combination with everolimus and any other product candidates;
- commencement or termination of collaborations for our development programs;
- failure or discontinuation of any of our development programs;
- results of clinical trials of product candidates of our competitors;

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- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results or development timelines;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years.

***We have broad discretion in the use of the net proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not yield a return on your investment.***

Although we currently intend to use the net proceeds from this offering in the manner described in the section titled “Use of Proceeds” in this prospectus, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. You will not have the opportunity to influence our decisions on how to use the net proceeds from this offering. The failure by our management to apply these funds effectively could result in financial losses that could harm our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

***We are an “emerging growth company,” and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.***

We are an emerging growth company, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to “emerging growth companies.” We could remain an “emerging growth company” for up to five years, or until the earliest of (1) the last day of the first fiscal year in which our annual gross revenue exceeds \$1.07 billion, (2) the date that we become a “large accelerated filer” as defined in



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Rule 12b-2 under the Securities Exchange Act of 1934, which would occur if the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the last business day of our most recently completed second fiscal quarter or (3) the date on which we have issued more than \$1.0 billion in non-convertible debt during the preceding three-year period. So long as we remain an “emerging growth company,” we expect to avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404. When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

***We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.***

As a public company, and particularly after we are no longer an “emerging growth company,” we will incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also anticipate that we will incur costs associated with relatively recently adopted corporate governance requirements, including requirements of the Securities and Exchange Commission, or SEC, and The Nasdaq Global Market. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers.

We are currently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the Securities and Exchange Commission, or the SEC, after we become a public company. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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***A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Following this offering, we will have \_\_\_\_\_ shares of common stock outstanding based on the \_\_\_\_\_ shares of our common stock outstanding as of \_\_\_\_\_ and after giving effect to the conversion of all outstanding shares of our preferred stock into 20,320,667 shares of our common stock upon the closing of this offering. Of these shares, the \_\_\_\_\_ shares sold by us in this offering may be resold in the public market immediately, unless purchased by our affiliates. The remaining \_\_\_\_\_ shares are currently restricted under securities laws or as a result of lock-up or other agreements, but will be able to be sold after this offering as described in the “Shares Eligible for Future Sale” section of this prospectus. The representatives of the underwriters may release these stockholders from their lock-up agreements with the underwriters at any time and without notice, which would allow for earlier sales of shares in the public market.

Moreover, after this offering, holders of an aggregate of \_\_\_\_\_ shares of our common stock will have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also plan to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

***We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment.***

We have never declared nor paid cash dividends on our capital stock. We currently plan to retain all of our future earnings, if any, to finance the operation, development and growth of our business. In addition, the terms of any future debt or credit agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

***Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.***

Based upon shares outstanding as of \_\_\_\_\_, and after giving effect to the conversion of all outstanding shares of preferred stock into \_\_\_\_\_ shares of our common stock, upon the closing of this offering, our executive officers and directors, combined with our stockholders who owned more than 5% of our outstanding common stock before this offering and their affiliates, will, in the aggregate, beneficially own shares representing approximately \_\_\_\_\_ % of our common stock. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management or the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

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Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares are being sold in this offering and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors or they may want us to pursue strategies that deviate from the interests of other stockholders.

### ***Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management or hinder efforts to acquire a controlling interest in us.***

Provisions in our corporate charter and our bylaws that will become effective upon the closing of this offering may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders. This could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

***Our restated certificate of incorporation will provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.***

Our restated certificate of incorporation, which will become effective upon the closing of this offering, specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against us by stockholders. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our restated certificate of incorporation described above.

We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.***

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, or one or more of the analysts who cover us issues an adverse opinion about our company, our stock price would likely decline. If one or more of these analysts ceases research coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this prospectus, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our plans to develop and commercialize RTB101 alone or in combination with everolimus and other product candidates, including the therapeutic potential and clinical benefits thereof;
- our ongoing and future clinical trials for RTB101 alone or in combination with everolimus, whether conducted by us or by any future collaborators, including the timing of initiation of these trials and of the anticipated results;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of any products for which we receive regulatory approval;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy;
- our ability to identify additional product candidates with significant commercial potential;
- our plans to enter into collaborations for the development and commercialization of product candidates;
- the potential benefits of any future collaboration;
- our expectations related to the use of proceeds from this offering;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- developments relating to our competitors and our industry; and
- the impact of government laws and regulations.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the “Risk Factors” section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

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You should read this prospectus and the documents that we have filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this prospectus, and we believe these industry publications and third-party research, surveys and studies are reliable.

## USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of \_\_\_\_\_ shares of our common stock in this offering will be approximately \$ \_\_\_\_\_ million, assuming an initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise in full their option to purchase additional shares, we estimate that the net proceeds from this offering will be approximately \$ \_\_\_\_\_ million.

A \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease our net proceeds from this offering by approximately \$ \_\_\_\_\_ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions. An increase or decrease of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease our net proceeds from this offering by approximately \$ \_\_\_\_\_ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions.

We currently estimate that we will use the net proceeds from this offering, together with our existing cash and cash equivalents:

- approximately \$ \_\_\_\_\_ million to fund the development of RTB101, alone and in combination with everolimus, for RTIs, through the completion of \_\_\_\_\_ ;
- approximately \$ \_\_\_\_\_ million to fund the development of RTB101, alone and in combination with other rapalogs such as everolimus, for other indications, through the completion of \_\_\_\_\_ ;
- approximately \$ \_\_\_\_\_ million to fund the development of our TORC1 follow-on candidate and other pipeline candidates, through the completion of \_\_\_\_\_ ; and
- the remainder, if any, for working capital and other general corporate purposes, which may include funding for the costs of operating as a public company.

This expected use of the net proceeds from this offering and our existing cash represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. For example, we may use a portion of the net proceeds for the acquisition of businesses or technologies to continue to build our pipeline, our research and development capabilities and our intellectual property position, although we currently have no agreements, commitments or understandings with respect to any such transaction. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development and commercialization efforts, the status of and results from clinical trials, any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. Moreover, our estimates of the costs to fund our trials are based on the current designs of the trials. If we were to modify the design of any of these trials, for instance, to increase the number of patients in the trials, our costs to fund the trials could increase. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our current plans, we believe that our existing cash and cash equivalents, together with the net proceeds from this offering, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements at least through \_\_\_\_\_. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. We do not have any committed external source of funds.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

**DIVIDEND POLICY**

We have never declared nor paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We do not intend to pay cash dividends in respect of our common stock in the foreseeable future.



## CAPITALIZATION

The following table sets forth our cash and capitalization as of September 30, 2017:

- on an actual basis;
- on a pro forma basis to give effect to (i) the sale and issuance of 7,763,975 shares of our Series A preferred stock in October 2017 for aggregate net proceeds of \$15.0 million, (ii) the sale and issuance of 4,792,716 shares of our Series B preferred stock in November 2017 for aggregate net proceeds of \$39.9 million, (iii) the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 20,320,667 shares of common stock upon the closing of this offering, and (iv) the filing and effectiveness of our amended and restated certificate of incorporation upon the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of \_\_\_\_\_ shares of our common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Our capitalization following the closing of this offering will depend on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with our financial statements and the related notes appearing at the end of this prospectus and the sections of this prospectus titled “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	As of September 30, 2017		
	Actual	Pro Forma	Pro Forma As Adjusted
	(In thousands, except share and per share data)		
Cash	\$ 3,965	\$ 58,895	\$
Redeemable convertible preferred stock (Series A), \$0.0001 par value; 10,351,968 shares authorized, 7,763,976 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	\$ 9,764	\$ —	\$
Redeemable convertible preferred stock (Series B), \$0.0001 par value; no shares authorized, issued or outstanding, actual, pro forma and pro forma as adjusted	—		
Stockholders’ equity (deficit):			
Preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding, actual; shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—		
Common stock, \$0.0001 par value; 19,000,000 shares authorized, 7,245,900 shares issued and outstanding, actual; 30,000,000 shares authorized, 27,566,567 shares issued and outstanding, pro forma; _____ shares authorized, _____ shares issued and outstanding, pro forma as adjusted	1	3	
Additional paid-in capital	1,680	66,372	
Accumulated deficit	(10,725)	(9,346)	
Total stockholders’ (deficit) equity	(9,044)	57,029	
Total capitalization	\$ 720	\$ 57,029	\$

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A \$1.00 increase or decrease in the assumed initial public offering price of \$      per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash, additional paid-in capital, total stockholders' equity and total capitalization by \$      million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions. An increase or decrease of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash, additional paid-in capital, total stockholders' equity and total capitalization by \$      million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions.

The table above does not include:

- 142,535 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2017, at a weighted average exercise price of \$0.63 per share;
- 546,212 additional shares of our common stock available for future issuance as of September 30, 2017 under our 2017 stock incentive plan, and the subsequent increase by 1,581,739 shares available for future issuance in November 2017; and
- additional shares of our common stock that will become available for future issuance under our 2018 stock incentive plan and our 2018 employee stock purchase plan that we intend to adopt in connection with this offering.

## DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Our historical net tangible book value (deficit) as of September 30, 2017 was \$(9.0) million, or \$(1.25) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and preferred stock, which is not included within stockholders' equity (deficit). Historical net tangible book value (deficit) per share represents our historical net tangible book value (deficit) divided by the 7,245,900 shares of our common stock outstanding as of September 30, 2017.

Our pro forma net tangible book value as of September 30, 2017 was \$57.0 million, or \$2.07 per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to (i) the sale and issuance of 7,763,975 shares of our Series A preferred stock in October 2017 for aggregate gross proceeds of \$15.0 million, (ii) the sale and issuance of 4,792,716 shares of our Series B preferred stock in November 2017 for aggregate net proceeds of \$39.9 million and (iii) the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 20,320,667 shares of our common stock upon the closing of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of September 30, 2017, after giving effect to the foregoing adjustments and the automatic conversion of all outstanding shares of our preferred stock into common stock upon the closing of this offering.

After giving further effect to our issuance and sale of \_\_\_\_\_ shares of our common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2017 would have been \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of \$ \_\_\_\_\_ to existing stockholders and immediate dilution of \$ \_\_\_\_\_ in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share	\$
Historical net tangible book value (deficit) per share as of September 30, 2017	\$(1.25)
Increase per share attributable to the automatic conversion of preferred stock upon the closing of this offering	<u>2.07</u>
Pro forma net tangible book value per share as of September 30, 2017	0.82
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing shares in this offering	<u>          </u>
Pro forma as adjusted net tangible book value per share after this offering	<u>          </u>
Dilution per share to new investors purchasing shares in this offering	<u>\$</u>

A \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease our pro forma as adjusted net tangible book value by \$ \_\_\_\_\_ million, our pro forma as adjusted net tangible book value per share after this offering by \$ \_\_\_\_\_ and dilution per share to new investors purchasing shares in this offering by \$ \_\_\_\_\_, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions. An increase of

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1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase the pro forma as adjusted net tangible book value per share after this offering by \$      and decrease the dilution per share to new investors participating in this offering by \$      , assuming no change in the assumed initial public offering price and after deducting estimated underwriting discounts and commissions. A decrease of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value per share after this offering by \$      and increase the dilution per share to new investors participating in this offering by \$      , assuming no change in the assumed initial public offering price and after deducting estimated underwriting discounts and commissions.

If the underwriters exercise their option to purchase additional shares in full, our pro forma as adjusted net tangible book value per share after this offering would be \$      per share, representing an immediate increase in pro forma as adjusted net tangible book value per share of \$      to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of \$      to new investors purchasing common stock in this offering, assuming an initial public offering price of \$      per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If any shares are issued upon exercise of outstanding options, you will experience further dilution.

The following table summarizes, as of September 30, 2017, on the pro forma as adjusted basis described above, the differences between the number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid by existing stockholders and by new investors purchasing shares of common stock in this offering. The calculation below is based on an assumed initial public offering price of \$      per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	27,566,567	%	\$65,000,010	%	\$ 2.36
New investors					\$
Total		100.0%	\$	100.0%	

A \$1.00 increase or decrease in the assumed initial public offering price of \$      per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the total consideration paid by new investors by \$      million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by      percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by      percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase or decrease of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease the total consideration paid by new investors by \$      million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by      percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by      percentage points, assuming no change in the assumed initial public offering price.

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to      % of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors participating in the offering would be increased to      % of the total number of shares of our common stock outstanding after this offering.

The number of shares purchased from us by existing stockholders is based on 7,245,900 shares of our common stock outstanding as of September 30, 2017, and gives effect to (i) the sale and issuance of 7,763,975

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shares of our Series A preferred stock in October 2017, (ii) the sale and issuance of 4,792,716 shares of Series B preferred stock in November 2017 and (iii) the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 20,320,667 shares of common stock upon the closing of this offering, and excludes:

- 142,535 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2017, at a weighted average exercise price of \$0.63 per share;
- 546,212 additional shares of our common stock available for future issuance as of September 30, 2017 under our 2017 stock incentive plan, and the subsequent increase by 1,581,739 shares available for future issuance in November 2017; and
- additional shares of our common stock that will become available for future issuance under our 2018 stock incentive plan and our 2018 employee stock purchase plan that we intend to adopt in connection with this offering.

## SELECTED FINANCIAL DATA

The following tables summarize our financial data as of the dates and for the periods indicated. The selected statements of operations data for the period from July 5, 2016 (inception) through December 31, 2016 and the nine months ended September 30, 2017 and the balance sheet data as of December 31, 2016 and September 30, 2017 have been derived from our audited financial statements included elsewhere in this prospectus. The statement of operations data for the period from July 5, 2016 (inception) through September 30, 2016 have been derived from our unaudited financial statements included elsewhere in this prospectus and have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal, recurring adjustments, necessary for a fair statement of the financial information in those statements. Our historical results from any prior period are not necessarily indicative of results to be expected in any future period, and our interim period results are not necessarily indicative of results to be expected for a full year or any other interim period. The selected financial data below should be read in conjunction with the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes included elsewhere in this prospectus.

	<u>July 5, 2016 (inception) through December 31, 2016</u>	<u>July 5, 2016 (inception) through September 30, 2016</u>	<u>Nine Months Ended September 30, 2017</u>
(In thousands, except share and per share data)			
<b>Statements of Operations Data:</b>			
Operating expenses:			
Research and development	\$ —	\$ —	\$ 10,047
General and administrative	1	1	1,312
Total operating expenses	<u>1</u>	<u>1</u>	<u>11,359</u>
Loss from operations	(1)	(1)	(11,359)
Other income, net	—	—	635
Net loss	<u>\$ (1)</u>	<u>\$ (1)</u>	<u>\$ (10,724)</u>
Net loss per share, basic and diluted <sup>(1)</sup>	<u>\$ (0.00)</u>	<u>\$ (0.00)</u>	<u>\$ (2.18)</u>
Weighted-average common shares used in computing net loss per share, basic and diluted <sup>(1)</sup>	<u>2,532,807</u>	<u>2,458,164</u>	<u>4,915,847</u>
Pro forma net loss per share, basic and diluted (unaudited) <sup>(1)</sup>			<u>\$ (1.02)</u>
Weighted-average common shares used in computing pro forma net loss per share, basic and diluted (unaudited) <sup>(1)</sup>			<u>10,538,278</u>

- (1) See Notes 2 and 12 in the notes to our financial statements included elsewhere in this prospectus for an explanation of the calculation of our basic and diluted net loss per share, the weighted-average common shares used in computing basic and diluted net loss per share, basic and diluted pro forma net loss per share and the weighted-average common shares used in computing basic and diluted pro forma net loss per share. The information presented in this table does not give effect to the sale and issuance of our Series A preferred stock in October 2017 and Series B preferred stock in November 2017.

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	As of	
	December 31, 2016	September 30, 2017
	(In thousands)	
<b>Balance Sheet Data:</b>		
Cash	\$ —	\$ 3,965
Working capital(1)	—	684
Total assets	—	4,215
Total liabilities	—	3,495
Redeemable convertible preferred stock	—	9,764
Total stockholders' (deficit) equity	—	(9,044)

(1) We define working capital as current assets less current liabilities.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with the section entitled "Selected Financial Data" and our financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions and beliefs. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section entitled "Risk Factors" included elsewhere in this prospectus.*

### Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapeutics for the treatment of aging-related diseases. Our lead program has demonstrated in several clinical trials, including a randomized, placebo-controlled trial, the potential to treat multiple diseases of aging for which there are no approved therapies. The decline in immune function that occurs during aging, or immunosenescence, increases susceptibility to a variety of diseases, including respiratory tract infections, or RTIs, that significantly contribute to morbidity and mortality in the elderly. Our approach focuses on the mechanistic target of rapamycin, or mTOR, pathway, an evolutionarily conserved pathway that regulates aging, and specifically on selective inhibition of the target of rapamycin complex 1, or TORC1. Our initial focus is on the development of RTB101, an orally administered, small molecule, potent TORC1 inhibitor, alone and in combination with other mTOR inhibitors such as everolimus—as a first-in-class immunotherapy program designed to improve immune function and thereby reduce the incidence of RTIs in the elderly regardless of the causative pathogen. We licensed the worldwide rights to our TORC1 program, including RTB101 alone or in combination with everolimus or other mTOR inhibitors, from Novartis International Pharmaceutical Ltd., or Novartis, in March 2017. We are evaluating RTB101 alone and in combination with everolimus in a Phase 2b clinical trial for the reduction of RTI incidence in the elderly and expect to report top-line data from this trial in the second half of 2018.

Since our inception in July 2016, we have devoted substantially all of our resources to: identifying, acquiring, and developing our product candidate portfolio; organizing and staffing our company; raising capital; developing manufacturing capabilities; conducting clinical trials; and providing general and administrative support for these operations. To date, we have primarily financed our operations through the issuance and sale of our redeemable convertible preferred stock. From our inception through September 30, 2017, we received gross proceeds of \$10.0 million from the issuance and sale of our redeemable convertible preferred stock. In October 2017, we received an additional \$15.0 million in gross proceeds from the issuance and sale of our redeemable convertible Series A preferred stock. In November 2017, we received an additional \$40.0 million in gross proceeds from the issuance and sale of our redeemable convertible Series B preferred stock.

We have never generated revenue and have incurred significant net losses since inception. Our net losses were \$1,000, \$1,000 and \$10.7 million, for the period from July 5, 2016 (inception) through December 31, 2016, the period from July 5, 2016 (inception) to September 30, 2016 and for the nine months ended September 30, 2017, respectively. As of September 30, 2017, we had an accumulated deficit of \$10.7 million. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- invest significantly to further develop and seek regulatory approval for RTB101 alone or in combination with everolimus, including to continue our ongoing Phase 2b clinical trial;
- expand our pipeline of potential product candidates, including the initiation of at least one additional proof of concept trial in an additional indication;



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- require the manufacture of larger quantities of our product candidates for clinical development and potentially commercialization;
- hire additional clinical, scientific, management and administrative personnel;
- ultimately establish a sales, marketing and distribution infrastructure or collaborate with third parties to commercialize any drugs for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other assets and technologies; and
- add additional operational, financial and management information systems and processes to support our ongoing development efforts, any future manufacturing or commercialization efforts and our transition to operating as a public company.

We believe that our available funds subsequent to this offering will be sufficient to fund our operations into . We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for a product candidate or enter into collaborative agreements with third parties, which we expect will take a number of years and the outcome of which is subject to significant uncertainty. Additionally, we currently use third parties such as contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, to carry out our preclinical and clinical development activities and we do not yet have a sales organization. If we obtain regulatory approval for our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. To fund our current and future operating plans, we will need additional capital, which we may obtain through one or more equity offerings, debt financings or other third-party funding, including potential strategic alliances and licensing or collaboration arrangements. We may, however, be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our current product candidates, or any additional product candidates, if developed. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our preclinical and clinical development efforts. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

### ***Novartis License Agreement***

On March 23, 2017, we entered into a license agreement with Novartis, pursuant to which we were granted an exclusive, field-restricted, worldwide license to certain intellectual property rights owned or controlled by Novartis, including patents, patent applications, proprietary information, know-how and other intellectual property, to develop, commercialize and sell one or more therapeutic products comprising RTB101 or RTB101 and everolimus in a fixed dose combination. Under the license agreement, we have been licensed a patent portfolio of ten patent families directed to composition of matter of RTB101 and its salts, formulations of everolimus and methods of using RTB101 and everolimus to enhance the immune response among others. The exclusive field under the license agreement is for the treatment, prevention and diagnosis of diseases and other conditions in all indications in humans and animals.

As initial consideration for the license, we issued Novartis Institutes for Biomedical Research, or NIBR, 2,587,992 shares of our Series A Preferred Stock.

The agreement may be terminated by either party upon a material breach of obligation by the other party that is not cured with 60 days after written notice. We may terminate the agreement in its entirety or on a product-by-product or country-by-country basis with or without cause with 60 days' prior written notice.

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Novartis may terminate the portion of the agreement related to everolimus if we fail to use commercially reasonable efforts to research, develop and commercialize a product utilizing everolimus for a period of three years. Novartis may terminate the license agreement upon our bankruptcy, insolvency, dissolution or winding up.

As additional consideration for the license, we are required to pay up to an aggregate of \$4.3 million upon the satisfaction of clinical milestones, up to an aggregate of \$24 million upon the satisfaction of regulatory milestones for the first indication approved, and up to an aggregate of \$18 million upon the satisfaction of regulatory milestones for the second indication approved. In addition, we are required to pay up to an aggregate of \$125 million upon the satisfaction of commercial milestones, based on the amount of annual net sales. We are also required to pay tiered royalties ranging from a mid-single digit percentage to a low-teen digit percentage on annual net sales of products. These royalty obligations last on a product-by-product and country-by-country basis until the latest of (i) the expiration of the last valid claim of a Novartis patent covering a subject product, (ii) the expiration of any regulatory exclusivity for the subject product in a country, or (iii) the 10<sup>th</sup> anniversary of the first commercial sale in the country, and are subject to a reduction after the expiration of the last valid claim of a Novartis patent or the introduction of a generic equivalent of a product in a country. In addition, if we sublicense the rights under the license agreement, we are required to pay a certain percentage of the sublicense revenue to Novartis. Novartis will no longer be entitled to sublicense revenue following the last visit of the 400<sup>th</sup> subject in any human clinical trial conducted by us or a sublicensee of ours, which we expect to occur by the end of our ongoing Phase 2b clinical trial.

Milestone payments to Novartis will be recorded as research and development expenses in our statements of operations once achievement of each associated milestone has occurred or the achievement is considered probable. In May 2017, we initiated a Phase 2b clinical trial for a first indication, triggering the first milestone payment under the agreement. Accordingly, we paid the related \$0.3 million payment in May 2017. As of September 30, 2017, none of the remaining development milestones, regulatory milestones, sales milestones, or royalties had been reached or were probable of achievement. We also enter into contracts in the normal course of business with various third parties for preclinical research studies, clinical trials, testing and other services. These contracts generally provide for termination upon notice, and therefore we believe that our noncancelable obligations under these agreements are not material.

### **Financial Operations Overview**

#### ***Revenue***

We have not generated any revenue from the sale of our products, and we do not expect to generate any revenue unless and until we obtain regulatory approval of and commercialize RTB101, alone or in combination with everolimus.

#### ***Research and Development Expenses***

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- personnel costs, which include salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with consultants, third-party contract organizations and investigative clinical trial sites that conduct research and development activities on our behalf;
- costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical studies and clinical trials; and
- lab supplies and equipment used for internal research and development activities.

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We have not provided program costs since inception because historically we have not tracked or recorded our research and development expenses on a program-by-program basis. We use our personnel and infrastructure resources across multiple research and development programs directed toward developing our TORC1 program and for identifying and developing product candidates. We manage certain activities such as contract research and manufacturing of RTB101 alone or in combination with everolimus and our discovery programs through our third-party vendors, and do not track the costs of these activities on a program-by-program basis.

We expense all research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in manufacturing, as our programs advance into later stages of development and we continue to conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

Because of the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration and completion costs of the current or future preclinical studies and clinical trials or if, when, or to what extent we will generate revenues from the commercialization and sale of our product candidates. We may never succeed in achieving regulatory approval for our product candidates. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- successful completion of preclinical studies and Investigational New Drug-enabling studies;
- successful enrollment in, and completion of, clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies and treatment options;
- a continued acceptable safety profile following approval;
- enforcing and defending intellectual property and proprietary rights and claims; and
- achieving desirable medicinal properties for the intended indications.

A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development. We expect our research and development expenses to increase for the foreseeable future as we continue the development of product candidates.

#### ***General and Administrative Expenses***

General and administrative expenses consist primarily of personnel costs, costs related to maintenance and filing of intellectual property, depreciation expense and other expenses for outside professional services, including legal, human resources, audit and accounting services. Personnel costs consist of salaries, benefits and stock-based compensation expense. We expect our general and administrative expenses to increase for the foreseeable future due to anticipated increases in headcount to advance our product candidates and as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, The Nasdaq Global Market, additional insurance expenses, investor relations activities and other administration and professional services.

#### ***Other Income, Net***

Other income, net, consists of non-cash changes in fair value of the tranche rights liability associated with the redeemable convertible preferred stock.

#### **Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

#### ***Accrued Research and Development Costs***

We accrue for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided, and include these costs in accrued liabilities in our balance sheets and within research and development expense in our statements of operations. These costs are a significant component of our research and development expenses. We accrue for these costs based on factors such as estimates of the work completed and in accordance with agreements established with our third-party service providers. We make judgments and estimates in determining the accrued liabilities balance in each reporting period.

#### ***Research and Development Costs***

Research and development costs are expensed as incurred and consist of personnel costs, lab supplies and other costs, as well as fees paid to third parties to conduct research and development activities on our behalf.

Amounts incurred in connection with license agreements are also included in research and development expenses. We record payments made to outside vendors for services performed or goods being delivered for use in research and development activities as either prepaid expenses or accrued expenses, depending on the timing of when services are performed or goods are delivered.

#### ***Determination of Fair Value of Common and Preferred Shares and Tranche Rights Liabilities***

As there has been no public market for our equity securities to date, the estimated fair value of our common and preferred shares has been determined by the board of directors as of the grant date, with input from management, considering our most recently available third-party valuations of common shares and preferred shares and the board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or the Practice Aid. Our common and preferred share valuations were prepared using either an option-pricing method, or OPM, or a probability-weighted expected return method, or PWERM, which uses a combination of market approaches and an income approach to estimate our enterprise value. The OPM treats common securities and preferred securities as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common and preferred shares have value only if the funds available for distribution to stockholders are expected to exceed the value of the preferred security liquidation preference at the time of the liquidity event, such as a strategic sale or a merger. The PWERM is a scenario-based methodology that estimates the fair value of common and preferred shares based upon an analysis of future values for the enterprise, assuming various outcomes. The common and preferred share values are based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of common and preferred securities. The future value of the common and preferred shares under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common and preferred shares. The estimated fair value of the tranche liability was determined using the difference between the total purchase price of our Series A Preferred Stock and the total fair value of the Series A Preferred Stock using a risk-adjusted forward contract model.

#### ***Stock-Based Compensation Expense***

We recognize equity-based compensation expense for awards of equity instruments to employees and non-employees based on the grant date fair value of those awards in accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718, *Stock Compensation*, or ASC 718. ASC 718 requires all equity-based compensation awards to employees and non-employee directors, including grants of restricted shares and stock options, to be recognized as expense in the Statements of Operations based on their grant date fair values. We estimate the fair value of stock options using the Black-Scholes option pricing model. We use the value of our common stock to determine the fair value of restricted shares.

We account for restricted stock and common stock options issued to nonemployees under FASB ASC Topic 505-50, *Equity-Based Payments to Non-Employees*, or ASC 505-50. As such, the value of such options is periodically remeasured and income or expense is recognized over their vesting terms. Compensation cost related to awards with service-based vesting schedules is recognized using the straight-line method. We determine the fair value of the restricted stock and common stock granted to nonemployees as either the fair value of the consideration received or the fair value of the equity instruments issued.

The Black-Scholes option pricing model requires the input of certain subjective assumptions, including (i) the expected volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) the expected

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dividend yield. Due to the lack of a public market for the trading of our common stock and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The group of representative companies has characteristics similar to us, including stage of product development and focus on the life science industry. We use the simplified method, which is the average of the final vesting tranche date and the contractual term, to calculate the expected term for options granted to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For options granted to nonemployees, we utilize the contractual term of the arrangement as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. We use an assumed dividend yield of zero as we have never paid dividends and have no current plans to pay any dividends on our common stock.

There were no stock options granted during the period from July 5, 2016 (inception) to December 31, 2016. The following table presents the assumptions used to estimate the fair value of options granted during the nine months ended September 30, 2017:

	<b>Nine Months Ended September 30, 2017</b>
<b>Employees:</b>	
Fair value of common stock	\$ 0.62
Expected volatility	74.4%
Expected term (in years)	6.1
Risk-free interest rate	1.9%
Expected dividend yield	0.0%
<b>Nonemployees:</b>	
Fair value of common stock	\$ 0.62 - \$0.78
Expected volatility	74.6% - 76.9%
Expected term (in years)	10.0
Risk-free interest rate	2.3%
Expected dividend yield	0.0%

For the period from July 5, 2016 (inception) through December 31, 2016, the nine months ended September 30, 2017, and the period from July 5, 2016 (inception) through September 30, 2016, stock-based compensation expense was \$0, \$0.3 million, and \$0, respectively. As of September 30, 2017, we had \$1.0 million of total unrecognized stock-based compensation expense, which we expect to recognize over a weighted-average period of 2.84 years.

The following table presents the grant dates of common shares, stock options, and awards that we granted from July 5, 2016 (inception) through September 30, 2017 along with the corresponding purchase or exercise price for each grant and our estimate of the fair value per share of our common stock on each grant date, which we utilized to calculate stock-based compensation expense:

<u>Grant Date</u>	<u>Type of Award</u>	<u>Number of Shares</u>	<u>Purchase or Exercise Price per Share</u>	<u>Estimate of Common Stock Fair Value per Share on Grant Date</u>
7/11/2016	Restricted common shares	4,830,600	\$ 0.0001	\$ 0.0001
3/1/2017	Common shares	2,415,300	\$ 0.0001	\$ 0.0001
6/12/2017	Options	130,535	\$ 0.62	\$ 0.62
9/14/2017	Options	12,000	\$ 0.78	\$ 0.78

### ***Determination of the Fair Value of Common Stock on Grant Dates***

Historically, for all periods prior to this offering, the fair values of the shares of common stock underlying our share-based awards were estimated on each grant date by our board of directors. The restricted common shares were granted to non-employees and subsequently were marked to market at each reporting date. On April 4, 2017, the non-employees became employees of our company and the fair value of the remaining unvested shares was fixed at \$0.62 per share. In order to determine the fair value of our common stock our board of directors considered, among other things, contemporaneous valuations of our common stock prepared by an independent third-party valuation specialist in accordance with the guidance provide by the Practice Aid.

Given the absence of a public trading market for our common stock, our board of directors exercised their judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including our stage of development; progress of our research and development efforts; the rights, preferences and privileges of our preferred stock relative to those of our common stock; equity market conditions affecting comparable public companies; the lack of marketability of our common stock; and valuations obtained from issuance of our preferred stock to unrelated parties.

We performed common stock valuations, with the assistance of an independent third-party valuation specialist, as of March 23, 2017 and September 8, 2017, which resulted in valuations of our common stock of \$0.62 and \$0.78, respectively. In conducting the valuations, the independent third-party valuation specialist considered all objective and subjective factors that it believed to be relevant for each valuation conducted in accordance with the Practice Aid, including our best estimate of our business condition, prospects and operating performance at each valuation date. Other significant factors included:

- the prices of our preferred stock sold to outside investors in arm's length transactions, and the rights, preferences and privileges of our preferred stock as compared to those of our common stock, including the liquidation preferences of our preferred stock;
- our stage of development and business strategy and the material risks related to our business and industry;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of guideline companies;
- our results of operations and financial position;
- the composition of, and changes to, our management team and board of directors;
- the lack of liquidity of our common stock;
- any external market conditions affecting the life sciences and biotechnology industry sectors;
- the likelihood of achieving a liquidity event for the holders of our common stock and stock options, such as an initial public offering, or IPO, or a sale of our company, given prevailing market conditions; and
- the state of the IPO market for similarly situated privately held life sciences companies.

The dates of our contemporaneous valuations have not always coincided with the dates of our stock option grants. In determining the exercise prices of the stock options set forth in the table above, our board of directors considered, among other things, the most recent valuation of our common stock and their assessment of additional objective and subjective factors that were relevant as of the grant dates. The additional factors

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considered when determining whether any changes in the fair value of our common stock had occurred between the most recent valuation and the grant dates included our stage of research and development, our operating and financial performance and current business conditions.

The estimates of fair value of our common stock are highly complex and subjective. There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates include assumptions regarding our future operating performance, the time to completing an IPO or other liquidity event, the related valuations associated with these events, and the determinations of the appropriate valuation methods at each valuation date. The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per share applicable to common stockholders could have been materially different.

For valuations after the completion of this offering, our board of directors will determine the fair value of each share of underlying common stock based on the closing price of our common stock as reported on the date of grant.

### ***Determination of Estimated Offering Price***

In September 2017, we selected underwriters for this offering. The midpoint of the range of the initial public offering price listed on the cover page of this prospectus as determined by us and the underwriters was \$        per share. In comparison, our estimate of the fair value of our common stock was \$0.78 per share as of the September 8, 2017 valuation. We note that, as typical in initial public offerings, the range of the initial public offering price listed on the cover page of this prospectus was not derived using a formal determination of fair value, but was determined based upon discussions between us and the underwriters. Among the factors that were considered in setting this range were our prospects and the recent market prices of, and the demand for, publicly traded common stock of comparable companies.

We believe that the difference between the fair value of our common stock as of        and the midpoint of the range of the initial public offering price listed on the cover page of this prospectus is the result of these factors as well as the facts that we have continued to advance our lead product candidate and our research and development efforts. In addition, the range of the initial public offering price listed on the cover page of this prospectus necessarily assumes that the initial public offering has occurred, a public market for our common stock has been created and our convertible preferred stock has converted into common stock in connection with the initial public offering. The range of the initial public offering price listed on the cover page of this prospectus therefore excludes any discount for lack of marketability of our common stock and any consideration of the preferences of our convertible preferred stock, which we factored into the September 8, 2017 contemporaneous valuation.



**Results of Operations**

*Comparison of the periods from July 5, 2016 (Inception) to December 31, 2016, the Nine Months Ended September 30, 2017, and the period from July 5, 2016 (Inception) to September 30, 2016*

	July 5, 2016 (inception) through December 31, 2016	July 5, 2016 (inception) through September 30, 2016 (In thousands)	Nine Months Ended September 30, 2017
Operating expenses:			
Research and development	\$ —	\$ —	\$ 10,047
General and administrative	1	1	1,312
Total operating expenses	1	1	11,359
Loss from operations	(1)	(1)	(11,359)
Other income, net	—	—	635
Net loss	<u>\$ (1)</u>	<u>\$ (1)</u>	<u>\$ (10,724)</u>

*Research and Development*

Research and development expenses were \$0 for the periods from July 5, 2016 (inception) through December 31, 2016 and from July 5, 2016 (inception) through September 30, 2016, as our primary operations did not commence until March 23, 2017, when we acquired our license to develop, make, use, and sell products incorporating RTB101 alone or in combination with everolimus. Research and development expenses increased to \$10.0 million for the nine months ended September 30, 2017, and were primarily attributable to \$3.9 million of costs associated with our license agreement, including the license of the intellectual property in exchange for Series A preferred stock, \$1.0 million of costs related to contract research and supplies, \$4.0 million of costs related to clinical trials, including the ongoing Phase 2b clinical trial, \$0.5 million of costs related to external consulting incurred to supplement our research and development personnel, and \$0.6 million of personnel costs.

*General and Administrative*

General and administrative expenses were \$1,000 for the periods from July 5, 2016 (inception) through December 31, 2016 and from July 5, 2016 (inception) through September 30, 2016, and consisted entirely of registration and filing fees related to our incorporation. General and administrative expenses increased to \$1.3 million for the nine months ended September 30, 2017, and were primarily attributable to \$0.5 million of personnel, and \$0.8 million of professional services fees, including costs related to intellectual property, legal and filing costs, accounting costs, and external consulting costs incurred to supplement our personnel.

*Other Income, Net*

Other income, net was \$0 for the periods from July 5, 2016 (inception) through December 31, 2016 and from July 5, 2016 (inception) through September 30, 2016. Other income, net was \$0.6 million for the nine months ended September 30, 2017, and entirely consisted of the change in fair value of our tranche liability related to our redeemable convertible preferred stock.

**Liquidity, Capital Resources and Plan of Operations**

Since inception through September 30, 2017, our operations have been financed solely by net proceeds of \$10.0 million from the issuance and sale of shares of our redeemable convertible preferred stock. As of September 30, 2017, we had \$4.0 million in cash and an accumulated deficit of \$10.7 million. In October 2017, we received an additional \$15.0 million in gross proceeds from the issuance and sale of our redeemable

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convertible Series A preferred stock, or the Series A preferred stock, at the final closing of our Series A financing, as well as \$40.0 million in gross proceeds from the issuance and sale of our redeemable convertible Series B preferred stock, or the Series B preferred stock.

Our primary use of cash has been to fund operating expenses, which consist of research and development and general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Based upon our current operating plan, we believe that the net proceeds from this offering, together with our existing cash will enable us to fund our operating expenses and capital expenditure requirements through . We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will continue to require additional financing to advance our current product candidate through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds through equity or debt financings, collaborative or other arrangements, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms, or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

If we need to raise additional capital to fund our operations, funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials, research and development programs or commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, and collaborations or licensing arrangements. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If additional funding is required, there can be no assurance that additional funds will be available to us on acceptable terms on a timely basis, if at all. If we are unable to raise capital, we will need to curtail planned activities to reduce costs. Doing so will likely have an unfavorable effect on our ability to execute our business plans.

The following table summarizes our cash flows for the periods indicated:

	<b>July 5, 2016 (inception) through December 31, 2016</b>	<b>July 5, 2016 (inception) through September 30, 2016</b>	<b>Nine Months Ended September 30, 2017</b>
Net cash used in operating activities	\$ —	\$ —	\$ (5,996)
Net cash used in investing activities	—	—	(39)
Net cash provided by financing activities	—	—	10,000
Net increase in cash	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,965</u>

### ***Cash Flows from Operating Activities***

No cash was used in operating activities for the periods from July 5, 2016 (inception) through December 31, 2016 and from July 5, 2016 (inception) through September 30, 2016. Cash used in operating activities for the nine months ended September 30, 2017 was \$6.0 million, consisting of a net loss of \$10.7 million adjusted for noncash items primarily including stock-based compensation expense of \$0.3 million and expense related to the acquisition of intellectual property of \$3.2 million partially offset by gains resulting from the change in fair value of the tranche liability of \$0.6 million. The change in our net operating assets and liabilities were due primarily to an increase in accounts payable of \$1.1 million as a result of payment timing and an increase in accrued liabilities of \$1.0 million primarily due to increased clinical activities, which were partially offset by an increase in prepaid expenses and other current assets of \$0.2 million due to prepayments for our research and development activities.

### ***Cash Flows from Investing Activities***

No cash was used in investing activities for the periods from July 5, 2016 (inception) through December 31, 2016 and from July 5, 2016 (inception) through September 30, 2016. Cash used in investing activities for the nine months ended September 30, 2017 was \$39,000 and consisted of the purchases of property and equipment.

### ***Cash Flows from Financing Activities***

No cash was provided by financing activities for the periods from July 5, 2016 (inception) through December 31, 2016 and from July 5, 2016 (inception) through September 30, 2016. Cash provided by financing activities for the nine months ended September 30, 2017 was \$10.0 million from the issuance of redeemable convertible preferred stock.

### **Contractual Obligations and Other Commitments**

The following table summarizes our outstanding contractual obligations as of payment due date by period at September 30, 2017.

<u>Total</u>	<u>Less than 1 Year</u>	<u>1 to 3 Years</u>	<u>3 to 5 Years</u>	<u>More than 5 Years</u>
\$—	\$—	\$—	\$—	\$—

In March 2017, we entered into a license Agreement with Novartis. See “—Overview—Novartis License Agreement.” Amounts owed under this license agreement are not included in the table above as they were considered a contingent payment as of September 30, 2017.

### **Net Operating Loss Carryforwards.**

As of September 30, 2017, we had federal and state net operating loss carryforwards of \$7.5 million and \$7.4 million, respectively, which begin to expire in various amounts in 2036. As of September 30, 2017, we also had federal research and development tax credit carryforwards of \$0.1 million, which begin to expire in 2037. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who own at least 5% of a corporation’s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing

period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after this offering, our ability to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. If we determine that an ownership change has occurred and our ability to use our historical NOLs or credits is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. We have not performed an ownership change analysis.

Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U. S. federal and state taxable income. As described above under “Risk Factors—Risks Related to our Financial Position and Need for Additional Capital,” we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOL or credit carryforwards that are subject to limitation by Sections 382 and 383 of the Code.

#### **Off-Balance Sheet Arrangements**

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

#### **Quantitative and Qualitative Disclosures about Market Risk**

We are exposed to market risks in the ordinary course of our business. We had no cash equivalents, investments or outstanding debt as of December 31, 2016 and September 30, 2017 and, as such, minimal exposure to market risk. At December 31, 2016 and September 30, 2017, we had cash in an operating account of \$0 and \$4.0 million, respectively.

#### **JOBS Act Accounting Election**

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We are considering whether to “opt out” of this provision and thereby comply with new or revised accounting standards as required when they are adopted. If we do decide to “opt out,” this decision to “opt out” of the extended transition period under the JOBS Act is irrevocable.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation, providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We would cease to be an emerging growth company upon the earliest of: (1) the last day of the fiscal year ending after the fifth anniversary of our initial public offering; (2) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (3) the date we qualify as a “large accelerated filer,” with at least \$700.0 million of equity securities held by non-affiliates; or (4) the issuance, in any three-year period, by our company of more than \$1.0 billion in non-convertible debt securities held by non-affiliates.

#### **Recently Issued and Adopted Accounting Pronouncements**

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*, or ASU 2014-15. ASU 2014-15 requires management to evaluate relevant conditions, events, and certain management plans that are known or reasonably knowable that, when considered

in the aggregate, raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued, for both annual and interim periods. ASU 2014-15 also requires certain disclosures around management's plans and evaluation, as well as the plans, if any, that are intended to mitigate those conditions or events that will alleviate the substantial doubt. ASU 2014-15 is effective for fiscal years ending after December 15, 2016. We adopted this guidance on July 5, 2016 (inception).

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718)*, or ASU 2016-09. The guidance changes how companies account for certain aspects of equity-based payments to employees. Entities will be required to recognize income tax effects of awards in the income statement when the awards vest or are settled. The guidance also allows an employer to repurchase more of an employee's shares than it can under current guidance for tax withholding purposes providing for withholding at the employee's maximum rate as opposed to the minimum rate without triggering liability accounting and to make a policy election to account for forfeitures as they occur. The updated guidance is effective for annual periods beginning after December 15, 2017. Early adoption is permitted. We adopted this guidance on July 5, 2016 (inception) and made the policy election to account for forfeitures as they occur. No awards have been forfeited as of September 30, 2017.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows*, or ASU 2016-18, which requires that amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2018 and should be applied using a retrospective transition method to each period presented. Early adoption is permitted. We do not expect the impact of ASU 2016-18 to be material to our financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*, or ASU 2017-09. ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The guidance is effective for annual periods beginning after December 15, 2017, with early adoption permitted, including adoption in any interim period for which financial statements have not yet been issued. We are currently evaluating the potential effects of adopting the provisions of ASU 2017-09.

In July 2017, the FASB issued ASU 2017-11, *Accounting for Certain Financial Instruments with Down Round Features*, or ASU 2017-11, which updates the guidance related to the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. Under ASU 2017-11, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. ASU 2017-11 is effective for public entities for all annual and interim periods beginning after December 15, 2019. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2017-11 will have on our financial statements.

## BUSINESS

### Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapeutics for the treatment of aging-related diseases. Our lead program has demonstrated in several clinical trials, including a randomized, placebo-controlled trial, the potential to treat multiple diseases of aging for which there are no approved therapies. The decline in immune function that occurs during aging, or immunosenescence, increases susceptibility to a variety of diseases, including respiratory tract infections, or RTIs, that significantly contribute to morbidity and mortality in the elderly. Our approach focuses on the mechanistic target of rapamycin, or mTOR, pathway, an evolutionarily conserved pathway that regulates aging, and specifically on selective inhibition of the target of rapamycin complex 1, or TORC1. Our initial focus is on the development of RTB101, an orally administered, small molecule, potent TORC1 inhibitor, alone and in combination with other mTOR inhibitors such as everolimus—as a first-in-class immunotherapy program designed to improve immune function and thereby reduce the incidence of RTIs in the elderly regardless of the causative pathogen. We licensed the worldwide rights to our TORC1 program, including RTB101 alone or in combination with everolimus or other mTOR inhibitors, from Novartis International Pharmaceutical Ltd., or Novartis, in March 2017.

Our TORC1 immunotherapy approach is supported by a randomized, placebo-controlled Phase 2a clinical trial in 264 elderly subjects that provided statistically significant and clinically meaningful results. This trial demonstrated that treatment with RTB101 alone and in combination with everolimus can enhance the ability of the aging immune system to fight infectious pathogens and consequently reduce the incidence of all infections, including RTIs in elderly subjects. Six weeks of treatment with RTB101 alone and in combination with everolimus met a prespecified endpoint of reducing the incidence of infections by 33% ( $p=0.008$ ) and 38% ( $p=0.001$ ), respectively, during a period of one year following initiation of therapy. We are evaluating RTB101 alone and in combination with everolimus in a Phase 2b clinical trial for the reduction in the incidence of RTIs in the elderly and expect to report top-line data from this trial in the second half of 2018. We expect market exclusivity for RTB101 alone and in combination with everolimus until at least 2031 in the United States 2032 in major European markets, and 2030 in Japan, and additional pending patent applications may prolong the exclusivity of these product candidates up to 2036.

Recent scientific findings, including those published in the scientific journals *Cell*, *Nature* and *Science*, suggest that aging and aging-related conditions, such as immunosenescence, are attributable not only to random cellular wear and tear, but also to specific intra-cellular signaling pathways, including the mTOR pathway. mTOR is a protein kinase that signals via two multiprotein complexes, known as TORC1 and TORC2. TORC1 inhibition has been observed to prolong lifespan, enhance immune function, ameliorate heart failure, enhance memory and mobility, decrease adiposity and delay the onset of aging-related diseases in multiple animal studies. Specifically with respect to enhanced immune function, TORC1 inhibition was observed in preclinical studies to rejuvenate blood, or hematopoietic, stem cell function, increase infection-fighting white blood cell production and enhance antibody-mediated, or adaptive, immunity. On the other hand, TORC2 inhibition has been observed to decrease lifespan in preclinical studies and cause unwanted side effects of hyperlipidemia and hyperglycemia in certain animals and humans. Therefore, based on these observations and data from the Phase 2a clinical trial, we believe our TORC1 program is well-suited to improve immune function and counteract immunosenescence in the elderly.

The reduced ability of elderly patients to effectively detect and fight infections is most commonly manifested in their susceptibility to RTIs and the negative effects such infections have on their overall health. According to the U.S. Census Bureau, RTIs are the fifth leading cause of death in people age 85 and over and the seventh leading cause of death in people age 65 and over, and result in high healthcare burdens and costs for the elderly population and the healthcare system. The majority of RTIs are caused by viruses for which there are no approved therapies. Despite this, antibiotics, which are ineffective against viruses, are often prescribed

indiscriminately to treat RTIs, which may cause side effects related to antibiotic use and contribute to the growing global problem of antibiotic resistance. As the elderly represent the fastest growing population in all regions of the world, we believe there is significant unmet medical need for innovative therapeutic options for reducing the incidence of RTIs by enhancing the function of the aging immune system.

We believe our approach to addressing RTIs in the elderly possesses several clinical and commercial advantages. Our TORC1 program offers an immunotherapy approach that has the potential to address a broad range of viral, and bacterial, pathogens. Statistically significant and clinically meaningful reductions in RTI incidence were observed in the Phase 2a clinical trial that evaluated RTB101 alone and in combination with everolimus. We believe the risk-to-benefit ratio of our program is well-suited to the elderly due to the following observations: our oral product candidates were well-tolerated in elderly subjects and were associated with no study drug-related serious adverse events in the Phase 2a clinical trial, and the doses being investigated in our ongoing Phase 2b clinical trial are 60 to 240 times lower than maximum tolerated doses established in prior clinical trials for other indications. Based on communications including those during a high-level policy meeting with the U.S. Food and Drug Administration, or FDA, to date, we believe a reduction in the incidence of RTIs has the potential to be a clinically relevant endpoint. Subject to receiving positive results from our ongoing Phase 2b clinical trial with respect to reduction in RTI incidence, we plan to conduct a Phase 3 pivotal program and to seek regulatory approval for commercialization of RTB101 alone or in combination with everolimus in the United States, Europe and Japan. In some markets, we may collaborate with third parties for the development and commercialization of our product candidates.

We were founded by Chen Schor, who serves as our chief executive officer, Joan Mannick, M.D., who serves as our chief medical officer, and PureTech Health, an advanced clinical-stage biopharmaceutical company. Dr. Mannick led the TORC1 clinical program at Novartis Institutes for Biomedical Research, or NIBR, prior to our in-licensing of the program. Our management team includes veterans in drug development and discovery, with executive experience in leading global pharmaceutical companies. We are supported by investors that include both private equity venture capital funds and public healthcare investment funds. Our investors include OrbiMed Advisors, Fidelity Management & Research Company, Rock Springs Capital, Quan Capital and Nest Bio.

### **Our Strategy**

Our goal is to be a leading biopharmaceutical company focused on treating aging-related diseases. We strive to maintain a leadership position in the TORC1 inhibitor class of pharmaceutical products. The key elements of our strategy to achieve this goal include:

- *Rapidly advance our TORC1 program as immunotherapy for reducing the incidence of RTIs in elderly subjects.* We initiated our Phase 2b clinical trial of RTB101 alone and in combination with everolimus in elderly subjects at increased risk of mortality and morbidity due to RTIs in the second quarter of 2017, and we expect to report top-line data from this trial in the second half of 2018. If the results of our Phase 2b clinical trial are positive, we plan to initiate a Phase 3 clinical trial in 2019 with a goal to submit a new drug application, or NDA, to the FDA for regulatory approval of RTB101 alone or in combination with everolimus in the United States in 2020.
- *Develop our TORC1 program for additional indications.* We also intend to develop RTB101, alone or in combination with everolimus, for the treatment of additional aging-related diseases based on preclinical and clinical evidence on the effects of TORC1 inhibition. We believe that there is strong rationale to support the investigation of RTB101, alone or in combination with everolimus, for the treatment of additional aging-related indications, such as urinary tract infections, heart failure and neurodegenerative diseases.
- *Commercialize our product candidates in the United States and potentially collaborate with others globally to maximize their commercial value.* We plan to directly commercialize our product

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candidates in the United States with a sales force targeting top-prescribing physicians with high flow of elderly patients and may consider collaborating with third parties to broaden the distribution of our product candidates in the United States. In other markets for which commercialization may be less capital efficient for us, we may selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates. We believe there are significant opportunities to market RTB101, if approved, in Europe and Japan, which we may choose to pursue in collaboration with others.

- *Maintain and grow a robust intellectual property portfolio in the field of TORC1 inhibition for aging-related diseases.* We have an exclusive license to ten patent families directed to compositions of matter, methods and formulations covering RTB101 alone or in combination with everolimus. We intend to aggressively pursue and maintain broad intellectual property protection for RTB101 alone or in combination with everolimus or other compounds for the prevention of RTIs and the prevention or treatment of other aging-related diseases through U.S. and international patents.
- *Develop, acquire or in-license product candidates that enhance our global leadership position.* We have additional TORC1 inhibitor compounds in discovery that we may develop, and we may acquire or in-license other product candidates targeting TORC1 and other pathways that regulate aging to support our goal to be the leading biopharmaceutical company focused on the treatment of aging-related diseases with significant unmet medical need.

**Our Product Pipeline**

The following table summarizes key information about our product candidates.

Program	Indication	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones
TORC1 Program: RTB101 and RTB101+ Everolimus	Respiratory Tract Infections	[Progress bar from Discovery to Phase 2]					Phase 2b top-line data in 2H 2018
	Other Infections*	[Progress bar from Discovery to Phase 1]					
	Heart Failure with Preserved Ejection Fraction	[Progress bar from Discovery to Phase 1]					Initiation of at least one Phase 2 trial in 2018**
	Autophagy-Related Neurodegenerative Diseases	[Progress bar from Discovery to Phase 1]					

\* Other infections include those that the elderly are at increased risk of contracting, such as urinary tract infections.

\*\* For heart failure with preserved ejection fraction, autophagy-related neurodegenerative diseases and certain other infections, we may be required to file an investigational new drug application, or IND, prior to initiating Phase 2 clinical trials. We expect to have the ability to initiate these Phase 2 clinical trials without the need to conduct prior Phase 1 clinical trials.

We also have a follow-on TORC1 inhibitor program at discovery stage.



## **Aging and its Regulation by the mTOR Pathway**

### ***Advances in the scientific understanding of aging have until recently been limited, despite high growth in the elderly population***

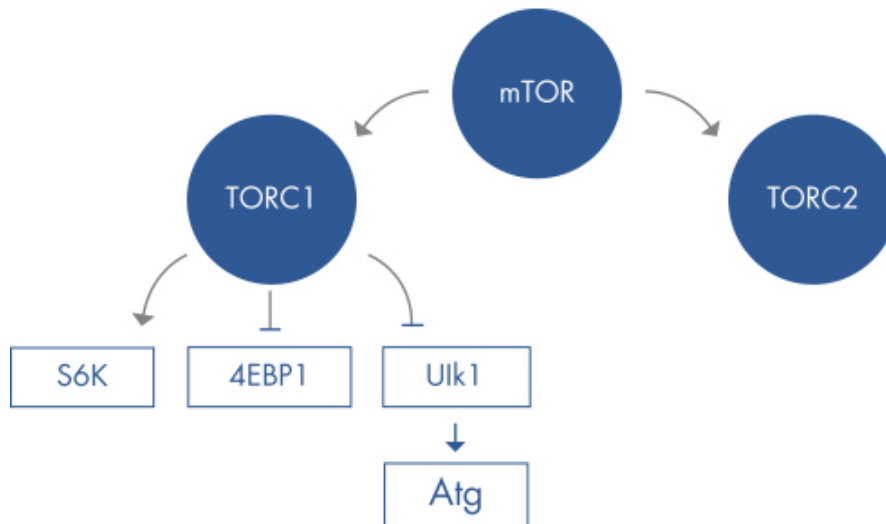
The elderly are the fastest growing population around the globe. According to the U.S. Census Bureau, the population age 65 and older in the United States is expected to double by 2050 compared to 2012 estimates. According to global census data, there are nearly 150 million people age 65 and older, and approximately 20 million people age 85 years and older in the United States, the major European countries and Japan. Despite age being the major risk factor for multiple chronic diseases, we believe few therapies are being developed to target the aging immune system, and none have been approved.

### ***mTOR is an evolutionarily conserved pathway that regulates aging***

mTOR is a serine/threonine protein kinase that regulates the process of aging and aging-related diseases and conditions. Inhibition of the mTOR pathway has been observed to prolong lifespan in multiple animals. These data support the potential for drugs that target the mTOR pathway to have therapeutic benefits for aging and aging-related conditions in humans.

In preclinical studies, the mTOR pathway has been observed to be hyperactivated in some cell types, including hematopoietic stem cells, or HSCs, at an advanced age. It was observed that suppressing mTOR activity in these cell types to levels found at younger ages may enhance cell function, including their ability to generate white blood cells. Furthermore, preclinical studies found that mTOR activity stimulates protein synthesis and cell growth, but inhibits protective processes such as autophagy in which damaged proteins and organelles are broken down and recycled. Therefore, these studies suggest that increased mTOR activity is beneficial during years of growth and reproduction but may be harmful during post-reproductive years when cells accumulate damage and require protective mechanisms such as autophagy to prevent and repair damage.

mTOR signals via two multiprotein complexes, known as TORC1 and TORC2. TORC1 inhibition has been observed to prolong lifespan, enhance immune responses, ameliorate heart failure, enhance memory and mobility, decrease adiposity, and delay onset of aging-related diseases in multiple animal studies. On the other hand, TORC2 inhibition has been observed to decrease lifespan and cause hyperlipidemia and hyperglycemia in certain animals and humans. Therefore, we believe the optimal approach for the treatment of aging-related conditions through mTOR inhibition is a regimen that inhibits TORC1 without inhibiting TORC2. mTOR within the TORC1 complex introduces phosphates to, or phosphorylates, multiple proteins including S6K, 4EBP1 and Ulk1, as shown in the figure below. More complete inhibition of TORC1, as measured by decreased phosphorylation of multiple proteins downstream of TORC1, may also be more beneficial compared to partial inhibition of TORC1 for the treatment of aging-related diseases.



We believe TORC1 inhibition may have therapeutic benefit in multiple aging-related diseases. Preclinical studies suggest that key mechanisms involved in the anti-aging effects of TORC1 inhibition include improved stem cell function, increased autophagy, increased expression of mitochondrial proteins that are important for energy production, decreased adiposity and increased expression of proteins that are responsible for cellular maintenance and repair. Based on preclinical data, these biological effects have the potential to improve multiple aging-related pathologies:

1. *Decreased immune function and increased risk of infections.* The immune system has several important functions, including protection against harmful pathogens, cancer immunosurveillance and clearance of senescent cells. Innate immunity is the body's first line of defense against a wide range of pathogens, while adaptive immunity is a more pathogen-specific immune response that develops over time. Immune cells are produced by HSCs in the bone marrow, which can lose functionality with age. In preclinical studies, aged dendritic cells, a type of innate immune cell, demonstrated defective Type 1 interferon production, a central component of anti-viral immunity, in response to a virus. This response is consistent with the observation that dendritic cells from older subjects produced less interferon upon stimulation with a virus than those from younger subjects. Adaptive immunity also declines with age. The number and functionality of certain white blood cells known as lymphocytes, including antibody-producing B lymphocytes, have been observed to be decreased in elderly human subjects. We believe that this decline in immune function contributes to the higher incidence of common infections such as respiratory and urinary tract infections in the elderly.
2. *Decreased mitochondrial function and organ dysfunction.* During aging, mitochondrial function, which is important for metabolism and energy production in cells, is diminished. This diminution is

linked to a switch from more efficient fatty acid oxidation to less efficient glucose oxidation in aging organs. The detrimental nature of this metabolic change has been extensively described in animal and human studies of aging-related conditions, including heart failure.

3. *Decreased autophagy and accumulation of damaged proteins.* Autophagy is the process in which a cell breaks down and recycles damaged cellular components, including damaged and aggregated proteins. Preclinical data suggests that an aging-associated decrease in autophagy leads to the accumulation of toxic proteins and may result in aging-associated pathologies such as neurodegeneration.

## **Immunosenescence and Respiratory Tract Infections in the Elderly**

### ***Potential for TORC1 inhibition to address decreased immune function associated with aging***

TORC1 inhibition has been observed to enhance immune function in at least three independent preclinical studies to date, conducted by laboratories at the University of Michigan, Emory University and St. Jude Children's Research Hospital, where administration of mTOR inhibitors improved immune response to influenza vaccination. Further, findings from these preclinical studies suggest that short-term treatment of aged animals with a TORC1 inhibitor can rejuvenate HSC function, increase the number of infection-fighting white blood cells, and increase longevity. We believe these findings suggest that TORC1 inhibition has the potential to improve immune function in elderly humans.

### ***Respiratory tract infections in the elderly***

The reduced ability of the aging immune system to effectively detect and fight infections results in increased susceptibility of the elderly to RTIs, which, in turn negatively impacts such patients' overall health and quality of life. We believe that decreasing the incidence of RTIs is a large unmet medical need in the elderly, particularly in subjects at an increased risk of RTI-related morbidity and mortality. We believe there is a significant unmet medical need for an innovative therapy to reduce the incidence of RTIs in the elderly for the following reasons:

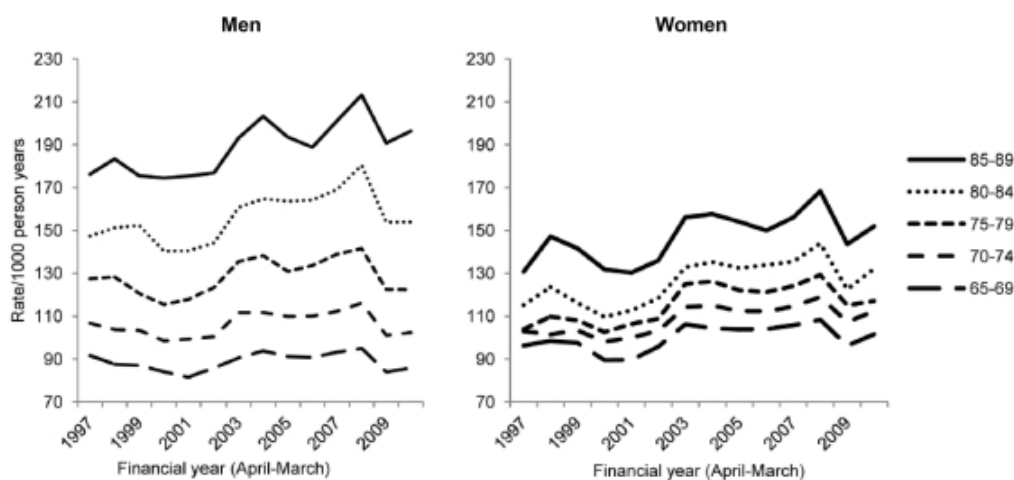
- *The large and growing elderly population is particularly susceptible to morbidity and mortality from RTIs.* The elderly represent the fastest growing population across the globe. In the United States, RTIs are the fifth leading cause of death in people age 85 and over and the seventh leading cause of death in people age 65 and over. Mortality among people age 75 and over is highest each year during winter cold and flu season. Age is a risk factor for RTIs, with men aged 85-89 experiencing lower RTIs at twice the rate of men aged 65-69. As a result, RTIs, which are typically not serious in healthy adults, are exacerbated in the elderly. Elderly patients with comorbidities may also be at a higher risk of morbidity and mortality due to RTIs as compared to healthy elderly subjects. Comorbidities among the elderly aged 65 and older are common, with approximately 14% having chronic obstructive pulmonary disease, or COPD, 7% having asthma, 20% having type 2 diabetes mellitus, or T2DM, and 13% having congestive heart failure, or CHF. Prior to initiating the Phase 2b clinical trial, PureTech Health conducted a market survey with five payers and 55 physicians in the United States. The results of the survey suggested that the efficacy demonstrated in our Phase 2a clinical trial is clinically meaningful and that there is unmet medical need in the elderly, particularly in the elderly at high risk of mortality from RTIs. Furthermore, the survey illustrated that, subject to FDA approval, payers may be able to include a product with our efficacy and safety profile in their formularies and may request a modest rebate. The following figures highlight the number of elderly people in the United States, major European countries and Japan, along with their comorbidities, based on global census data and our market research performed in the U.S., and the historical rates of lower RTIs in the elderly population in the U.K.

### Estimated Size of Population Susceptible to RTI-related Morbidity and Mortality

	U.S.	EU5	JP
<b>Elderly people (65-74 years old):</b>			
With comorbidities (COPD, asthma, T2DM, CHF)	11M	13M	7M
<b>Elderly people (75-84 years old):</b>			
With comorbidities (COPD, asthma, T2DM, CHF)	7M	11M	6M
<b>Elderly people (85+ years old):</b>	6M	9M	5M
<b># Elderly people (2016)</b>	<b>24M</b>	<b>33M</b>	<b>18M</b>
<b>Average Annual Growth Rate</b>	<b>3%</b>	<b>2%</b>	<b>1%</b>

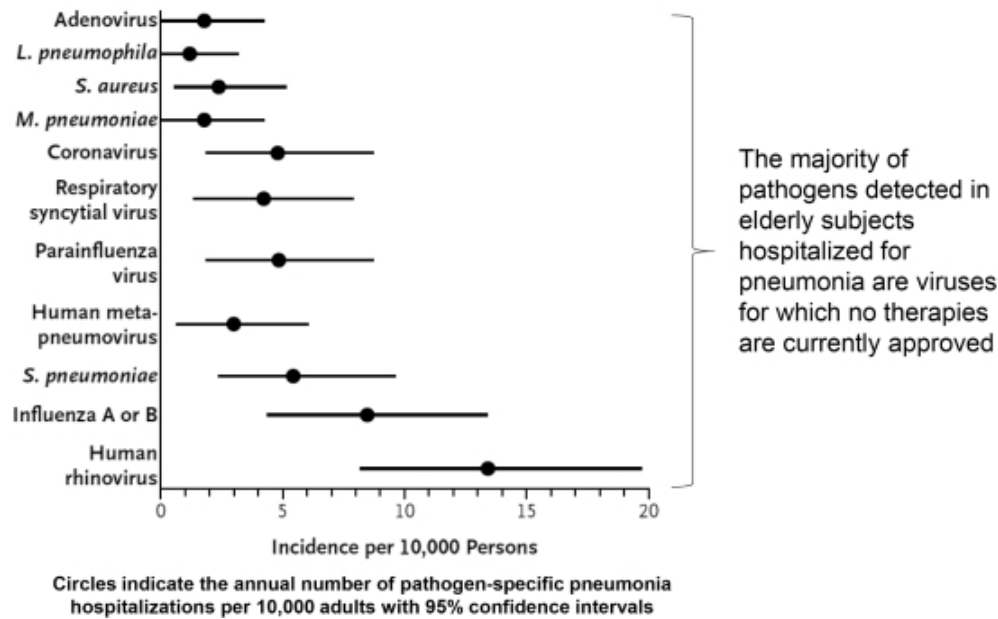
An estimated 75 million elderly people in 2016 were at increased risk of RTI-related morbidity and mortality in U.S., the major European countries and Japan

### Lower Respiratory Tract Infection Rates Increase with Age



- *RTIs contribute to high healthcare burden and costs.* At least 11%, 56% and 80% of CHF exacerbations, COPD exacerbations requiring hospitalization and asthma exacerbations, respectively, are associated with RTIs, and 7% of people aged 85 years and over go to the emergency room with RTIs each year. In addition, two-thirds of people aged 85 and over who go to the emergency room for infection-related reasons are hospitalized, and once hospitalized, one-third of people aged 85 and over are admitted to a nursing home. These figures illustrate the large economic impact of RTIs on the healthcare system in the United States.
- *The majority of RTIs are caused by viruses for which no available therapy exists.* The majority of RTIs are caused by viruses, most of which lack approved prophylactics or therapies, leaving physicians with few treatment options. Based on Center for Disease Control, or CDC, guidelines, vaccines are given to prevent influenza and pneumococcal infections. However, even if vaccinated, the elderly are less likely to develop sufficient protective immunity against influenza and pneumococcal infections due to immunosenescence. In addition, vaccines against most of the viral

pathogens that cause RTIs are not currently available. The following figure illustrates the specific pathogens detected in patients 80 years or older hospitalized with community-acquired pneumonia.



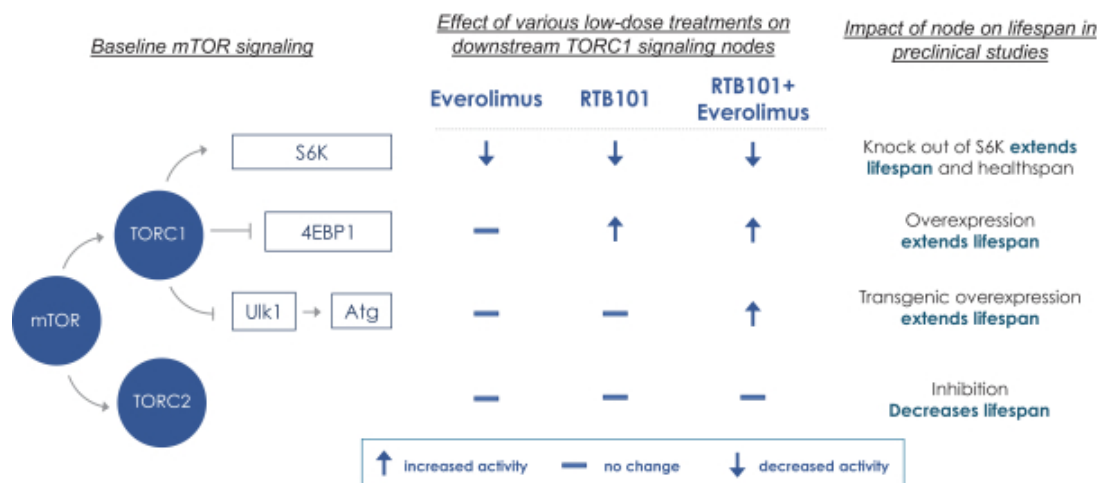
- **Antibiotics are often prescribed indiscriminately to treat RTIs, leading to potential side effects and contributing to growing antibiotic resistance.** Antibiotics, which are ineffective against viruses, are often prescribed indiscriminately to treat RTIs, which may cause side effects related to antibiotic use and contribute to the growing global problem of antibiotic resistance. As antibiotic use is a primary driver of antibiotic resistance, we believe that reducing the incidence of RTIs in the elderly could also indirectly limit the rise of antibiotic-resistant bacteria. Furthermore, the elderly are at increased risk of antibiotic-related adverse events due to increased organ sensitivity, increased exposure due to changes in pharmacokinetics, and polypharmacy. According to a study conducted by McGill University, antibiotics have been linked to 17% of adverse drug-related events in the elderly who visit emergency departments. Antibiotic use can also lead to lethal superinfections such as *C. difficile* infections.
- **Lack of immunotherapy drugs to address RTIs.** Immunotherapies ideally enhance both innate and adaptive immunity to provide broad, acute and long-lasting protection against pathogens. Currently, however, there are no approved immunotherapies to enhance either innate or adaptive immunity in the elderly. We believe RTB101 alone or in combination with everolimus represent immunotherapies aimed at enhancing either innate or innate and adaptive immunity in the elderly, and thereby decreasing the incidence of RTIs caused by a broad spectrum of pathogens, particularly viral pathogens. In addition, beyond an individual level, we believe immunotherapies may benefit the wider population through indirect protection that occurs when a large percentage of the population has become immune to a disease, thereby preventing or limiting the spread of infection and providing a measure of protection for individuals who are not immune, a phenomenon known as herd immunity.

**Our TORC1 Program**

**Overview**

In March 2017, we obtained a license from Novartis to the worldwide rights to RTB101 for all indications, and the rights to use everolimus in combination with RTB101 for all aging-related indications. RTB101 is an orally administered, small molecule, potent TORC1 inhibitor that binds to the active site of mTOR on the TORC1 complex, a mechanism known as catalytic inhibition. In contrast, everolimus, also an orally administered small molecule, inhibits mTOR activity by changing the shape of TORC1, a mechanism known as allosteric inhibition, that is distinct from and synergistic with catalytic inhibition.

The downstream signaling cascade of TORC1 that we believe occurs in scenarios of baseline, RTB101 alone and RTB101 in combination with everolimus are pictured in the following figure.



Our TORC1 program includes evaluation of RTB101 alone because we believe RTB101 monotherapy can effectively inhibit phosphorylation of multiple downstream signaling nodes of TORC1, specifically S6K and 4EBP1, that are key drivers of TORC1 downstream activity. Decreased phosphorylation of S6K leads to decreased activity, while decreased phosphorylation of 4EBP1 and Ulk1 leads to increased activity. We believe RTB101 alone consistently inhibits more downstream signaling nodes of TORC1 than a rapalog, such as everolimus, alone. Furthermore, we believe RTB101 at the low doses that we are evaluating in our clinical studies can achieve these effects without inhibiting TORC2. RTB101 at higher doses, while able to more completely inhibit TORC1, may also inhibit TORC2, which may lead to undesirable side effects.

Our TORC1 program also includes evaluation of RTB101 in combination with everolimus, as the combination of catalytic and allosteric inhibitors may yield complete inhibition of all nodes downstream of TORC1, including 4EBP1 and Ulk1, without affecting TORC2. It was observed in preclinical in vitro studies that RTB101 and everolimus at the comparable doses that we are evaluating in our clinical trials synergistically inhibit 4EBP1. The synergy of RTB101 and everolimus, as measured by Loewe additivity, was up to 43% in those studies. Loewe additivity in excess of 30% is considered to be high. We believe everolimus may induce a conformation change in TORC1 that allows lower concentrations of RTB101 to inhibit TORC1 without inhibiting TORC2. Preclinical and clinical data suggest that for some indications, RTB101 monotherapy may be adequate to yield clinically meaningful benefit to patients, while for other indications, the combination of RTB101 and everolimus may be more beneficial. Accordingly, our TORC1 program includes evaluation of both RTB101 alone and in combination with everolimus.

### ***Clinical Development of RTB101 Alone and in Combination with Everolimus***

We consider data from a Phase 2a clinical trial to be the most directly relevant dataset for our near-term development of RTB101 alone and in combination with everolimus, including the design of our ongoing Phase 2b trial evaluating the safety, tolerability and efficacy of our product candidates to reduce the incidence of RTIs in the elderly. If results from our ongoing Phase 2b clinical trial are positive, we intend to initiate a Phase 3 program for RTB101 alone or in combination with everolimus in 2019. We believe that preclinical and clinical safety data of high-dose RTB101 alone and in combination with everolimus that was generated by our licensor provide additional support for the clinical development of our program. The potential for TORC1 inhibition to ameliorate immunosenescence was also demonstrated in a previous Phase 2a clinical trial.

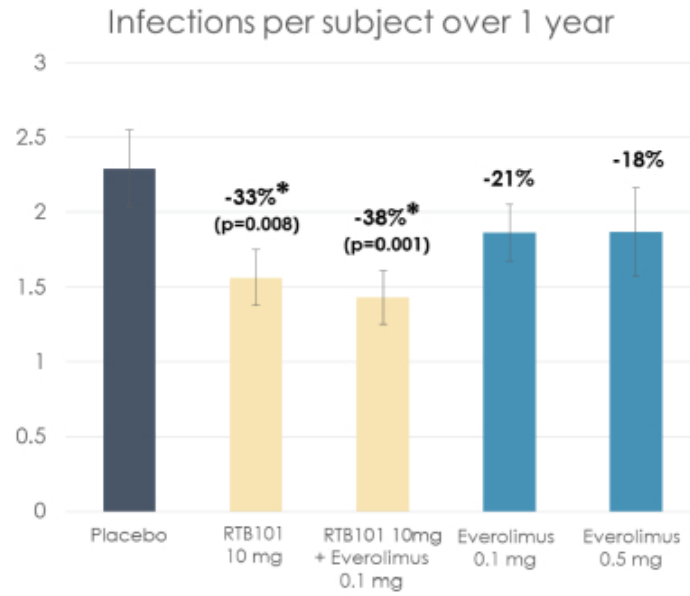
#### ***Phase 2a Clinical Development***

The primary objectives of the Phase 2a clinical trial were to assess the safety, tolerability and efficacy of RTB101 alone and in combination with everolimus compared to placebo in enhancing the immune response to vaccination in elderly subjects, as determined by the subjects' immune response to the seasonal influenza vaccine. A pre-specified exploratory endpoint assessed the effect of a six-week course of RTB101 alone or in combination with everolimus on infection rates during the year following initiation of study drug treatment. The trial was a double-blinded, placebo-controlled, randomized clinical trial that enrolled a total of 264 male and female subjects at least 65 years of age without underlying unstable medical conditions, and was conducted across 12 trial centers in the southern hemisphere. Subjects were randomized to one of five treatment arms, in which they were administered daily oral doses of everolimus 0.1 mg, everolimus 0.5 mg, RTB101 10 mg, RTB101 10 mg+everolimus 0.1 mg, or placebo. The trial met its primary endpoint and the pre-specified exploratory infection rate endpoint.

Subjects were treated for six weeks with the study drug and, after a two week drug-free interval, were given the seasonal influenza vaccine. The subjects were followed for one year following initiation of study drug treatment. The overall infection rate in each treatment group was assessed by having subjects record any infections they experienced during the year following the initiation of study drug treatment in a diary. The sites reviewed the infection diary at each study visit. In addition, sites administered infection questionnaires during phone calls with subjects that occurred weekly during the six-week study drug dosing period and then monthly for the remainder of the trial. Investigators reviewed and approved the information contained in the telephone questionnaire reports within 24 hours. The infection data in the diaries and telephone reports were reconciled by sites prior to entering infections in the clinical trial database.

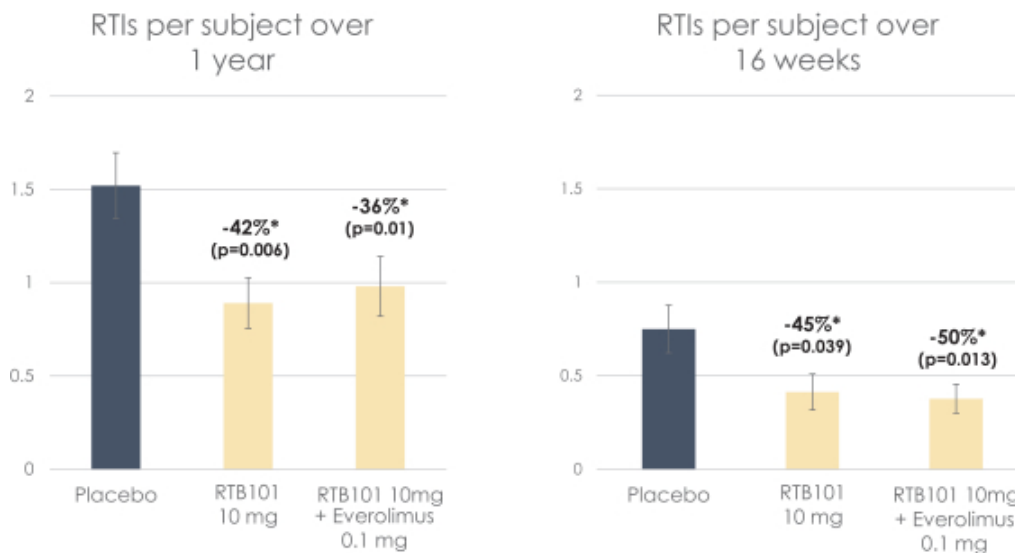
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In the RTB101 monotherapy and RTB101+everolimus combination treatment arms in the intent-to-treat population, statistically significant and clinically meaningful reductions in the annual rate of infections of 33% (p=0.008) and 38% (p=0.001), respectively, compared to placebo, were observed. Reductions with p-values less than 0.05 are considered to be statistically significant. A lesser, non-statistically significant effect was observed with everolimus monotherapy.



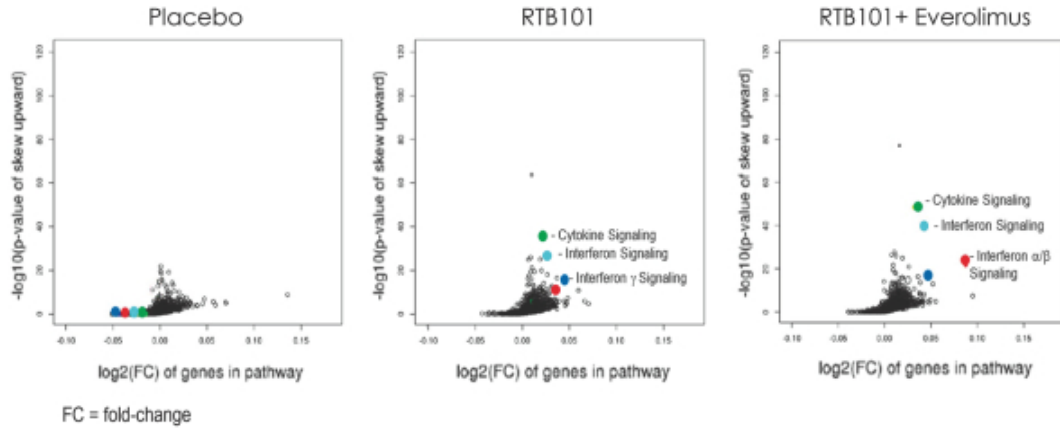


Since the most common infections that occurred during the trial were RTIs, a post-hoc analysis was performed to determine whether a reduction in RTIs contributed to the significant reduction in infections at one year following initiation of study drug treatment in the RTB101 monotherapy and RTB101+everolimus combination treatment arms. As shown in the figure below, both RTB101 monotherapy and the RTB101+everolimus combination therapy were observed to reduce the incidence of RTIs at one year by 42% ( $p=0.006$ ) and 36% ( $p=0.01$ ), respectively, in the intent-to-treat population. Greater reductions in the incidence of RTIs were observed during the six-week dosing period in the RTB101 monotherapy and RTB101+everolimus combination arms. Given that the magnitude of the reduction in RTI incidence was greater at six weeks than at one year, these findings suggest that the reduction in RTI rates was greatest during the period when subjects were receiving the study drug. The typical duration of the peak cold and flu season is approximately 16 weeks. As shown in the figure below, analysis of the Phase 2a clinical data also revealed reductions of 45% ( $p=0.039$ ) and 50% ( $p=0.013$ ) in RTIs from treatment with RTB101 alone and in combination with everolimus, respectively, during the 16 weeks following initiation of therapy despite only six weeks of treatment.



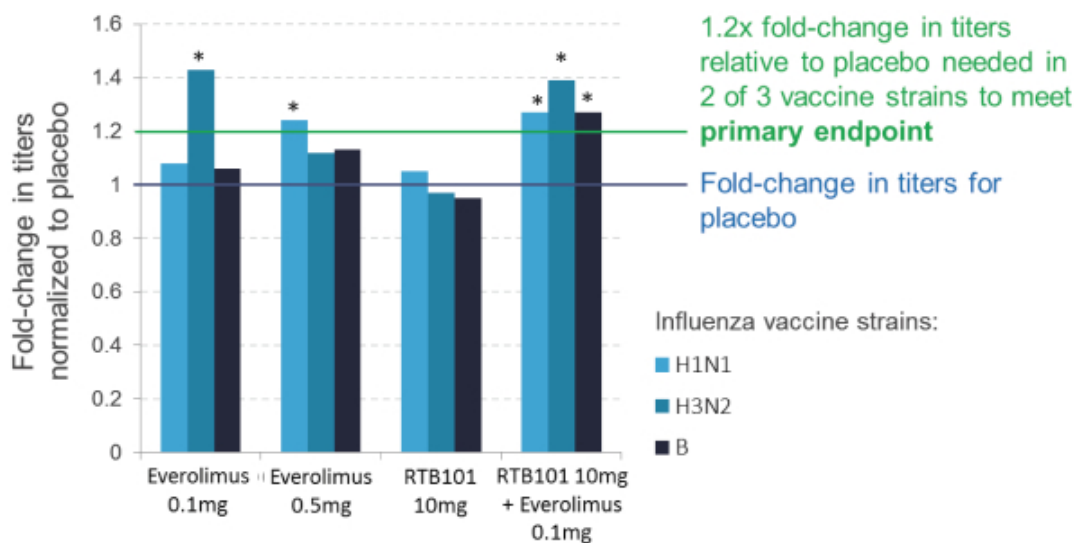
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To assess possible molecular mechanisms underlying the decrease in infection rates in the RTB101 monotherapy and RTB101+everolimus combination treatment groups, mRNA sequencing analysis of whole blood from subjects at baseline and after six weeks of study drug treatment was conducted. Analysis of whole-blood gene expression data revealed a highly statistically significant up-regulation of pathways related to interferon signaling in the RTB101 monotherapy and RTB101+everolimus combination treatment arms but not in the placebo arm, as shown in the figures below. Genes that were up-regulated the most, including MX1, OAS3, ISG15 and IFIT1, encode a subset of Type 1 interferon-induced proteins that play a critical role in the acute, innate immune response to viruses, suggesting that RTB101 alone and in combination with everolimus may enhance innate immunity. Pathways, or groups of genes, related to cytokine signaling and interferon signaling were significantly upregulated, with p-values ranging between  $10^{-45}$  to  $10^{-10}$ .



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While the effects of RTB101 monotherapy and RTB101+everolimus combination therapy on reducing RTIs incidence in the elderly and up-regulating innate immunity genes were comparable, only the combination therapy met the primary endpoint of the Phase 2a clinical trial of enhancing influenza vaccination response, defined as a greater than 20% increase in antibody concentrations, or titers, to at least two of the three tested influenza vaccine strains as compared to placebo, measured at 12 weeks following initial dosing of the study drug. We believe these results suggest that the RTB101+everolimus combination therapy may also enhance the adaptive immune system, in addition to enhancing the innate immune system, given that the RTB101+everolimus combination resulted in broader TORC1 inhibition. The adaptive immune response to influenza vaccination across all treatment arms is shown in the figure below, where asterisks indicate a 100% probability that titers are greater than those observed in the placebo group.

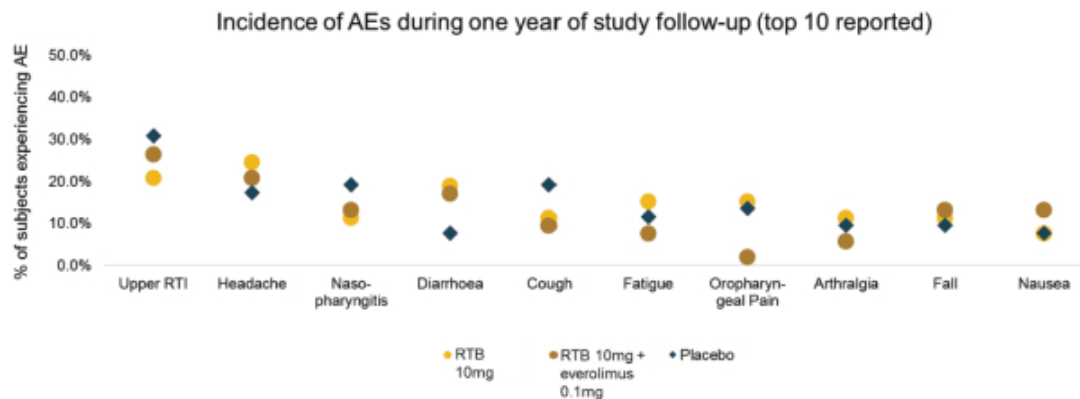


Overall, all treatment regimens were well tolerated. None of the participants in the treatment arms experienced a serious adverse event, or SAE, that was related to the study drug. The following table summarizes the SAEs experienced by trial subjects during the year they were followed in the trial.

	Everolimus 0.1mg	Everolimus 0.5mg	RTB101 10mg	RTB101 10mg + Everolimus 0.1mg	Placebo
Total SAEs	4	9	9	6	8
Subjects with SAEs	3	8	6	3	5
% of subjects with SAEs*	5.8	14.8	11.3	5.7	9.6

\* Percentages are based on the total number of subjects in each arm that received at least part of one dose of study drug

The ten most prevalent adverse events, or AEs, during the 12 months that patients were followed in the trial is summarized in the figure below. Diarrhea was the most frequently reported AE that occurred more often in the study drug treatment groups than the placebo groups and was generally mild or moderate in severity, transient and resolved with no treatment. Of note, the rate of upper RTI, nasopharyngitis and cough was lower for RTB101 monotherapy and RTB101+everolimus combination than for placebo, suggesting greater freedom from respiratory symptoms in the treatment groups as compared to the placebo groups. Furthermore, rates of hyperglycemia and hypercholesterolemia, which are AEs associated with TORC2 inhibition, were less than 5% in all treatment groups and were the same or lower in the mTOR inhibitor treatment groups than the placebo groups, suggesting that these low dose mTOR inhibitor treatment regimens did not inhibit TORC2.



We believe that the Phase 2a clinical trial results provide proof of concept for the potential therapeutic benefit of RTB101 alone or in combination with everolimus as immunotherapy to reduce the incidence of RTIs in elderly patients, given the statistically significant and clinically meaningful reduction in RTI rates, the increased expression of innate anti-viral genes and the enhanced immune response to vaccination observed across the treatment groups.

*Ongoing Phase 2b Clinical Development*

We are conducting a randomized, double-blinded, placebo-controlled Phase 2b clinical trial to assess the safety, tolerability and efficacy of 16 weeks of treatment with RTB101 alone or in combination with everolimus as compared to placebo in elderly patients without unstable medical conditions but who are at increased risk of RTI-related morbidity or mortality. Elderly patients at increased risk of RTI-associated morbidity and mortality are defined as subjects who are 85 years of age or older or subjects 65 years of age or older with asthma, chronic obstructive pulmonary disease, chronic bronchitis, Type 2 diabetes mellitus, congestive heart failure, an emergency room visit or hospitalization for an RTI within the past 12 months, or who are current smokers. We are conducting the trial in two parts across two hemispheres. The first part was conducted during the winter cold and flu season in the southern hemisphere. Following an interim analysis that we conducted in October 2017, we commenced the second part during the winter cold and flu season in the United States in the fourth quarter of 2017. We expect to report top-line data from this trial in the second half of 2018. The primary endpoint of the trial is to determine if RTB101 alone or in combination with everolimus decreases the percentage of subjects with RTIs compared to placebo during the 16-week administration period.

In the first part of the trial, 179 patients were randomized to receive RTB101 10 mg daily, RTB101 5 mg daily or placebo daily. We selected RTB101 10 mg daily as a dose because in the Phase 2a clinical trial, the same dose was well-tolerated and was observed to significantly decrease the rate of all infections as well as the rate of RTIs, and was associated with upregulation of antiviral gene expression in whole blood. To determine the minimal efficacious dose of RTB101, we also evaluated RTB101 5 mg daily in the Phase 2b trial.

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An interim analysis on data from the first part of the trial was completed in October 2017 by an independent data monitoring committee, or DMC. The DMC reviewed the safety and efficacy data from the first part of the trial and selected the doses of RTB101 and RTB101 in combination with everolimus to be tested in the second part of the trial in the United States.

We commenced the second part of the Phase 2b clinical trial in the fourth quarter of 2017. Based on the DMC recommendation, we expect to randomize at least 424 patients to receive placebo or one or more of the following TORC1 inhibitor treatment regimens: RTB101 10 mg once daily, RTB101 10 mg twice daily and RTB101 10 mg in combination with everolimus 0.1 mg.

We are studying the combination of RTB101 and everolimus 0.1mg because in the Phase 2a clinical trial, this combination not only reduced the incidence of infections similar to RTB101 monotherapy, but also led to a greater improvement in influenza vaccination response than either RTB101 or everolimus monotherapy.

The Phase 2b clinical trial has a greater than 80% power to detect a statistically significant reduction in the percentage of subjects with RTIs, assuming an effect size of 40% reduction. The effect size of 40% was conservatively estimated based on the reduction observed in the Phase 2a RTI rates at 16 weeks, which is the duration specified for the Phase 2b primary endpoint, of 45% ( $p=0.039$ ) and 50% ( $p=0.013$ ) in the RTB101 monotherapy and RTB101+everolimus combination arms respectively.

Based on communications with the FDA, including those during a high-level policy meeting, to date, we believe a reduction in the incidence of RTIs has the potential to be a clinically relevant endpoint. We completed a pre-investigational new drug, or pre-IND meeting, with the FDA in July 2017 and subsequently submitted an investigational new drug application, or IND, for RTB101 alone and in combination with everolimus as immunotherapy designed to reduce the incidence of RTIs in elderly patients at increased risk of RTI-related morbidity or mortality.

### *Phase 3 Clinical Development Plan*

If the results from the ongoing Phase 2b clinical trial are positive, we intend to conduct two Phase 3 pivotal clinical trials across two hemispheres. The Phase 3 clinical program is expected to start in the southern hemisphere in the first half of 2019 at the beginning of the winter cold and flu season and run through the second quarter of 2020. If our Phase 3 clinical trials are successful, we anticipate filing an NDA with the FDA in 2020, and an MAA with the EMA in 2021.

If the results from the ongoing Phase 2b clinical trial are favorable for RTB101 monotherapy, we expect to randomize approximately 600 elderly subjects at increased risk of RTI-associated morbidity and mortality to receive daily oral administration of RTB101 monotherapy or placebo for 16 weeks in each of the proposed Phase 3 clinical trials. The primary endpoint would be the reduction in RTI incidence over the dosing period.

If the results from the ongoing Phase 2b are not positive for RTB101 monotherapy but are positive for the RTB101+everolimus combination therapy, we expect to initiate a Phase 3 program with the combination of RTB101+everolimus and may include enhanced immune response to vaccination as an additional co-primary endpoint.

### *Safety Data from Clinical and Preclinical Development at High Doses of RTB101 Alone and in Combination with Everolimus*

Originally, RTB101 was developed for oncology indications. In preclinical studies, at doses higher than those we are developing, RTB101 was found to prevent cellular proliferation and tumor progression. Clinical trials in humans were conducted under two open INDs for RTB101 filed with the FDA Division of Oncology Products. More than 440 oncology patients have been treated with RTB101 alone in doses up to 1,600 mg per

day, or in combination with other drugs including 200 mg of RTB101 in combination with 2.5 mg of everolimus per day. RTB101 has also been administered to more than 60 healthy volunteers in pharmacokinetic, or PK, studies at doses of up to 1,000 mg per day. To date, the majority of the reported adverse events, or AEs, were mild or moderate and include gastrointestinal disturbances, fatigue, decreased appetite, rash and thrombocytopenia, which are consistent with those that have been reported for marketed mTOR inhibitors such as rapamycin and everolimus. No dose-limiting toxicities occurred at doses less than 800 mg per day, and the maximum tolerated dose for RTB101 as a monotherapy was established at 1,200 mg per day. We are developing RTB101 at daily doses of 5 mg to 20 mg, 60 to 240 times lower than the established maximum tolerated dose, and therefore expect the RTB101 to have an acceptable tolerability profile for the indications that we plan to pursue.

Standard preclinical safety and good laboratory practice, or GLP, toxicology studies, up to six months in rats and dogs, have been completed for RTB101, which we believe support the clinical development of the program.

### **Other Potential Indications for Our TORC1 Program**

We may evaluate RTB101 alone or in combination with everolimus or other drugs for the treatment of additional indications, such as heart failure with preserved ejection fraction, urinary tract infections, Huntington's disease and Parkinson's disease. We plan to initiate at least one Phase 2 proof of concept study in 2018. We expect to select indications based on strong scientific rationale, preclinical or clinical data, unmet medical need and other relevant considerations.

### ***Prevention of recurrent urinary tract infections***

Urinary tract infections, or UTIs, are the most common bacterial infection in the elderly, with the incidence higher in women than men. According to studies of 959 and 395 women published in 2000 and 2010, respectively, nearly 10% of women older than 65 years of age and nearly 30% of women over the age of 85 reported having a UTI within the 12-month period preceding the study. The incidence of UTIs also increases substantially in men over the age of 85 years. Elderly subjects who have had a prior UTI are at increased risk of a recurrent UTI. Urinary tract infections are most commonly bacterial, and *E. coli* is the organism most frequently responsible for UTIs. Hence, empiric treatment of UTIs with antibiotics is common, and UTIs are the most common reason for antibiotic prescriptions in older adults.

In the Phase 2a clinical trial, a decrease in the rate of UTIs was observed in the RTB101 10 mg monotherapy and RTB101 10 mg+everolimus 0.1 mg combination arms as compared to placebo. We believe these data suggest that RTB101 alone or in combination with everolimus may have therapeutic benefit for reducing the rate of UTIs in the elderly, particularly elderly at risk for recurrent UTIs.

### ***Treatment of viral respiratory tract infections***

In the Phase 2a clinical trial, an increase of antiviral gene expression was observed in the RTB101 10 mg monotherapy and RTB101 10 mg+everolimus 0.1 mg combination arms. We plan to conduct a biomarker study to assess the speed at which antiviral genes are upregulated after elderly subjects are treated with RTB101 alone or in combination with everolimus. If we observe a rapid increase of antiviral gene expression, we believe RTB101 alone or in combination with everolimus may have therapeutic benefit for the treatment of viral RTIs.

### ***Heart failure with preserved ejection fraction***

Heart failure is one of the most common causes of hospitalizations in people age 65 and older, and heart failure with preserved ejection fraction, or HFpEF, affects about 2.25 million people in the United States, and a combined 6.24 million in the United States, Europe and Japan. HFpEF predominantly affects elderly subjects,

particularly older women, in whom 90% of new heart failure cases are HFpEF. Patients with HFpEF experience the clinical symptoms of heart failure, despite having the percentage of total blood in the left ventricle of the heart that is pushed out with each heartbeat, known as ejection fractions, in the normal range. These symptoms are attributable in part to stiffened heart muscle that limits blood flow into the heart, known as diastolic dysfunction. Outcomes following hospitalization for decompensated HFpEF are poor. Approximately one third of patients are rehospitalized or die within 90 days of discharge. To date, there are no FDA approved therapies to reduce hospitalization or mortality for HFpEF.

According to scientific literature published by research groups at the Harvard Stem Cell Institute and the University of Washington, aging mice develop stiffened heart muscle and diastolic dysfunction similar to elderly humans with HFpEF. Preclinical studies have shown that a 10 week course of mTOR inhibitor therapy reverses diastolic dysfunction in aging mice. This beneficial effect is likely partly due to an increase in proteins involved in mitochondrial function and fatty acid oxidation. Fatty acids are the predominant substrate used in mitochondrial energy production in healthy adults, but are replaced by glucose as the preferred substrate in heart failure. The shift to glucose as a substrate results in less ATP production by mitochondria. Since ATP is the main cellular fuel, a decrease in ATP production may contribute to heart failure. mTOR inhibitors shift mitochondria back to using fatty acids as a substrate and as a result may increase ATP production in the heart and improve heart function. These findings suggest that RTB101 alone or in combination with everolimus may have therapeutic benefit for the treatment of HFpEF in humans.

### ***Huntington's disease***

Huntington's disease, or HD, is a disease that affects neurons in the brain and causes movement, psychiatric and cognitive impairment. HD is caused by mutations in a gene encoding protein called huntingtin. Mutant huntingtin forms aggregate in neurons and cause the neurons to degenerate. The mutant huntingtin aggregates can be cleared from neurons by a process called autophagy in which cells remove and recycle intracellular debris including protein aggregates. Preclinical data from brain slices in a HD mouse model has shown that RTB101 in combination with everolimus synergize to prevent neurodegeneration, likely by inducing autophagy and clearing mutant huntingtin aggregates. We believe these findings support the potential that RTB101 in combination with everolimus to have therapeutic benefit for the treatment of HD.

### ***Parkinson's disease***

Parkinson's disease, or PD, is a progressive neurodegenerative disease that affects approximately 7.5 million people worldwide. The incidence of PD increases rapidly in people 60 years of age and older, with a mean age at diagnosis of 70.5 years. Patients with PD develop shaking, rigidity, slowness of movement and difficulty walking. Similar to HD, PD may be attributed in part to neuronal damage caused by the accumulation within neurons of abnormal aggregates containing the protein  $\alpha$ -synuclein. Preclinical studies in mouse models of PD have shown that mTOR inhibition can induce autophagy, reduce  $\alpha$ -synuclein accumulation and decrease neuronal cell death. Therefore, induction of autophagy with RTB101 in combination with everolimus may have therapeutic benefit for patients with PD.

### **Intellectual Property**

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the composition of matter of our product candidates, including RTB101, their methods of use, related technology, and other inventions that are important to our business. We licensed a patent portfolio of ten patent families from Novartis. See “—License Agreement with Novartis.” As of October 31, 2017, one family within this patent portfolio covering compositions of matter was issued in 42 countries and is pending in five. This patent family is expected to expire in 2026 before patent term extensions. We expect market exclusivity for RTB101, alone and in combination with everolimus, until at least 2031 in the United States, 2032 in major European markets, and 2030 in Japan, and additional pending patent

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applications covering methods of enhancing immunity, reducing incidence of RTIs and other infections, and other indications, may prolong the exclusivity of these product candidates up to 2036. In October 2017, we filed an additional patent application directed to compositions of matter for novel mTOR inhibitors.

In addition to patent protection, we rely on trade secrets and confidentiality agreements to protect our technology, know-how and other aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions, and know-how related to our business, defend and enforce the patents we own or control, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets, and operate without infringing the valid and enforceable patents and other proprietary rights of third parties.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold or control may be challenged, circumvented or invalidated by third parties.

### ***License Agreement with Novartis***

In March 2017, we entered into a license agreement with Novartis, pursuant to which we were granted an exclusive, field-restricted, worldwide license to certain intellectual property rights owned or controlled by Novartis, including patents, patent applications, proprietary information, know-how and other intellectual property, to develop, commercialize and sell one or more therapeutic products comprising RTB101 alone or RTB101 and everolimus in a fixed dose combination. Under the license agreement, we have been licensed a patent portfolio of ten patent families directed to composition of matter of RTB101 and its salts, formulations of everolimus and methods of using RTB101 and everolimus to enhance the immune response among others. These families include certain granted patents and pending patent applications in the United States and foreign jurisdictions, including Canada, the United Kingdom, Germany, France, Italy, Spain, Russia, Japan, Korea and China. Patents in these families will begin expiring in 2026, subject to possible patent term extensions. We believe that patent term extension and the potential grant of certain pending patent application may provide exclusivity for RTB101 and RTB101+everolimus combination until 2036 in the United States and the major European markets.

The exclusive field for RTB101 is for the treatment, prevention and diagnosis of diseases and other conditions in all indications in humans and animals. With respect to the fixed dose combination of RTB101 and everolimus, the exclusive field of use is for any indication in humans related to the improvement in immune function or immunosenescence in the elderly, the reduction of infection frequency, severity, duration, health care resource utilization, hospitalization, morbidity or mortality, or the treatment of infections, the reduction of pulmonary disease exacerbation frequency, severity, or related hospitalization, the enhancement of therapeutic or prophylactic benefits of vaccines, or any aging-related disease, excluding in each case the application of everolimus in connection with organ transplantation, oncology, immune-oncology or in the cardiac stent field. Novartis has agreed not to enforce any rights to improvements related to RTB101 developed after the effective date in connection with the exercise of our rights under this agreement. In addition, we have agreed to grant back to Novartis for use outside of the exclusive fields any improvements related to everolimus that we develop after the effective date.



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We are required to use commercially reasonable efforts to develop and commercialize at least one product in the field in at least one major market, which includes the United States, Japan and certain identified countries in Europe.

As initial consideration for the license, we issued NIBR 2,587,992 shares of our Series A preferred stock.

As additional consideration for the license, we are required to pay up to an aggregate of \$4.3 million upon the satisfaction of clinical milestones, up to an aggregate of \$24 million upon the satisfaction of regulatory milestones for the first indication approved, and up to an aggregate of \$18 million upon the satisfaction of regulatory milestones for the second indication approved. In addition, we are required to pay up to an aggregate of \$125 million upon the satisfaction of commercial milestones, based on the amount of annual net sales. We are also required to pay tiered royalties ranging from a mid-single digit percentage to a low-teen digit percentage on annual net sales of products. These royalty obligations last on a product-by-product and country-by-country basis until the latest of (i) the expiration of the last valid claim of a Novartis patent covering a subject product, (ii) the expiration of any regulatory exclusivity for the subject product in a country, or (iii) the 10th anniversary of the first commercial sale of the product in the country, and are subject to a reduction after the expiration of the last valid claim of a Novartis patent or the introduction of a generic equivalent of a product in a country. In addition, if we sublicense the rights under the license agreement, we are required to pay a certain percentage of the sublicense revenue to Novartis. Novartis will no longer be entitled to sublicense revenue following the last visit of the 400th subject in any human clinical trial conducted by us or a sublicensee of ours, which we expect to occur by the end of our ongoing Phase 2b clinical trial.

Either we or Novartis may terminate the license agreement if the other party commits a material breach and fails to cure such breach within 60 days after written notice. Novartis may terminate the license agreement upon our bankruptcy, insolvency, dissolution or winding up. In addition, Novartis may partially terminate the license agreement with respect to everolimus if we fail or cease to use commercially reasonable efforts to research, develop and commercialize a product utilizing everolimus for a period of three years, provided that our license related to RTB101 and Novartis's license to our improvements related to everolimus will continue. In addition, we may terminate the license agreement, with or without cause, in its entirety or on a product-by-product or country-by-country basis, upon 60 days' prior written notice.

In connection with the license agreement, NIBR entered into certain stockholder agreements related to this investment. See "Certain Relationship and Related Party Transactions—Series A Preferred Stock Financing."

### **Sales and Marketing**

We hold worldwide commercialization rights to our product candidates. We do not have our own marketing, sales or distribution capabilities. In order to commercialize our product candidate if approved for commercial sale, we must either develop a sales and marketing infrastructure or collaborate with third parties that have sales and marketing experience. We plan to directly commercialize our product candidates in the United States with a focused sales force targeting top-prescribing physicians with high flow of elderly patients. For some indications, we may also directly commercialize our product candidates in the European Union. In other markets or for certain indications outside the United States for which commercialization may be less capital efficient for us, we may selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates.

### **Manufacturing**

RTB101 and everolimus are small molecules that can be manufactured using commercially available technologies. We acquired data from Novartis related to the chemical synthesis and manufacturing of RTB101,

which is currently being manufactured by a single contract manufacturing organization, and are outsourcing the manufacturing of everolimus.

We believe there are multiple sources for all of the materials required for the manufacture of our product candidates. Our manufacturing strategy enables us to more efficiently direct financial resources to the research, development, and commercialization of product candidates rather than diverting resources to internally develop manufacturing facilities. As our product candidates advance through development, we expect to enter into longer-term commercial supply agreements with key suppliers and manufacturers to fulfill and secure the ongoing and planned preclinical, clinical, and, if our product candidates are approved for marketing, our commercial supply needs for ourselves and our collaborators. Our long-term strategy is to secure at least two sources for the manufacturing of our products.

Manufacturing of any product candidate is subject to extensive regulations that impose various procedural and documentation requirements, which govern recordkeeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. We expect that all of our contract manufacturing organizations will manufacture RTB101 under current Good Manufacturing Practice, or cGMP, conditions. cGMP is a regulatory standard for the production of pharmaceuticals to be used in humans.

## **Competition**

We consider Navitor Pharma to be our most direct competitor in developing novel therapeutics targeting TORC1 for aging-related diseases. However, Navitor has not publicly announced testing of any pipeline candidate in human subjects to date. We are aware of multiple other allosteric and catalytic mTOR inhibitors in development by other companies. We are not aware of any product with comparable TORC1 selectivity being commercially developed.

We are also aware of other companies seeking to develop treatments to prevent or treat aging-related diseases through biological pathways unrelated to mTOR inhibition, including Calico and Unity. Calico has not yet disclosed any pipeline candidates, and Unity's most advanced candidate, based on publicly disclosed information, is in preclinical development. Hence, we believe that we currently have the most clinically advanced program based on the stage of development of our competitors' programs.

We are aware of other companies that are potential competitors for prevention or treatment of respiratory tract infections. Companies pursuing broad-spectrum prophylactic and therapeutic treatments in respiratory tract infections include PrEP BioPharm and Innavac. Based on publicly disclosed information, we believe that we have the most clinically advanced program, and the only program based on TORC1 selectivity. Narrow-spectrum prophylactic treatments are also being developed by potential competitors. Several of these treatments target the respiratory syncytial virus, or RSV, one of the top known causes of RTIs in older adults. However, as RTIs in the elderly are largely caused by many different viruses, we believe that our approach may be more broadly applicable in addressing RTIs.

Drug development is highly competitive and subject to rapid and significant technological advancements. Our ability to compete will significantly depend upon our ability to complete necessary clinical trials and regulatory approval processes, and effectively market any drug that we may successfully develop. Our current and potential future competitors may include pharmaceutical and biotechnology companies, academic institutions and government agencies. The primary competitive factors that will affect the commercial success of any product candidate for which we may receive regulatory approval include efficacy, safety and tolerability profile, dosing convenience, price, formulary coverage and reimbursement. Our existing or potential future competitors may have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Our current and potential future competitors may also have significantly more experience commercializing drugs that have been approved

for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

Accordingly, our competitors may be more successful than us in obtaining regulatory approval for therapies and in achieving widespread market acceptance of their drugs. It is also possible that the development of a more effective treatment method for prevention of respiratory tract infections by a competitor could render our product candidate non-competitive or obsolete or reduce the demand for our product candidate before we can recover our development and commercialization expenses.

### **Government Regulation**

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

### **Review and Approval of Drugs in the United States**

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The failure to comply with applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities. In addition, an applicant may need to recall a product.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of nonclinical, or preclinical, laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which must take effect before human clinical trials may begin;
- approval by an independent Institutional Review Board, or IRB, representing each clinical site before each clinical trial may be initiated at that site;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of a new drug application, or NDA, and payment of user fees;
- review of the product by an FDA advisory committee, where appropriate or if applicable;

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- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- FDA review and approval of the NDA; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and post-approval studies required by the FDA.

### **Preclinical Studies**

Before an applicant begins testing a compound in humans, the drug candidate enters the preclinical testing stage. Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as in vitro and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

### **The IND and IRB Processes**

An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of the investigational drug. In an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments. In addition, the results of the preclinical tests, manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. At any time during this 30-day period, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that trial. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study is conducted in accordance with good clinical practice, or GCP, including review and approval by an independent ethics

committee, or IEC, and informed consent from subjects. The GCP requirements are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. FDA must also be able to validate the data from the study through an on-site inspection if necessary.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review of the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the subjects or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by us based on evolving business objectives and/or competitive climate.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on its ClinicalTrials.gov website.

### ***Human Clinical Trials in Support of an NDA***

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- *Phase 1.* The drug is initially introduced into healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.
- *Phase 2.* The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- *Phase 3.* The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.
- *Phase 4.* Post-approval studies may be conducted after initial regulatory approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the applicant must develop methods for testing the identity, strength, quality, purity, and potency of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

### **Review of an NDA by the FDA**

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee, currently exceeding \$2.4 million for applications requiring clinical data, and an annual prescription drug program fee exceeding \$304,000. These fees are typically increased annually. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for drugs with orphan designation.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt, before accepting the NDA for filing, to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of NDAs. Applications for drugs containing novel active moieties are meant to be reviewed within ten months from the date of filing, and applications for "priority review" products containing novel active moieties are meant to be reviewed within six months of filing. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA submission, including drug component manufacturing (such as active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

### ***Fast Track, Breakthrough Therapy, and Priority Review***

The FDA has a number of programs intended to facilitate and expedite development and review of new drugs if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. Three of these programs are referred to as fast track designation, breakthrough therapy designation, and priority review designation.

Specifically, the FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the application is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, a product may be designated as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to Breakthrough Therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious or life-threatening disease or condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial

reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

### ***Accelerated Approval Pathway***

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, could result in the FDA's withdrawal of the approval and require the withdrawal of the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

### **The FDA's Decision on an NDA**

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities and select clinical trial sites, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.



If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety or effectiveness after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs.

### **Post-Approval Requirements**

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, many changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are annual program fee requirements for certain marketed products.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the NDA holder and any third-party manufacturers that the NDA holder may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or voluntary product recalls;
- fines, warning or untitled letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of

the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

### **Hatch-Waxman Amendments**

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product, known as a reference listed drug, or RLD. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

### **Non-Patent Exclusivity**

Under the Hatch-Waxman Amendments, the FDA may not approve (or in some cases accept) an ANDA or 505(b)(2) application until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity, or NCE. For the purposes of this provision, an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, which states the proposed generic drug will not infringe one or more of the already approved product's listed patents or that such patents are invalid or unenforceable, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity for non-NCE drugs if the NDA or a supplement to the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application or supplement. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication, but it generally would not protect the original, unmodified product from generic competition. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product; it only prevents FDA from approving such ANDAs.

## **Hatch-Waxman Patent Certification and the 30-Month Stay**

In seeking approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Upon approval, each of the patents listed by the NDA sponsor is published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Upon submission of an ANDA or 505(b)(2) NDA, an applicant is required to certify to the FDA concerning any patents listed for the RLD in the Orange Book that:

- no patent information on the drug product that is the subject of the application has been submitted to the FDA;
- such patent has expired;
- the date on which such patent expires; or
- such patent is invalid, unenforceable or will not be infringed upon by the manufacture, use, or sale of the drug product for which the application is submitted.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired. If the ANDA or 505(b)(2) NDA applicant has provided a paragraph IV certification the applicant must send notice of the paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation. If the drug has NCE exclusivity and the ANDA is submitted four years after approval, the 30-month stay is extended so that it expires 7 ½ years after approval of the innovator drug, unless the patent expires or there is a decision in the infringement case that is favorable to the ANDA applicant before then.

## **Pediatric Studies and Exclusivity**

Under the Pediatric Research Equity Act of 2003, a NDA or supplement thereto for a drug with certain innovative features (*e.g.*, new active ingredient, new indication, new dosage form) must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted,

consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of certain existing non-patent exclusivity periods, including orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data within certain time periods. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application after expiration of a patent.

### ***Orphan Drug Designation and Exclusivity***

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the drug for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives regulatory approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

### **Patent Term Restoration and Extension**

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Amendments, which permits a patent term restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question and within 60 days of drug approval. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

## **Review and Approval of Medicinal Products in the European Union**

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. It also requires the submission to the relevant competent authorities of a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union.

### ***Clinical Trial Approval***

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on Good Clinical Practice, or GCP, and the related national implementing provisions of the individual EU Member States govern the system for the approval of clinical trials in the European Union. Under this system, an applicant must obtain prior approval from the competent national authority of the EU Member States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by, among other documents, an investigational medicinal product dossier (the Common Technical Document) with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, where relevant the implementing national provisions of the individual EU Member States and further detailed in applicable guidance documents.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (Clinical Trials Regulation) was adopted. The Regulation is anticipated to apply in 2019. The Clinical Trials Regulation will be directly applicable in all the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the European Union will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the “EU portal”; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

### ***Marketing Authorization***

To obtain a marketing authorization for a product under European Union regulatory systems, an applicant must submit an MAA either under a centralized procedure administered by the European Medicines Agency, or EMA, or one of the procedures administered by competent authorities in the EU Member States

(decentralized procedure or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the European Union. Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, applicants have to demonstrate compliance with all measures included in an EMA-approved Paediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted (1) a product-specific waiver, (2) a class waiver or (3) a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU Member States and three of the four European Free Trade Association, or EFTA, States, Iceland, Liechtenstein and Norway. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of HIV or AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are a significant therapeutic, scientific or technical innovation and whose authorization would be in the interest of public health at EU level, the centralized procedure is optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. If the CHMP accepts such request, the time limit of 210 days will be reduced to 150 days but it is possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. At the end of this period, the CHMP provides a scientific opinion on whether or not a marketing authorization should be granted in relation to a medicinal product. Within 67 days from the date of the CHMP Opinion, the European Commission will adopt its final decision on the marketing authorization application.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all EU Member States.

The mutual recognition procedure similarly is based on the acceptance by the competent authorities of the EU Member States of the marketing authorization of a medicinal product by the competent authorities of other EU Member States. The holder of a national marketing authorization may submit an application to the competent authority of an EU Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU Member State.

### ***Regulatory Data Protection in the European Union***

In the European Union, innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Directive 2001/83/EC. Regulation (EC) No 726/2004 repeats this entitlement for medicinal products authorized in accordance the centralized authorization procedure. Data exclusivity prevents applicants for authorization of generics of these innovative products from referencing the innovator's data to assess a generic (abbreviated) application for a period of eight years. During an additional two-year period of market exclusivity, a generic marketing authorization application can be submitted and authorized, and the innovator's data may be referenced, but no generic medicinal product can be placed on the European Union market until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

### ***Periods of Authorization and Renewals***

A marketing authorization has an initial validity for five years in principle. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five year period of marketing authorization. Once subsequently definitively renewed, the marketing authorization shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the European Union market (in case of centralized procedure) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

### ***Regulatory Requirements after a Marketing Authorization has been Obtained***

In case an authorization for a medicinal product in the European Union is obtained, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include:

- Compliance with the European Union's stringent pharmacovigilance or safety reporting rules must be ensured. These rules can impose post-authorization studies and additional monitoring obligations.
- The manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the applicable European Union laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with European Union cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the European Union with the intention to import the active pharmaceutical ingredients into the European Union.

- The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union notably under Directive 2001/83/EC, as amended, and EU Member State laws.

### ***Brexit and the Regulatory Framework in the United Kingdom***

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as “Brexit”). Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the United Kingdom from the European Union will take effect either on the effective date of the withdrawal agreement or, in the absence of agreement, two years after the United Kingdom provides a notice of withdrawal pursuant to the EU Treaty. Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the United Kingdom.

### **Healthcare Law and Regulation**

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted regulatory approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, reporting of payments to physicians and teaching hospitals and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid; a person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation; in addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious or fraudulent; knowingly making a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to



have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the United States Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing information. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

### **Pharmaceutical Insurance Coverage and Healthcare Reform**

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide

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coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage and the amount of reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. For example, in March 2010, the United States Congress enacted the Affordable Care Act, which, among other things, includes changes to the coverage and payment for products under government health care programs. Among the provisions of the Affordable Care Act of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April

2013 and will remain in effect through 2025 unless additional Congressional action is taken. In January 2013, then-President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further legislative changes to or regulatory changes under the Affordable Care Act remain possible in the 115th U.S. Congress and under the Trump Administration. The nature and extent of any legislative or regulatory changes to the Affordable Care Act are uncertain at this time, however.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states, and parallel trade, i.e., arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

**Employees**

As of \_\_\_\_\_, 2017, we had \_\_\_\_\_ full-time employees, including a total of \_\_\_\_\_ employees with M.D. or Ph.D. degrees. Of our workforce, \_\_\_\_\_ employees are directly engaged in research and development activities, and \_\_\_\_\_ employees providing administrative, business and operations support. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider the relationship with our employees to be good. We also use outside consultants and contractors for limited engagements.

**Facilities**

We occupy office space within the offices of PureTech Health pursuant to the terms of our Business Services, Personnel and Information Management Agreement with PureTech Health. We believe that this office is sufficient to meet our current needs and that suitable additional space will be available as and when needed. See “Transactions with Related Persons.”

**Legal Proceedings**

We are not currently subject to any material legal proceedings.

## MANAGEMENT

The following table sets forth the name, age as of the date of this prospectus, and position of each of our executive officers and directors.

<u>Name</u>	<u>Age</u>	<u>Position</u>
<b>Executive Officers</b>		
Chen Schor	45	President, Chief Executive Officer and Director
Joan Mannick, M.D.	59	Chief Medical Officer
John J. McCabe	50	Vice President, Finance
<b>Non-Employee Directors</b>		
Raju Kucherlapati, Ph.D.	74	Director
David Steinberg	45	Director
Jonathan Silverstein	50	Director

- (1) Member of audit committee
- (2) Member of compensation committee
- (3) Member of nominating and corporate governance committee

### Executive Officers

**Chen Schor** has served as our President and Chief Executive Officer and as a member of our board of directors since our incorporation in July 2016. Mr. Schor previously served as President, Chief Executive Officer and director of Synta Pharmaceuticals Corp. from May 2015 until its merger with Madrigal Pharmaceuticals in July 2016, and prior to that, from 2014 until 2016, Mr. Schor served as its Executive Vice President and Chief Operation Officer. From 2012 to 2014, Mr. Schor served as President and Chief Executive Officer of Novalere FP, Inc., a pre-commercial stage allergy therapeutics company. From 2011 to 2012, Mr. Schor served as Chief Business Officer of Eleven Biotherapeutics, an emerging therapeutics company. From 2009 until 2011, Mr. Schor served as Vice President of Business Development, global branded products at Teva Pharmaceuticals. Prior to joining Teva, Mr. Schor was Chief Business Officer at Epix Pharmaceuticals, Inc. (formerly known as Predix Pharmaceuticals Inc.) from 2003 until 2009. Prior to joining Epix, Mr. Schor was a Partner at Yozma Venture Capital from 1998 until 2003, managing the fund's investments in biotechnology and medical device companies. Mr. Schor currently sits on the board of Brainstorm Cell Therapeutics Inc., a public biotechnology company. Mr. Schor received his MBA from Tel Aviv University, a B.A. in Economics and Accounting from Haifa University and a B.A. in Biology from Tel Aviv University. We believe that Mr. Schor is qualified to serve on our board of directors due to his service as our President and Chief Executive Officer and his extensive knowledge of our company and industry.

**Joan Mannick, M.D.**, has served as our Chief Medical Officer since March 2017 and served as a member of our board of directors from March 2017 to November 2017. From November 2010 until March 2017, Dr. Mannick was Senior Director and subsequently Executive Director in the Translated Medical Division of NIBR, where Dr. Mannick led the clinical program at NIBR that targets pathways regulating aging to treat aging-related conditions. Prior to joining NIBR in 2010, Dr. Mannick was a Medical Director at Genzyme from 2007 to 2010 working in multiple therapeutic areas and a faculty member at Harvard Medical School from 1991 to 1999 and University of Massachusetts Medical School from 2000 to 2011. Her NIH-sponsored laboratory focused on the role of protein S-nitrosylation in physiology and pathophysiology. Dr. Mannick received her A.B. from Harvard College and her M.D. from Harvard Medical School. She completed her residency in Internal Medicine at Brigham and Women's Hospital and an Infectious Disease fellowship as part of the Harvard Combined Infectious Disease Program.

**John J. McCabe, C.P.A.**, has served as our Vice President, Finance since October 2017. Mr. McCabe served as Chief Financial Officer for Eleven Biotherapeutics, Inc. from January 2016 until October 2017 and

prior to that served as Senior Vice President from June 2013 to December 2015 and Director of Financial Reporting from April 2012 to June 2013. Mr. McCabe also provided independent financial and accounting consulting services from June 2011 to April 2012. Prior to that, Mr. McCabe served as Vice President of Finance at Clinical Data, Inc., from December 2010 to June 2011 and as the Senior Director of Financial Reporting of Clinical Data from August 2007 to December 2010. Prior to that, Mr. McCabe served in several financial roles at Interleukin Genetics, Inc. He began his career working for the accounting firm of Coopers & Lybrand LLP, now known as PricewaterhouseCoopers LLP. Mr. McCabe received a B.S. in Business Administration from the University of Vermont and is also a Certified Public Accountant.

#### **Non-Employee Directors**

**Raju Kucherlapati, Ph.D.**, has served as a member of our board of directors since March 2017. Dr. Kucherlapati is currently the Paul C. Cabot Professor of Genetics and a Professor of Medicine at Harvard Medical School, where he has worked since 2001 and was the first Scientific Director of the Harvard-Partners Center for Genetics and Genomics. He is a fellow of the American Association for the Advancement of Science and a member of the National Academy of Medicine. Dr. Kucherlapati has co-founded several companies including Millennium Pharmaceuticals, Inc. in 1993 (acquired by Takeda Pharmaceutical Company Limited in 2008) and Abgenix, Inc. in 1996 (acquired by Amgen in 2005), among others. Dr. Kucherlapati currently serves on the board of PureTech Health plc, Gelesis, Inc. and previously served as a director of Aveo, Inc. Dr. Kucherlapati holds a B.S. in Biology from P.R. College, Kakinada, India, a M.S. in Biology from Andhra University, Waltair, India and a Ph.D. from the University of Illinois at Urbana. We believe Dr. Kucherlapati's qualifications to sit on our board of directors include his clinical background and substantial experience as a member of the boards of directors of life sciences companies.

**David Steinberg** has served as a member of our board of directors since March 2017. Mr. Steinberg is a Co-founder of PureTech Health plc and has been the Chief Innovation Officer for over five years. PureTech Health (PRTC.L) is an advanced clinical stage biopharma company developing new categories of medicines targeting the brain-immune-gut "BIG" axis. As a senior executive officer of PureTech Health, Mr. Steinberg is a member of the executive committee. He has been involved in initiating and leading multiple PureTech programs, including PureTech's microbiome initiative, lymphatic biology platform and immune-oncology pipeline. Prior to joining PureTech Health, he was a strategy consultant with Vertex Partners and the Boston Consulting Group, where he focused on research and development and product strategy and strategic alliances for Fortune 500 pharmaceutical and biotechnology clients. Mr. Steinberg is also a member of the UChicago Tech Innovation Fund Advisory Committee. He received his B.A. in Biology with distinction from Cornell University and graduated with high honors from the University of Chicago Booth School of Business with an M.B.A. in Strategy and Finance. We believe that Mr. Steinberg is qualified to serve on our board of directors due to his finance background and industry experience.

**Jonathan Silverstein** has served as a member of our board of directors since November 2017. Mr. Silverstein is currently a general partner at OrbiMed, a healthcare investment firm, where he has worked since December 1998. Previously, Mr. Silverstein was a director of life sciences in the investment banking department at Sumitomo Bank. Mr. Silverstein serves on the board of directors of Glaukos Corporation and Ascendis Pharma A/S. Mr. Silverstein also serves on the boards of directors of several private companies. Mr. Silverstein holds a B.A. from Denison University and a J.D. and M.B.A. from the University of San Diego. We believe that Mr. Silverstein's strategic development and capital markets experience qualifies him to serve on our board of directors.

#### **Board Composition and Election of Directors**

##### ***Board Composition***

Our board of directors currently consists of five members. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal.

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Our certificate of incorporation and bylaws that will become effective as of the closing date of this offering provide that the authorized number of directors may be changed only by resolution of our board of directors. Our certificate of incorporation and bylaws will also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least 75% of our shares of capital stock present in person or by proxy and entitled to vote, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

In accordance with the terms of our certificate of incorporation and bylaws that will become effective as of the closing date of this offering, our board of directors will be divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms. Upon the closing of this offering, the members of the classes will be divided as follows:

- the class I directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their term will expire at the annual meeting of stockholders to be held in 2019;
- the class II directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their term will expire at the annual meeting of stockholders to be held in 2020; and
- the class III directors will be \_\_\_\_\_ and \_\_\_\_\_, and their term will expire at the annual meeting of stockholders to be held in 2021.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

We have no formal policy regarding board diversity. Our priority in selection of board members is identification of members who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business and understanding of the competitive landscape.

### ***Director Independence***

Applicable Nasdaq Stock Market, or Nasdaq, rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the Nasdaq rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under applicable Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: the source of compensation of the director, including any consulting, advisory or other compensatory fee paid by such company to the director; and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

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In 2017, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that [redacted] is an “independent director” as defined under applicable Nasdaq rules, including, in the case of all the members of our audit committee, the independence criteria set forth in Rule 10A-3 under the Exchange Act, and in the case of all the members of our compensation committee, the independence criteria set forth in Rule 10C-1 under the Exchange Act. In making such determination, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director. Mr. Schor is not an independent director under these rules because he is our President and Chief Executive Officer.

There are no family relationships among any of our directors or executive officers.

### **Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Each of these committees will operate under a charter that has been approved by our board of directors. The composition of each committee will be effective as of the date of this prospectus.

#### ***Audit Committee***

The members of our audit committee are [redacted], and [redacted] is the chair of the audit committee. Effective as of the date of this prospectus, our audit committee’s responsibilities will include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from that firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- overseeing our internal audit function, if any;
- discussing our risk assessment and risk management policies;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our internal auditing staff, if any, our independent registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by the SEC rules.



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All audit and non-audit services, other than *de minimis* non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

Our board of directors has determined that \_\_\_\_\_ is an “audit committee financial expert” as defined in applicable SEC rules and that each of the members of our audit committee possesses the financial sophistication required for audit committee members under Nasdaq rules. We believe that the composition of our audit committee will meet the requirements for independence under current Nasdaq and SEC rules and regulations.

### **Compensation Committee**

The members of our compensation committee are \_\_\_\_\_, and \_\_\_\_\_ is the chair of the compensation committee. Effective as of the date of this prospectus, our compensation committee’s responsibilities will include:

- reviewing and approving, or making recommendations to our board of directors with respect to, the compensation of our chief executive officer and our other executive officers;
- overseeing an evaluation of our senior executives;
- reviewing and making recommendations to our board of directors with respect to our incentive-compensation and equity-based compensation plans;
- overseeing and administering our equity-based plans;
- reviewing and making recommendations to our board of directors with respect to director compensation;
- reviewing and discussing annually with management our “Compensation Discussion and Analysis” disclosure if and to the extent then required by SEC rules; and
- preparing the compensation committee report if and to the extent then required by SEC rules.

We believe that the composition of our compensation committee will meet the requirements for independence under current Nasdaq and SEC rules and regulations.

### **Nominating and Corporate Governance Committee**

The members of our nominating and corporate governance committee are \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and \_\_\_\_\_ is the chair of the nominating and corporate governance committee. Effective as of the date of this prospectus, our nominating and corporate governance committee’s responsibilities will include:

- identifying individuals qualified to become members of our board of directors;
- recommending to our board of directors the persons to be nominated for election as directors and to each of our board’s committees;
- developing and recommending to our board of directors corporate governance principles; and
- overseeing an annual evaluation of our board of directors.

We believe that the composition of our nominating and corporate governance committee will meet the requirements for independence under current Nasdaq and SEC rules and regulations.

**Compensation Committee Interlocks and Insider Participation**

None of our executive officers serves, or in the past year has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee. None of the members of our compensation committee is, or has ever been, an officer or employee of ours.

**Code of Business Conduct and Ethics**

We plan to adopt a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, which will be effective upon the closing of this offering. Following this offering, we will post a copy of the code on the Corporate Governance section of our website. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

**EXECUTIVE COMPENSATION**

This section describes the material elements of compensation awarded to, earned by or paid to our sole named executive officer in 2016, Chen Schor, our President and Chief Executive Officer, and other individuals who became executive officer in 2017. We are an “emerging growth company,” within the meaning of the JOBS Act, and have elected to comply with the reduced compensation disclosure requirements available to emerging growth companies under the JOBS Act. This section also provides qualitative information regarding the manner and context in which compensation is awarded to and earned by our named executive officer and is intended to place in perspective the data presented in the tables and narrative that follow.

**Summary Compensation Table**

The following table sets forth information regarding compensation awarded to, earned by or paid to our named executive officer during 2016.

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary</u> <u>(\$)</u>	<u>Bonus</u> <u>(\$)</u>	<u>Stock</u> <u>Awards</u> <u>(\$)(1)</u>	<u>Option</u> <u>Awards</u> <u>(\$)</u>	<u>Total</u> <u>(\$)</u>
Chen Schor(2) <i>President and Chief Executive Officer</i>	2016	—	—	—	—	—

- (1) The amounts reported in the “Stock Awards” column reflects the aggregate grant date fair value of share-based compensation awarded during the year computed in accordance with the provisions of Financial Accounting Standards Board Accounting Standards Codification, or ASC, Topic 718. See Note 2 to our financial statements appearing at the end of this prospectus regarding assumptions underlying the valuation of equity awards.
- (2) Mr. Schor has served as a director and as our President and Chief Executive Officer since July 2016, but did not become an employee of our company until April 4, 2017. Mr. Schor did not earn any cash compensation for his services to us in 2016. He purchased 2,415,300 shares of restricted common stock as founder shares at the then-current fair market value.

**Narrative to Summary Compensation Table**

Our sole executive officer during 2016 was our President and Chief Executive Officer, Chen Schor. Mr. Schor did not receive any cash compensation for his services in 2016, but purchased restricted stock at the then-current fair market value at incorporation. We have elected to provide disclosure in this narrative section for Dr. Mannick and Mr. McCabe who were not executive officers of our company during 2016, but who became executive officers in 2017.

In March 2017, we appointed Dr. Joan Mannick as our Chief Medical Officer. In April 2017, Mr. Schor and Dr. Mannick commenced an employment relationship with us, and at that time, began receiving base salary and eligibility for performance-based bonuses, as described in greater detail below under “— Employment Arrangements with Our Named Executive Officer and Other Executive Officers.” John McCabe, our Vice President, Finance, has provided consulting services to us since September 2017, and was appointed to his current position in October 2017.

In July 2016, the board of directors issued and sold at the then-current fair market value 2,415,300 shares of restricted common stock to each of Mr. Schor and Dr. Mannick as founder shares. These equity awards are subject to a repurchase option in favor of us, pursuant to which we may repurchase any unvested shares at the purchase price paid for such shares in the event that either Mr. Schor or Dr. Mannick ceases providing services to us. In the case of a qualified funding (as defined in the applicable award agreement), which was satisfied upon the closing of our Series A preferred stock financing, a portion of the unvested shares accelerated and vested in full. In the case of a liquidity event (as defined in the applicable award agreement), which includes this initial public offering, the remaining unvested shares will accelerate and vest in full.

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We use base salaries and performance-based bonuses to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our named executive officers. Although we do not have a formal policy with respect to the grant of equity incentive awards to our current and future named executive officers, we believe that equity grants provide these officers with a strong link to our long-term performance, create an ownership culture and help to align the interests of these officers and our stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incents our current and future named executive officers to remain in our employment during the vesting period. Accordingly, our board of directors intends to periodically review the equity incentive compensation of our current and future named executive officers and from time to time may grant equity incentive awards to them in the form of stock options.

### **Outstanding Equity Awards at 2016 Year End**

The following table sets forth information regarding outstanding equity awards held by our named executive officer as of December 31, 2016:

<u>Name</u>	<u>Number of Shares of Stock that have not Vested (#)</u>	<u>Market Value of Shares of Stock that have not Vested (#)</u>
Chen Schor	108,185(1)	\$ 11
	973,668(2)	\$ 97

- (1) These shares of restricted stock were issued on July 11, 2016 and vest in 48 equal monthly installments through July 11, 2020. Upon the closing of our Series A preferred stock financing, the unvested shares of restricted stock accelerated and vested in full.
- (2) These shares of restricted stock were issued on July 11, 2016 and vest in 48 equal monthly installments through July 11, 2020. Upon the closing of a liquidity event (as defined in the award agreement), which includes this initial public offering, the unvested shares of restricted stock will accelerate and vest in full.

### ***Employment Arrangements with Our Named Executive Officer and Other Executive Officers***

#### *Chen Schor*

In March 2017, we entered into an offer letter with Mr. Schor. The offer letter establishes Mr. Schor's title, his base salary of \$361,000 per year, his eligibility for an annual bonus, and his eligibility for benefits made available to employees generally and also provides for certain benefits upon termination of his employment under specified conditions. Mr. Schor's annual base salary shall be subject to increase in the discretion of our board of directors; provided that his base salary shall be increased by no less than 5% upon the earlier of April 4, 2019 or his eligibility to receive the bonus described in clause (iii) of the following paragraph. Our board of directors has determined that Mr. Schor is eligible to receive an annual bonus of up to 40% of his base salary, including a bonus at the same rate for the period from January 1, 2017 through March 31, 2017, when his offer letter was signed.

Mr. Schor's offer letter also provides for the following milestone-based bonuses. Mr. Schor will receive a bonus of: (i) \$18,000 after the first subject is dosed in a Phase 2 study following the pre-IND meeting or call with the FDA (or written feedback to a pre-IND briefing book from the FDA) provided such dosing occurs by April 4, 2018; (ii) \$18,000 after we enroll the first subject following interim analysis review by a committee defined by the Phase 2 study protocol, provided such enrollment occurs by April 4, 2019; and (iii) \$36,000 after we achieve the primary end point with a p-value equal to or less than 0.05 in a Phase 2 study, provided such achievement occurs by April 4, 2020. In the event that Mr. Schor earns the bonus described in clause (iii) of the prior sentence but has not yet earned the bonuses described in clauses (i) and (ii), such bonuses shall be payable at that time.

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Mr. Schor's employment is at will. Under the terms of his offer letter, if Mr. Schor's employment is terminated by us without cause or by Mr. Schor for good reason, each as defined in his offer letter, and subject to Mr. Schor's execution of a general release of potential claims against us, we have agreed to pay Mr. Schor an amount equal to 6 months of his then-current base salary and provide continued coverage under our health and dental plans for 6 months if such termination occurs within the first 12 months of his employment or an amount equal to 12 months of his then-current base salary and continued coverage under our health and dental plans for 12 months if such termination occurs thereafter. In addition, if such termination occurs following a change in control, Mr. Schor will also be eligible to receive a pro-rated portion of his annual performance bonus for the calendar year in which his employment was terminated.

Mr. Schor's offer letter also provides that he will (1) not compete with us during his employment and for a period of six months after the termination of his employment, (2) not solicit our employees, independent contractors or customers during his employment and for a period of six months after the termination of his employment, (3) protect our confidential and proprietary information and (4) assign to us related intellectual property developed during the course of his employment.

### *Joan Mannick*

In March 2017, we entered into an offer letter with Dr. Mannick. The offer letter establishes Dr. Mannick's title, her base salary of \$318,500 per year, her eligibility for an annual bonus, and her eligibility for benefits made available to employees generally and also provides for certain benefits upon termination of her employment under specified conditions. Dr. Mannick's annual base salary shall be subject to increase in the discretion of our board of directors; provided that her base salary shall be increased by no less than 5% upon the earlier of April 4, 2019 or her eligibility to receive the bonus described in clause (iii) of the following paragraph. Our board of directors has determined that Dr. Mannick is eligible to receive an annual bonus of up to 35% of her base salary, and a bonus at the rate of 23.33% for the period from January 1, 2017 through March 31, 2017, when her offer letter was signed.

Dr. Mannick's offer letter also provides for the following milestone-based bonuses. Dr. Mannick will receive a bonus of: (i) \$15,000 after the first subject is dosed in a Phase 2 study following the pre-IND meeting or call with the FDA (or written feedback to a pre-IND briefing book from the FDA) provided such dosing occurs by April 4, 2018; (ii) \$15,000 after we enroll the first subject following interim analysis review by a committee defined by the Phase 2 study protocol, provided such enrollment occurs by April 4, 2019; and (iii) \$30,000 after we achieve the primary end point with a p-value equal to or less than 0.05 in a Phase 2 study, provided such achievement occurs by April 4, 2020. In the event that Dr. Mannick earns the bonus described in clause (iii) of the prior sentence but has not yet earned the bonuses described in clauses (i) and (ii), such bonuses shall be payable at that time.

Dr. Mannick's employment is at will. Under the terms of his offer letter, if Dr. Mannick's employment is terminated by us without cause or by Dr. Mannick for good reason, each as defined in her offer letter, and subject to Dr. Mannick's execution of a general release of potential claims against us, we have agreed to pay Dr. Mannick an amount equal to 6 months of her then-current base salary and provide continued coverage under our health and dental plans for 6 months if such termination occurs within the first 12 months of her employment or an amount equal to 9 months of her then-current base salary and continued coverage under our health and dental plans for 9 months if such termination occurs thereafter. In addition, if such termination occurs following a change in control, Dr. Mannick will also be eligible to receive a pro-rated portion of her annual performance bonus for the calendar year in which her employment was terminated.

Dr. Mannick's offer letter also provides that she will (1) not compete with us during her employment and for a period of six months after the termination of her employment, (2) not solicit our employees, independent contractors or customers during her employment and for a period of six months after the termination of her employment, (3) protect our confidential and proprietary information and (4) assign to us related intellectual property developed during the course of her employment.

*John McCabe*

In October 2017, we entered into an offer letter with Mr. McCabe. The offer letter establishes Mr. McCabe's title, his base salary of \$250,000 per year, his eligibility for an annual bonus, and his eligibility for benefits made available to employees generally and also provides for certain benefits upon termination of his employment under specified conditions. Our board of directors has determined that Mr. McCabe is eligible to receive an annual bonus of up to 30% of his base salary, pro-rated for 2017 to reflect his partial year of employment.

Mr. McCabe's employment is at will. Under the terms of his offer letter, if Mr. McCabe's employment is terminated by us without cause or by Mr. McCabe for good reason, each as defined in his offer letter, and such termination occurs following the 12-month anniversary of his start and not in connection with a change in control, then subject to Mr. McCabe's execution of a general release of potential claims against us and continued compliance with the restrictive covenants described below, we have agreed to pay Mr. McCabe an amount equal to three months of his then-current base salary and provide continued coverage under our health and dental plans on the same terms and conditions in effect prior to his termination until the earlier of the expiration of the three-month period for which he is entitled to receive severance and the date Mr. McCabe commences new employment which offers health coverage. If Mr. McCabe's employment is terminated by us without cause or by Mr. McCabe for good reason within 12 months after a change in control, and subject to Mr. McCabe's execution of a general release of potential claims against us and continued compliance with the restrictive covenants described below, we have agreed to pay Mr. McCabe (1) an amount equal to six months of his then-current base salary, (2) up to 50% of a pro-rated portion of his annual performance bonus for any partial year of service and (3) continued coverage under the Company's health and dental plans until the earlier of the expiration of 6 months and the date Mr. McCabe commences new employment which offers health coverage. In addition, all equity-based awards held by Mr. McCabe shall accelerate in full.

Mr. McCabe's offer letter also provides that he will (1) not compete with us during his employment and for a period of one year after the termination of his employment, (2) not solicit our employees, independent contractors or customers during his employment and for a period of one year after the termination of his employment, (3) protect our confidential and proprietary information and (4) assign to us related intellectual property developed during the course of his employment.

In connection with this offering, we intend to enter into new executive employment agreements with each of our executive officers, including our named executive officer.

**Stock Option and Other Compensation Plans**

The three equity incentive plans described in this section are our 2017 stock incentive plan, or the 2017 Plan, our 2018 stock incentive plan, or the 2018 Plan, and our 2018 employee stock purchase plan, or the ESPP. Prior to this offering, we granted awards to eligible participants under the 2017 Plan. Following the closing of this offering, we expect to grant awards to eligible participants only under the 2018 Plan and the ESPP.

**2017 Stock Incentive Plan**

The 2017 Plan was adopted by our board of directors in June 2017 and approved by our stockholders in August 2017. The 2017 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards. Our employees, officers, directors, consultants and advisors are eligible to receive awards under the 2017 Plan; however, incentive stock options may only be granted to our employees. Our board of directors, or a committee appointed by our board, administers the 2017 Plan and, subject to any limitations set forth in the 2017 Plan, will select the recipients of awards and determine:

- the number of shares of common stock covered by options and the dates upon which those options become exercisable;

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- the type of options to be granted;
- the exercise prices of options;
- the duration of options; and
- the number of shares of common stock subject to any restricted stock or other stock-based awards and the terms and conditions of those awards, including the issue price, conditions for repurchase or forfeiture and repurchase price.

If our board of directors delegates authority to an executive officer to grant awards under the 2017 Plan, the executive officer has the power to make awards to employees and officers, except executive officers. Our board of directors will fix the terms of the awards to be granted by such executive officer, including the exercise price of such awards, and the maximum number of shares subject to awards that such executive officer may make.

The 2017 Plan provides that a maximum of 2,389,239 shares of our common stock are authorized for issuance under the plan. Our board of directors may amend, suspend, or terminate the 2017 Plan at any time.

Upon the occurrence of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spinoff, or other similar change in capitalization or event, or any dividend or distribution to holders of our common stock other than an ordinary cash dividend, under the terms of the 2017 Plan, we are required to equitably adjust (or make substitute awards, if applicable), in the manner determined by our board of directors:

- the number and class of securities available under the 2017 Plan;
- the number and class of securities and exercise price per share of each outstanding option;
- the share and per-share provisions and the measurement price of each outstanding stock appreciation right;
- the number of shares subject to and the repurchase price per share subject to each outstanding restricted stock award; and
- the share and per-share-related provisions and the purchase price, if any, of each outstanding other stock-based award.

Upon the occurrence of a merger or consolidation of our company with or into another entity as a result of which all of our common stock is converted into or exchanged for the right to receive cash, securities, or other property or is cancelled; any transfer or disposition of all of our common stock for cash, securities, or other property pursuant to a share exchange or other transaction; or a liquidation or dissolution of our company, our board of directors may, on such terms as our board of directors determines (except to the extent specifically provided otherwise in an applicable award agreement or other agreement between us and the plan participant), take any one or more of the following actions pursuant to the 2017 Plan, as to some or all outstanding awards, other than restricted stock awards:

- provide that awards shall be assumed, or substantially equivalent awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof);
- upon written notice to a plan participant, provide that the participant's unexercised awards will terminate immediately prior to the consummation of such transaction unless exercised by the participant (to the extent then exercisable) within a specified period;

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- provide that outstanding awards shall become exercisable, realizable or deliverable, or restrictions applicable to an award shall lapse, in whole or in part, prior to or upon such transaction;
- in the event of a transaction under the terms of which holders of common stock will receive upon consummation thereof a cash payment for each share surrendered in the transaction, make or provide for a cash payment to a plan participant;
- provide that, in connection with a liquidation or dissolution of the company, awards shall convert into the right to receive liquidation proceeds; or
- any combination of the foregoing.

Our board of directors is not obligated under the 2017 Plan to treat all awards, all awards held by a participant, or all awards of the same type, identically.

Upon the occurrence of any corporate transaction described above, other than our liquidation or dissolution, our repurchase and other rights under each outstanding restricted stock award will continue for the benefit of our successor and will, unless our board of directors determines otherwise, apply to the cash, securities, or other property which our common stock was converted into or exchanged for in the transaction in the same manner and to the same extent as they applied to the common stock subject to the restricted stock award; provided, however, that the board may provide termination or deemed satisfaction of such repurchase or other rights under the restricted stock award agreement, either initially or by amendment, or provide for forfeiture of such restricted stock if issued at no cost. Upon our liquidation or dissolution, except to the extent specifically provided to the contrary in the restricted stock award agreement or any other agreement between the plan participant and us, all restrictions and conditions on all restricted stock awards then outstanding will automatically be deemed terminated or satisfied.

Our board of directors, in its sole discretion, may accelerate the exercisability of any option or time at which any restrictions shall lapse or be removed from any restricted stock award, as the case may be.

As of \_\_\_\_\_, there were \_\_\_\_\_ shares of common stock outstanding under the 2017 Plan at a weighted average exercise price of \$ \_\_\_\_\_ per share, and \_\_\_\_\_ shares of common stock were available for future issuance under the 2017 Plan. On and after the effective date of the 2018 Stock Incentive Plan, or 2018 Plan, described below, we will grant no further stock options or other awards under the 2017 Plan. However, any shares of common stock subject to awards under our 2017 Plan that expire, terminate, or otherwise are surrendered, canceled, forfeited or repurchased without having been fully exercised or resulting in any common stock being issued will become available for issuance under our 2018 Plan up to a specified number of shares.

### ***2018 Stock Incentive Plan***

We expect our board of directors to adopt, and our stockholders to approve, the 2018 Plan, which will become effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. The 2018 Plan will replace our 2017 Plan. The 2018 Plan allows the board of directors and the compensation committee to make equity-based incentive awards to our officers, employees, directors and other key persons (including consultants).

Upon effectiveness of the 2018 Plan, the number of shares of our common stock that will be reserved for issuance under the 2018 Plan will be \_\_\_\_\_ shares, or the Initial Limit. The 2018 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2019, by \_\_\_\_\_ % of the outstanding number of shares of our common stock on the immediately preceding December 31 or such lesser number of shares as determined by our compensation committee, or the Annual Increase. The Initial Limits and other share limits in the 2018 Plan are subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.



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The shares we issue under the 2018 Plan will be authorized but unissued shares or shares that we acquire. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise of an option or settlement of an award to cover the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock or are otherwise terminated (other than by exercise) under the 2018 Plan will be added back to the shares of common stock available for issuance under the 2018 Plan.

Stock options and stock appreciation rights with respect to no more than \_\_\_\_\_ shares may be granted to any one individual in any one calendar year. The maximum number of shares that may be issued as incentive stock options may not exceed the Initial Limit cumulatively increased on January 1, 2019 and on each January 1 thereafter by the lesser of the Annual Increase or \_\_\_\_\_ shares. The value of all awards made under the 2018 Plan and all other cash compensation paid by us to any non-employee director in any calendar year shall not exceed \$ \_\_\_\_\_ million.

The 2018 Plan will be administered by our compensation committee. Our compensation committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2018 Plan. Persons eligible to participate in the 2018 Plan will be those full- or part-time officers, employees, non-employee directors and consultants as selected from time to time by our compensation committee in its discretion.

The 2018 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant. The term of each option will be fixed by our compensation committee and may not exceed ten years from the date of grant. Our compensation committee will determine at what time or times each option may be exercised.

Our compensation committee may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price may not be less than 100% of the fair market value of our common stock on the date of grant. The term of each stock appreciation right will be fixed by our compensation committee and may not exceed ten years from the date of grant. Our compensation committee will determine at what time or times each stock appreciation right may be exercised.

Our compensation committee may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period. Our compensation committee may also grant shares of common stock that are free from any restrictions under the 2018 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Our compensation committee may grant performance share awards to participants that entitle the recipient to receive awards of common stock upon the achievement of certain performance goals and such other conditions as our compensation committee may determine. Our compensation committee may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of common stock.

Our compensation committee may grant cash bonuses under the 2018 Plan to participants, subject to the achievement of certain performance goals.

Our compensation committee may grant awards of restricted stock, restricted stock units, performance share awards or cash-based awards under the 2018 Plan that are intended to qualify as “performance-based compensation” under Section 162(m) of the Code. Such awards will only vest or become payable upon the

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attainment of performance goals that are established by our compensation committee and related to one or more performance criteria. The performance criteria that could be used with respect to any such awards are limited to: total stockholder return, earnings before interest, taxes, depreciation and amortization, net income (loss) (either before or after interest, taxes, depreciation and/or amortization), changes in the market price of our common stock, economic value-added, sales or revenue, coverage decisions, research and development, publication clinical, regulatory or commercial milestones, acquisitions or strategic transactions, including licenses, collaborations, joint ventures or promotional arrangements, operating income (loss), cash flow (including, but not limited to, operating cash flow and free cash flow), return on capital, assets, equity, or investment, return on sales, gross or net profit levels, productivity, expense, margins, operating efficiency, customer satisfaction, working capital, earnings (loss) per share of our common stock, sales or market shares and number of customers, any of which may be measured either in absolute terms or as compared to any incremental increase or as compared to results of a peer group. From and after the time that we become subject to Section 162(m) of the Code, the maximum award that is intended to qualify as “performance-based compensation” under Section 162(m) of the Code that may be made to certain of our officers during any one calendar year period is \_\_\_\_\_ shares of common stock with respect to a share-based award and \$ \_\_\_\_\_ million with respect to a cash-based award.

The 2018 Plan provides that upon the effectiveness of a “sale event,” as defined in the 2018 Plan, an acquirer or successor entity may assume, continue or substitute outstanding awards under the 2018 Plan. To the extent that awards granted under the 2018 Plan are not assumed or continued or substituted by the successor entity, upon the effective time of the sale event, the 2018 Plan and all awards thereunder shall terminate. In the event of such termination, except as may otherwise be provided in the relevant award certificate, all options and stock appreciation rights that are not exercisable immediately prior to the effective time of the sale event shall become fully exercisable as of the effective time of the sale event, all other awards with time based vesting, conditions or restrictions, shall become fully vested and nonforfeitable as of the effective time of the sale event and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and nonforfeitable in the discretion of the administrator or to the extent specified in the relevant award certificate. In addition, in connection with the termination of the 2018 Plan and awards thereunder upon a sale event, we may make or provide for a cash payment to participants holding vested and exercisable options and stock appreciation rights equal to the difference between the per share cash consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights or each grantee, shall be permitted within a specified period of time prior to the sale event, to exercise all outstanding stock options and stock appreciation rights held by such grantee to the extent exercisable. We shall also have the option to make or provide for payment, in cash or in kind, to the grantees of other awards equal to the per share cash consideration payable to stockholders in the sale event multiplied by the number of vested shares of common stock subject to such awards.

Our board of directors may amend or discontinue the 2018 Plan and our compensation committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under an award without the holder’s consent. Certain amendments to the 2018 Plan require the approval of our stockholders.

No awards may be granted under the 2018 Plan after the date that is ten years from the date of stockholder approval of the 2018 Plan.

### ***2018 Employee Stock Purchase Plan***

We expect our board of directors to adopt, and our stockholders to approve, the ESPP, which will become effective immediately prior to the effectiveness of the registration statement of which this prospectus is a part. The ESPP is intended to qualify as an “employee stock purchase plan” within the meaning of Section 423(b) of the Code. The ESPP initially reserves and authorizes the issuance of up to a total of \_\_\_\_\_ shares of common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2019 and each January 1

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thereafter through January 1, 2028, by the least of (i) % of the outstanding number of shares of our common stock on the immediately preceding December 31; (ii) shares or (iii) such number of shares as determined by the ESPP administrator. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

All employees who have completed at least 30 days of employment and whose customary employment is for more than 20 hours per week are eligible to participate in the ESPP. However, any employee who owns 5% or more of the total combined voting power or value of all classes of stock is not eligible to purchase shares under the ESPP.

We will make one or more offerings each year to our employees to purchase shares under the ESPP. Offerings will usually begin on each January 1 and July 1 and will continue for six-month periods, referred to as offering periods. Each eligible employee may elect to participate in any offering by submitting an enrollment form at least 15 business days before the relevant offering date.

Each employee who is a participant in the ESPP may purchase shares by authorizing payroll deductions of up to 10% of his or her base compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase shares on the last business day of the offering period at a price equal to 85% of the fair market value of the shares on the first business day or the last business day of the offering period, whichever is lower. Under applicable tax rules, an employee may purchase no more than \$25,000 worth of shares of common stock, valued at the start of the purchase period, under the ESPP in any calendar year.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

The ESPP may be terminated or amended by our board of directors at any time. An amendment that increases the number of shares of common stock authorized under the ESPP and certain other amendments require the approval of our stockholders.

### **401(k) Retirement Plan**

We participate in a 401(k) retirement plan sponsored by PureTech Health, our shareholder, that is intended to be a tax-qualified defined contribution plan under Section 401(k) of the Internal Revenue Code. In general, all of our employees are eligible to participate, beginning two months after the commencement of their employment. The 401(k) plan includes a salary deferral arrangement pursuant to which participants may elect to reduce their current compensation by up to the statutorily prescribed limit and have the amount of the reduction contributed to the 401(k) plan. We currently contribute to each employee's 401(k) account, in the first quarter of each year, 3% of his or her eligible earnings from the prior year.

### **Limitations on Liability and Indemnification**

As permitted by Delaware law, we expect our board of directors and stockholders to adopt provisions in our certificate of incorporation, which will become effective as of the closing date of this offering, that limit or eliminate the personal liability of our directors. Our certificate of incorporation, which will become effective as of the closing date of this offering, limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the General Corporation Law of the State of Delaware and provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty. However, these provisions do not eliminate or limit the liability of any of our directors:

- for any breach of the director's duty of loyalty to us or our stockholders;

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- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- for voting for or assenting to unlawful payments of dividends, stock repurchases or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to such amendment or repeal. If the General Corporation Law of the State of Delaware is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the General Corporation Law of the State of Delaware.

In addition, our certificate of incorporation, which will become effective as of the closing date of this offering, provides that we must indemnify our directors and officers and we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to very limited exceptions.

We maintain a general liability insurance policy that covers specified liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers. In addition, we expect to enter into indemnification agreements with each of our officers and directors prior to the completion of this offering. These indemnification agreements will require us, among other things, to indemnify each such director or officer for some expenses, including attorneys' fees, judgments, fines and settlement amounts, incurred by him or her in any action or proceeding arising out of his or her service as one of our directors or officers.

Some of our non-employee directors may, through their relationships with their employers, be insured or indemnified against specified liabilities incurred in their capacities as members of our board of directors.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, executive officers or persons controlling us, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

### **Rule 10b5-1 Sales Plans**

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from the director or officer. The director or officer may amend or terminate the plan in some circumstances. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

### **Director Compensation**

We have historically not compensated our directors for their services to us. We reimburse our non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending board of directors and committee meetings.

Our board of directors intends to approve a compensation policy for our non-employee directors that will become effective upon the effectiveness of the registration statement of which this prospectus forms a part. This policy will be intended to provide a total compensation package that enables us to attract and retain qualified and experienced individuals to serve as directors and to align our directors' interests with those of our stockholders.

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Under the policy, each director who is not an employee will be paid cash compensation from and after the completion of this offering, as set forth below:

	<u>Member Annual Fee</u>	<u>Chairman Additional Annual Fee</u>
Board of Directors	\$	\$
Audit Committee		
Compensation Committee		
Nominating and Corporate Governance Committee		

Each annual cash retainer will be payable in arrears in four quarterly installments on the last day of each quarter, provided that the amount of each payment will be prorated for any portion of a quarter that a director is not serving on our board of directors and no fee will be payable in respect of any period prior to the completion of this offering.

**TRANSACTIONS WITH RELATED PERSONS**

Since our incorporation in July 2016, we have engaged in the following transactions in which the amount involved exceeded \$120,000 and any of our directors, executive officers or beneficial holders of more than 5% of any class of our voting securities, or any of their affiliates, had a material interest. We believe that all of these transactions were on terms comparable to terms that could have been obtained from unrelated third parties.

**Founders Shares**

In July 2016, Chen Schor and Joan Mannick purchased 2,415,300 shares of common stock at \$0.0001 per share. See the “Executive Compensation” section of this prospectus for a further discussion of these purchases. In addition, in March 2017, we issued 2,415,300 shares of our common stock to PureTech Health as founder shares at par value, the fair market value of the shares at the time of their issuance.

**Series A Preferred Stock Financing**

In March 2017, we entered into a Series A preferred stock purchase agreement for the sale of up to 10,351,968 shares of Series A preferred stock in one or more closings at a price per share of \$1.932. In March 2017, we issued and sold an aggregate of 5,434,783 shares of our Series A preferred stock in the first closing of our Series A preferred stock financing. PureTech Health paid \$5,017,989 for such Series A shares, and the remaining \$482,011 of the purchase price was net settled against invoices paid by PureTech Health on our behalf prior to the closing of our Series A financing and as reimbursement for certain due diligence costs incurred in connection with the financing. The shares of Series A preferred stock issued to NIBR were issued in consideration for a license from Novartis, as discussed further below.

The following table sets forth the number of shares of our Series A preferred stock purchased by our directors, executive officers and 5% stockholders and their affiliates and the aggregate purchase price paid for such shares.

<u>Name</u>	<u>Shares of Series A Preferred Stock Purchased</u>	<u>Aggregate Cash Purchase Price</u>
PureTech Health LLC	2,846,791	\$ 5,500,001
Novartis Institutes for Biomedical Research, Inc.	2,587,992	—
<b>Total</b>	<b>5,434,783</b>	<b>\$ 5,500,001</b>

In August 2017, we issued and sold an additional 2,329,193 shares of our Series A preferred stock at a price per share of \$1.932 in the second closing of our Series A preferred stock financing, for a purchase price of approximately \$4.5 million. The following table sets forth the number of shares of our Series A preferred stock purchased by our directors, executive officers and 5% stockholders and their affiliates and the aggregate purchase price paid for such shares.

<u>Name</u>	<u>Shares of Series A Preferred Stock Purchased</u>	<u>Aggregate Purchase Price</u>
PureTech Health LLC	2,329,193	\$ 4,500,001
<b>Total</b>	<b>2,329,193</b>	<b>\$ 4,500,001</b>

In October 2017, we issued and sold an additional 7,763,975 shares of our Series A preferred stock at a price per share of \$1.932 in the third and final closing of our Series A preferred stock financing, for a purchase price of approximately \$15.0 million. The following table sets forth the number of shares of our Series A

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preferred stock purchased by our directors, executive officers and 5% stockholders and their affiliates and the aggregate purchase price paid for such shares.

<u>Name</u>	<u>Shares of Series A Preferred Stock Purchased</u>	<u>Aggregate Cash Purchase Price</u>
PureTech Health LLC	4,658,385	\$ 9,000,000
OrbiMed Private Investments VI, LP	3,105,590	6,000,000
<b>Total</b>	<b>7,763,975</b>	<b>\$ 15,000,000</b>

### **Series B Preferred Stock Financing**

In October 2017, we entered into a Series B preferred stock purchase agreement for the sale of up to 4,792,716 shares of Series B preferred stock in one or more closings at a price per share of \$8.346. In November 2017, we issued and sold an aggregate of 4,792,716 shares of our Series B preferred stock for gross proceeds of approximately \$40.0 million. The following table sets forth the number of shares of our Series B preferred stock purchased by our directors, executive officers and 5% stockholders and their affiliates and the aggregate purchase price paid for such shares.

<u>Name</u>	<u>Shares of Series B Preferred Stock Purchased</u>	<u>Aggregate Cash Purchase Price</u>
OrbiMed Private Investments VI, LP	2,396,358	\$ 20,000,004
<b>Total</b>	<b>2,396,358</b>	<b>\$ 20,000,004</b>

### **License Agreement with Novartis**

In March 2017, we entered into a license agreement with Novartis pursuant to which we were granted an exclusive worldwide license to certain intellectual property rights owned or controlled by Novartis, including patents, patent applications, proprietary information, know-how and other intellectual property, to develop, commercialize and sell one or more therapeutic products comprising RTB101 or RTB101 and everolimus in a fixed dose combination. See “Business—Intellectual Property—License Agreement with Novartis.”

### **PureTech Health Shared Resources**

PureTech Health is a founder of our company and in that capacity has provided us with strategic medical, clinical and scientific advice pursuant to a business services, personnel and information management agreement. PureTech Health also played a significant role in securing our foundational intellectual property from Novartis, leveraging its connections to establish the relationship, assisting in the negotiation of the license agreement and providing strategic advice throughout the process. In addition, we currently share administrative resources and offices with PureTech Health, including legal, accounting and human resources support, computer and telecommunications systems and other office infrastructure pursuant to the agreement. Beginning in April 2017, PureTech has invoiced us at cost for such services, with such amounts totaling \$109,063 as of September 30, 2017. In addition, PureTech Health periodically invoices us for reimbursement of out of pocket expenses reasonably incurred on our behalf in connection with providing such business services.

### **Investors’ Rights Agreement**

We are a party to an investors’ rights agreement, dated as of November 29, 2017, with holders of our preferred stock, including some of our 5% stockholders and entities affiliated with our directors. Such holders consisted of entities affiliated with OrbiMed, PureTech Health and Novartis, each a 5% stockholder. Each of PureTech Health and OrbiMed have appointed representatives to our board of directors. The investor rights agreement provides these holders the right,

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following the completion of this offering, to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. See “Description of Capital Stock—Registration Rights” for additional information regarding these registration rights.

### **Voting Agreement**

We are a party to a voting agreement, dated as of November 29, 2017, with holders of our preferred stock, including some of our 5% stockholders and entities affiliated with our directors. Such holders consisted of entities affiliated with OrbiMed, PureTech Health and Novartis, each a 5% stockholder. Each of PureTech Health and OrbiMed have appointed representatives to our board of directors. The voting agreement provides the holders the right to elect certain directors to the Board. Pursuant to the voting agreement, we agreed to appoint to our board of directors two representatives designated by PureTech Health, who are David Steinberg and Raju Kucherlapati, and one representative designated by an entity affiliated with OrbiMed who is Jonathan Silverstein. The voting agreement will terminate upon completion of this offering.

### **Right of First Refusal and Co-Sale Agreement**

We are a party to a right of first refusal and co-sale agreement, dated as of November 29, 2017, with holders of our preferred stock, including some of our 5% stockholders and entities affiliated with our directors. Such holders consisted of entities affiliated with OrbiMed, PureTech Health and Novartis, each a 5% stockholder. Each of PureTech Health and OrbiMed have appointed representatives to our board of directors. The right of first refusal and co-sale agreement provides the key holders the right to purchase all or any portion of transfer stock, as well as the right of co-sale and participate in any proposed transfers. The agreement shall terminate upon completion of this offering.

### **Employment Agreements**

See the “Executive Compensation—Employment Arrangements with Our Named Executive Officer and Other Executive Officers” section of this prospectus for a further discussion of these arrangements.

### **Indemnification Agreements**

Our certificate of incorporation that will become effective as of the closing date of this offering provides that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, we plan to enter into indemnification agreements with each of our officers and directors that may be broader in scope than the specific indemnification provisions contained in the Delaware General Corporation Law. See “Executive Compensation—Limitations on Liability and Indemnification” for additional information regarding these agreements.

### **Policies and Procedures for Related Person Transactions**

Our board of directors reviews and approves transactions with directors, officers and holders of 5% or more of our voting securities and their affiliates, each a related party. Prior to this offering, the material facts as to the related party’s relationship or interest in the transaction are disclosed to our board of directors prior to their consideration of such transaction, and the transaction is not considered approved by our board of directors unless a majority of the directors who are not interested in the transaction approve the transaction. Further, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party’s relationship or interest in the transaction are disclosed to the stockholders, who must approve the transaction in good faith.

In connection with this offering, we have adopted a written related party transactions policy that such transactions must be approved by our audit committee. This policy will become effective on the date on which



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the registration statement of which this prospectus is part is declared effective by the SEC. Pursuant to this policy, the audit committee has the primary responsibility for reviewing and approving or disapproving “related party transactions,” which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed \$120,000 and in which a related person has or will have a direct or indirect material interest. For purposes of this policy, a related person will be defined as a director, executive officer, nominee for director, or greater than 5% beneficial owner of our common stock, in each case since the beginning of the most recently completed year, and their immediate family members. Our audit committee charter will provide that the audit committee shall review and approve or disapprove any related party transactions.

**PRINCIPAL STOCKHOLDERS**

The following table sets forth information with respect to the beneficial ownership of our common stock as of \_\_\_\_\_ by:

- each of our directors;
- our named executive officer;
- all of our directors and executive officers as a group; and
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock.

The column entitled “Percentage of Shares Beneficially Owned—Before Offering” is based on a total of 27,566,567 shares of our common stock outstanding as of November 30, 2017, and assumes the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 20,320,667 shares of our common stock upon the closing of this offering. The column entitled “Percentage of Shares Beneficially Owned—After Offering” is based on \_\_\_\_\_ shares of our common stock to be outstanding after this offering, including the \_\_\_\_\_ shares of our common stock that we are selling in this offering, but not including any additional shares issuable upon exercise of outstanding options or any exercise by the underwriters of their option to purchase additional shares.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. Shares of our common stock subject to options that are currently exercisable or exercisable within 60 days after \_\_\_\_\_ are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investment power with respect to all of the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise set forth below, the address of the beneficial owner is c/o resTORbio, Inc., 501 Boylston Street, Suite 6102, Boston, Massachusetts 02116.

<u>Name of Beneficial Owner</u>	<u>Shares Beneficially Owned</u>	<u>Percentage of Shares Beneficially Owned</u>	
		<u>Before Offering</u>	<u>After Offering</u>
<b><i>5% Stockholders</i></b>			
PureTech Health LLC(1)	12,249,669	44.4%	
Novartis Institutes for BioMedical Research, Inc.(2)	2,587,992	9.4%	
OrbiMed Private Investments VI, LP(3)	5,501,948	20.0%	
<b><i>Named Executive Officer, Other Executive Officers and Directors</i></b>			
Chen Schor	2,415,300	8.8%	
Joan Mannick, M.D.	2,415,300	8.8%	
John McCabe	—	*%	
Jonathan Silverstein	—	*%	
Raju Kucherlapati, Ph.D.	—	*%	
David Steinberg	—	*%	
All Current Executive Officers and Directors as a Group (6 persons)	4,830,600	17.5%	

\* Represents beneficial ownership of less than 1% of our outstanding stock.

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- (1) Consists of (a) 2,415,300 shares of common stock and (b) 9,834,369 shares of common stock issuable upon conversion of preferred stock. Voting and investment power over the shares held by PureTech Health LLC is exercised by its board of directors. The address for PureTech Health LLC and the individuals listed above is c/o PureTech Health LLC, 501 Boylston Street, Suite 6102, Boston, MA 02116.
- (2) Consists of 2,587,992 shares of common stock issuable upon conversion of preferred stock. All shares are held by NIBR. NIBR is an indirect wholly-owned subsidiary of, and controlled by, Novartis AG. The address for NIBR is 250 Massachusetts Avenue, Cambridge, MA 02139.
- (3) Consists of 5,501,948 shares of common stock issuable upon conversion of preferred stock held by OrbiMed Private Investments VI, LP (“OPI VI”). OrbiMed Capital GP VI LLC (“GP VI”) is the sole general partner of OPI VI. OrbiMed Advisors LLC (“OrbiMed Advisors”) is the managing member of GP VI. Samuel D. Isaly is the managing member of and owner of a controlling interest in OrbiMed Advisors. By virtue of such relationships, GP VI, OrbiMed Advisors, and Mr. Isaly may be deemed to have voting and investment power with respect to the shares held by OPI VI and as a result may be deemed to have beneficial ownership of such shares. Jonathan T. Silverstein, a member of OrbiMed Advisors, is a member of our board of directors. Each of GP VI, OrbiMed Advisors, Mr. Isaly and Mr. Silverstein disclaims beneficial ownership of the shares held by OPI VI, except to the extent of its or his pecuniary interest therein if any. The address of these entities is 601 Lexington Avenue, 54th floor, New York, New York 10022.

## DESCRIPTION OF CAPITAL STOCK

*The following descriptions are summaries of the material terms of our amended and restated certificate of incorporation, which will be effective upon the closing of this offering and amended and restated bylaws, which will be effective upon the effectiveness of the registration statement of which this prospectus is a part. The descriptions of the common stock and preferred stock give effect to changes to our capital structure that will occur immediately prior to the completion of this offering. We refer in this section to our amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.*

### General

Upon completion of this offering, our authorized capital stock will consist of \_\_\_\_\_ shares of common stock, par value \$0.0001 per share, and \_\_\_\_\_ shares of preferred stock, par value \$0.0001 per share, all of which shares of preferred stock will be undesignated.

As of \_\_\_\_\_, 7,245,900 shares of our common stock, 15,527,951 shares of Series A preferred stock and 4,792,716 shares of Series B preferred stock were outstanding and held by 11 stockholders of record.

### Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

### Preferred Stock

Upon the completion of this offering, all outstanding shares of our preferred stock will be converted into shares of our common stock. Upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to \_\_\_\_\_ shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

### Registration Rights

Upon the completion of this offering, the holders of \_\_\_\_\_ shares of our common stock, including those issuable upon the conversion of preferred stock, will be entitled to rights with respect to the registration of

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these securities under the Securities Act. These rights are provided under the terms of an investors' rights agreement between us and holders of our preferred stock. The investors' rights agreement includes demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations under this agreement will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

### ***Demand Registration Rights***

Beginning 180 days after the effective date of this registration statement, the holders of \_\_\_\_\_ shares of our common stock, including those issuable upon the conversion of preferred stock, are entitled to demand registration rights. Under the terms of the investors' rights agreement, we will be required, upon the written request of the holders of at least 40% of our outstanding registrable securities, as defined in the investors' rights agreement, to file a registration statement and use commercially reasonable efforts to effect the registration of all or a portion of their registrable securities for public resale so long as the total amount of registrable shares requested to be registered has an anticipated aggregate offering price to the public, net of selling expenses, of least \$15.0 million. We are required to effect only two registrations pursuant to this provision of the investors' rights agreement.

### ***Short-Form Registration Rights***

Pursuant to the investor rights agreement, if we are eligible to file a registration statement on Form S-3, upon the written request of the holders of at least 30% of our outstanding registrable securities, as defined in the investors' rights agreement so long as the total amount of registrable securities requested to be registered has an anticipated aggregate offering price to the public, net of selling expenses, of least \$10.0 million. We are required to effect only two registrations in any twelve month period pursuant to the investors' rights agreement. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

### ***Piggyback Registration Rights***

Pursuant to the investors' rights agreement, if we register any of our securities either for our own account or for the account of other security holders, the holders of these shares are entitled to include their shares in the registration. Subject to certain exceptions contained in the investors' rights agreement, we and the underwriters may limit the number of shares included in the underwritten offering to the number of shares which we and the underwriters determine in our sole discretion will not jeopardize the success of the offering.

### ***Indemnification***

Our investor rights agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

### ***Expiration of Registration Rights***

The demand registration rights and short form registration rights granted under the investor rights agreement will terminate on the fifth anniversary of the completion of this offering.

### ***Anti-Takeover Effects of our Certificate of Incorporation and Bylaws and Delaware Law***

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

### ***Board Composition and Filling Vacancies***

Our certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

### ***No Written Consent of Stockholders***

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

### ***Meetings of Stockholders***

Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

### ***Advance Notice Requirements***

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

### ***Amendment to Certificate of Incorporation and Bylaws***

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and the amendment of our bylaws and certificate of incorporation must be approved by not less than 75% of the outstanding shares entitled to vote on the amendment, and not less than 75% of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of at least 75% of the outstanding shares entitled to vote on the amendment, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

### ***Undesignated Preferred Stock***

Our certificate of incorporation provides for \_\_\_\_\_ authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

### **Choice of Forum**

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine. Our certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

### **Section 203 of the Delaware General Corporation Law**

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the

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affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

### **Nasdaq Global Market Listing**

We intend to apply to list our common stock on The Nasdaq Global Market under the trading symbol “TORC.”

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock will be .



## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our shares. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares outstanding as of \_\_\_\_\_, upon the completion of this offering \_\_\_\_\_ shares of our common stock will be outstanding, assuming the automatic conversion of all outstanding shares of our preferred stock into an aggregate of \_\_\_\_\_ shares of our common stock upon the closing of this offering, no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options. Of the outstanding shares, all of the shares sold in this offering will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below. All remaining shares of common stock held by existing stockholders immediately prior to the completion of this offering will be "restricted securities" as such term is defined in Rule 144. These restricted securities were issued and sold by us, or will be issued and sold by us, in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, summarized below.

### Rule 144

In general, under Rule 144, beginning 90 days after the date of this prospectus, any person who is not our affiliate and has not been our affiliate at any time during the preceding three months and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, subject to the availability of current public information about us. In addition, under Rule 144, any person who is not our affiliate and has not been our affiliate at any time during the preceding three months and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available.

Beginning 90 days after the date of this prospectus, a person who is our affiliate or who was our affiliate at any time during the preceding three months may sell any unrestricted securities, as well as restricted securities that the person has beneficially owned for at least six months, including the holding period of any prior owner other than one of our affiliates, under Rule 144. Affiliates selling restricted or unrestricted securities may sell a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares then outstanding, which will equal approximately \_\_\_\_\_ shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares; or
- the average weekly trading volume of our common stock on The Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

### Rule 701

In general, under Rule 701 of the Securities Act, any of our employees, consultants or advisors, other than our affiliates, who purchased shares from us in connection with a qualified compensatory stock plan or other

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written agreement is eligible to resell these shares 90 days after the date of this prospectus in reliance on Rule 144, but without compliance with the holding period requirements of Rule 144 and without regard to the volume of such sales or the availability of public information about us.

However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under “Underwriting” included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

### **Lock-Up Agreements**

All of our directors, executive officers and stockholders have signed a lock-up agreement which prevents them from selling any of our common stock or any securities convertible into or exercisable or exchangeable for common stock for a period of not less than 180 days from the date of this prospectus without the prior written consent of the representatives, subject to certain exceptions. See the section entitled “Underwriting” appearing elsewhere in this prospectus for more information.

### **Registration Rights**

Upon completion of this offering, certain holders of our securities will be entitled to various rights with respect to registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See the section entitled “Description of Capital Stock—Registration Rights” appearing elsewhere in this prospectus for more information.

### **Equity Incentive Plans**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register our shares issued or reserved for issuance under our equity incentive plans. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the SEC. Accordingly, shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above.

## **MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK**

The following is a general discussion of the material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a foreign corporation or any other foreign organization taxable as a corporation for U.S. federal income tax purposes; or
- a foreign estate or trust, the income of which is not subject to U.S. federal income tax on a net income basis.

This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons that hold their common stock through partnerships or other pass-through entities. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated hereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any such change could alter the tax consequences to non-U.S. holders described in this prospectus. There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset within the meaning of Section 1221 of the Code, generally property held for investment.

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any aspects of any U.S. federal tax other than the income tax, U.S. state, local or non-U.S. taxes, the alternative minimum tax, or the Medicare tax on net investment income. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt or governmental organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- controlled foreign corporations;
- passive foreign investment companies;

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- persons that have a functional currency other than the U.S. dollar;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons for whom our stock constitutes “qualified small business stock” within the meaning of Section 1202 of the Code; and
- certain U.S. expatriates.

This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

### **Distributions on Our Common Stock**

Distributions, if any, on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder’s investment, up to such holder’s tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in “Gain on sale, exchange or other disposition of our common stock.” Any such distributions will also be subject to the discussions below under the sections titled “Backup Withholding and Information Reporting” and “Withholding and Information Reporting Requirements—FATCA.”

Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence. Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional “branch profits tax” at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder’s country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing a U.S. tax return with the IRS.

## **Gain on Sale, Exchange or Other Disposition of Our Common Stock**

Subject to the discussions below under “Backup Withholding and Information Reporting” and “Withholding and Information Reporting Requirements—FATCA,” a non-U.S. holder generally will not be subject to any U.S. federal income tax on any gain realized upon such holder’s sale, exchange or other disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder’s conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in “Distributions on Our Common Stock” also may apply;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States, provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses); or
- we are, or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder’s holding period, if shorter) a “U.S. real property holding corporation,” unless our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. If we are determined to be a U.S. real property holding corporation and the foregoing exception does not apply, then a purchaser may withhold 15% of the proceeds payable to a non-U.S. holder from a sale of our common stock and the non-U.S. holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

## **Backup Withholding and Information Reporting**

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in “Distributions on Our Common Stock,” generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them. Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS in a timely manner.

#### **Withholding and Information Reporting Requirements—FATCA**

The Foreign Account Tax Compliance Act, or FATCA, generally imposes a U.S. federal withholding tax at a rate of 30% on payments of dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise exempt under FATCA. Under applicable U.S. Treasury regulations, withholding under FATCA currently applies to payments of dividends on our common stock, but will only apply to payments of gross proceeds from a sale or other disposition of our common stock made after December 31, 2018. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of the tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

## UNDERWRITING

Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Partners LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

<b>Underwriter</b>	<b>Number of Shares</b>
Merrill Lynch, Pierce, Fenner & Smith Incorporated	
Leerink Partners LLC	
Wedbush Securities Inc.	
Total	

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

### Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ \_\_\_\_\_ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	<b>Per Share</b>	<b>Without Option</b>	<b>With Option</b>
Public offering price	\$	\$	\$
Underwriting discount	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

The expenses of the offering, not including the underwriting discount, are estimated at \$ \_\_\_\_\_ and are payable by us. We have also agreed to reimburse the underwriters for up to \$ \_\_\_\_\_ of their expenses incurred in connection with the review and clearance by the Financial Industry Regulatory Authority, Inc., or FINRA, of the terms of this offering, as set forth in the underwriting agreement.

### **Option to Purchase Additional Shares**

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to \_\_\_\_\_ additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

### **No Sales of Similar Securities**

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of the representatives. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any common stock;
- sell any option or contract to purchase any common stock;
- purchase any option or contract to sell any common stock;
- grant any option, right or warrant for the sale of any common stock;
- lend or otherwise dispose of or transfer any common stock;
- request or demand that we file or make a confidential submission of a registration statement related to the common stock; or
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

### **Nasdaq Global Market Listing**

We expect the shares to be approved for listing on The Nasdaq Global Market, subject to notice of issuance, under the symbol "TORC."

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us;
- our financial information;
- the history of, and the prospects for, our company and the industry in which we compete;



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- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues;
- the present state of our development;
- the likelihood of approval for our product candidates; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

### **Price Stabilization, Short Positions and Penalty Bids**

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. "Naked" short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on The Nasdaq Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

## **Electronic Distribution**

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

## **Other Relationships**

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

## **European Economic Area**

In relation to each member state of the European Economic Area, no offer of shares which are the subject of the offering has been, or will be made to the public in that Member State, other than under the following exemptions under the Prospectus Directive:

- (a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), subject to obtaining the prior consent of the representatives for any such offer; or
- (c) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

*provided* that no such offer of shares referred to in (a) to (c) above shall result in a requirement for us or the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Directive, or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person located in a Member State to whom any offer of shares is made or who receives any communication in respect of an offer of shares, or who initially acquires any shares will be deemed to have represented, warranted, acknowledged and agreed to and with the representatives and us that (1) it is a “qualified investor” within the meaning of the law in that Member State implementing Article 2(1)(e) of the Prospectus Directive; and (2) in the case of any shares acquired by it as a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, the shares acquired by it in the offer have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Member State other than qualified investors, as that term is defined in the Prospectus Directive, or in circumstances in which the prior consent of the representatives has been given to the offer or resale; or where shares have been acquired by it on behalf of persons in any Member State other than qualified investors, the offer of those shares to it is not treated under the Prospectus Directive as having been made to such persons.

We, the representatives and their respective affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgments and agreements.

This prospectus has been prepared on the basis that any offer of shares in any Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly any person making or intending to make an offer in that Member State of shares which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for us or the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither we nor the representatives have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for us or the representatives to publish a prospectus for such offer.

For the purposes of this provision, the expression an “offer of shares to the public” in relation to any shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression “Prospectus Directive” means Directive 2003/71/EC (as amended) and includes any relevant implementing measure in each Member State.

The above selling restriction is in addition to any other selling restrictions set out below.

#### **Notice to Prospective Investors in the United Kingdom**

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the “Order”) and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

#### **Notice to Prospective Investors in Switzerland**

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (“SIX”) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (“CISA”). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

#### **Notice to Prospective Investors in the Dubai International Financial Centre**

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (“DFSA”). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other

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person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

### **Notice to Prospective Investors in Australia**

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (“ASIC”), in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the “Corporations Act”), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the “Exempt Investors”) who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

### **Notice to Prospective Investors in Hong Kong**

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

### **Notice to Prospective Investors in Japan**

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in

Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, “Japanese Person” shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

### **Notice to Prospective Investors in Singapore**

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the “SFA”), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries’ rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- (c) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- (d) where no consideration is or will be given for the transfer;
- (e) where the transfer is by operation of law;
- (f) as specified in Section 276(7) of the SFA; or
- (g) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

### **Notice to Prospective Investors in Canada**

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

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Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

## LEGAL MATTERS

The validity of the shares of our common stock offered hereby is being passed upon for us by Goodwin Procter LLP, Boston, Massachusetts. Certain legal matters relating to this offering will be passed upon for the underwriters by Latham & Watkins LLP.

## EXPERTS

The financial statements of resTORbio, Inc. as of December 31, 2016 and September 30, 2017 and for the period July 5, 2016 (inception) through December 31, 2016 and the nine months ended September 30, 2017, have been included herein in reliance upon the reports of KPMG LLP, an independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the common stock we are offering by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our common stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

Upon the completion of the offering, we will be subject to the informational requirements of the Exchange Act and will file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at [www.sec.gov](http://www.sec.gov). You may also read and copy any document we file with the SEC at its public reference facility at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. We also maintain a website at [www.restorbio.com](http://www.restorbio.com). Upon completion of the offering, you may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendment to those reported filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

resTORbio, Inc.

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors  
resTORbio, Inc.:

We have audited the accompanying balance sheets of resTORbio, Inc. as of December 31, 2016 and September 30, 2017, and the related statements of operations, statements of redeemable convertible preferred stock and stockholders' (deficit) equity, and cash flows for the period July 5, 2016 (inception) through December 31, 2016 and the nine months ended September 30, 2017. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States) and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of resTORbio, Inc. as of December 31, 2016 and September 30, 2017, and the results of its operations and its cash flows for the period July 5, 2016 (inception) through December 31, 2016 and the nine months ended September 30, 2017 in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

Cambridge, Massachusetts  
October 26, 2017

**resTORbio, Inc.**  
**Balance Sheets**  
(In thousands, except share and per share data)

	December 31, 2016	September 30, 2017	
		Actual	Pro Forma (unaudited)
<b>Assets</b>			
Current assets:			
Cash	\$ —	\$ 3,965	\$ 18,965
Prepaid expenses	—	210	210
Other current assets (including related party amounts of \$0 and \$4 as of December 31, 2016 and September 30, 2017, respectively)	—	4	4
Total current assets	—	4,179	19,179
Property and equipment, net	—	36	36
Total assets	<u>\$ —</u>	<u>\$ 4,215</u>	<u>\$ 19,215</u>
<b>Liabilities, redeemable convertible preferred stock and stockholders' (deficit) equity</b>			
Current liabilities:			
Accounts payable (including related party amounts of \$0 and \$45 as of December 31, 2016 and September 30, 2017, respectively)	\$ —	\$ 1,094	\$ 1,094
Accrued liabilities	—	1,022	1,022
Tranche rights liability	—	1,379	—
Total current liabilities	—	3,495	2,116
Total liabilities	—	3,495	2,116
Commitments and contingencies (see Note 11)			
Redeemable convertible preferred stock:			
Redeemable convertible preferred stock, Series A, \$0.0001 par value, None and 10,351,968 shares authorized as of December 31, 2016 and September 30, 2017, respectively; 0 and 7,763,976 shares issued and outstanding as of December 31, 2016 and September 30, 2017, respectively; no shares issued and outstanding pro forma (unaudited); aggregate liquidation preference of \$0 and \$15,000 as of December 31, 2016 and September 30, 2017, respectively, and none pro forma (unaudited)	—	9,764	—
Stockholders' (deficit) equity:			
Common stock, \$0.0001 par value, 7,000,000, 19,000,000 and 19,000,000 shares authorized as of December 31, 2016, September 30, 2017 actual and September 30, 2017 pro forma (unaudited), respectively; 4,830,600, 7,245,900 and 22,773,851 shares issued and outstanding as of December 31, 2016, September 30, 2017 actual and September 30, 2017 pro forma (unaudited), respectively; 2,666,894, 5,706,146 and 22,773,851 shares vested as of December 31, 2016, September 30, 2017 actual and September 30, 2017 pro forma (unaudited), respectively	1	1	2
Additional paid-in capital	—	1,680	26,443
Accumulated deficit	(1)	(10,725)	(9,346)
Total stockholders' (deficit) equity	—	(9,044)	17,099
Total liabilities, redeemable convertible preferred stock and stockholders' (deficit) equity	<u>\$ —</u>	<u>\$ 4,215</u>	<u>\$ 19,215</u>

See accompanying notes to these financial statements.

**resTORbio, Inc.**  
**Statements of Operations**  
**(In thousands, except share and per share data)**

	July 5, 2016 (inception) through December 31, 2016	July 5, 2016 (inception) through September 30, 2016 (unaudited)	Nine Months Ended September 30, 2017
Operating expenses:			
Research and development	\$ —	\$ —	\$ 10,047
General and administrative	1	1	1,312
Total operating expenses	<u>1</u>	<u>1</u>	<u>11,359</u>
Loss from operations	(1)	(1)	(11,359)
Other income, net	—	—	635
Net loss	<u>\$ (1)</u>	<u>\$ (1)</u>	<u>\$ (10,724)</u>
Net loss per share, basic and diluted	<u>\$ (0.00)</u>	<u>\$ (0.00)</u>	<u>\$ (2.18)</u>
Weighted-average common shares used in computing net loss per share, basic and diluted	<u>2,532,807</u>	<u>2,458,164</u>	<u>4,915,847</u>
Pro forma net loss per share, basic and diluted (unaudited)			<u>\$ (1.02)</u>
Weighted-average common shares used in computing pro forma net loss per share, basic and diluted (unaudited)			<u>10,538,278</u>

See accompanying notes to these financial statements.

**resTORbio, Inc.**  
**Statements of Redeemable Convertible Preferred Stock and Stockholders' (Deficit) Equity**  
(In thousands, except share data)

	Series A Redeemable Convertible Preferred Stock		Common Stock		Additional Paid In Capital	Accumulated Deficit	Shareholders' (Deficit) Equity
	Shares	Amount	Shares	Amount			
<b>Balance at July 5, 2016</b>	—	\$ —	—	\$ —	\$ —	\$ —	\$ —
Vesting of restricted shares	—	—	2,666,894	1	—	—	1
Net loss	—	—	—	—	—	(1)	(1)
<b>Balance at December 31, 2016</b>	<u>—</u>	<u>\$ —</u>	<u>2,666,894</u>	<u>\$ 1</u>	<u>\$ —</u>	<u>\$ (1)</u>	<u>\$ —</u>
Issuance of common shares to PureTech (see Note 13)	—	—	2,415,300	—	—	—	—
Issuance of Series A redeemable convertible preferred stock, net of tranche liability	7,763,976	9,764	—	—	1,379	—	1,379
Vesting of restricted shares	—	—	623,952	—	—	—	—
Stock-based compensation expense	—	—	—	—	301	—	301
Net loss	—	—	—	—	—	(10,724)	(10,724)
<b>Balance at September 30, 2017</b>	<u>7,763,976</u>	<u>\$ 9,764</u>	<u>5,706,146</u>	<u>\$ 1</u>	<u>\$ 1,680</u>	<u>\$ (10,725)</u>	<u>\$ (9,044)</u>
Issuance of Series A redeemable convertible preferred stock and corresponding extinguishment of tranche liability (unaudited)	7,763,975	15,000	—	—	—	1,379	1,379
Conversion of redeemable convertible preferred shares into common shares (unaudited)	(15,527,951)	(24,764)	15,527,951	1	24,763	—	24,764
Accelerated vesting of restricted shares (unaudited)	—	—	1,539,754	—	—	—	—
<b>Pro Forma Balance at September 30, 2017 (unaudited)</b>	<u>—</u>	<u>\$ —</u>	<u>22,773,851</u>	<u>\$ 2</u>	<u>\$ 26,443</u>	<u>\$ (9,346)</u>	<u>\$ 17,099</u>

See accompanying notes to these financial statements.

**resTORbio, Inc.**  
**Statements of Cash Flows**  
**(In thousands)**

	July 5, 2016 (inception) through December 31, 2016	July 5, 2016 (inception) through September 30, 2016 (unaudited)	Nine Months Ended September 30, 2017
<b>Operating activities:</b>			
Net loss	\$ (1)	\$ (1)	\$ (10,724)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	—	—	3
Stock-based compensation expense	—	—	301
Change in fair value of tranche liability (see Note 7)	—	—	(635)
Expense related to acquisition of intellectual property (see Note 6)	—	—	3,157
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	—	—	(214)
Accounts payable	—	—	1,094
Accrued liabilities	1	1	1,022
Net cash used in operating activities	<u>—</u>	<u>—</u>	<u>(5,996)</u>
<b>Investing activities:</b>			
Purchases of property and equipment	—	—	(39)
Net cash used in investing activities	<u>—</u>	<u>—</u>	<u>(39)</u>
<b>Financing activities:</b>			
Proceeds from issuance of Series A redeemable convertible preferred stock	—	—	10,000
Net cash provided by financing activities	<u>—</u>	<u>—</u>	<u>10,000</u>
Net increase in cash	—	—	3,965
Cash at beginning of period	—	—	—
Cash at end of period	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,965</u>

See accompanying notes to these financial statements.

**resTORbio, Inc.**  
**NOTES TO FINANCIAL STATEMENTS**

**1. Organization**

resTORbio, Inc. (“the Company”) was incorporated in the State of Delaware on July 5, 2016. The Company is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapeutics for the treatment of aging-related diseases and conditions. The Company’s principal operations are located in Boston, Massachusetts.

Since inception, the Company has been primarily involved in research and development activities. The Company devotes substantially all of its efforts to product research and development, initial market development and raising capital. The Company has not generated any product revenue related to its primary business purpose to date and is subject to a number of risks similar to those of other early stage companies, including dependence on key individuals, competition from other companies, the need for development of commercially viable products and the need to obtain adequate additional financing to fund the development of its product candidates. The Company is also subject to a number of risks similar to other companies in the life sciences industry, including regulatory approval of products, uncertainty of market acceptance of products, competition from substitute products and larger companies, the need to obtain additional financing, compliance with government regulations, protection of proprietary technology, dependence on third parties, product liability and dependence on key individuals.

***Liquidity***

In the course of its development activities, the Company has sustained operating losses and expects such losses to continue over the next several years. The Company’s ultimate success depends on the outcome of its research and development activities. The Company has incurred net losses from operations since inception and has an accumulated deficit of \$10.7 million as of September 30, 2017. The Company intends to raise additional capital through the issuance of additional equity, and potentially through strategic alliances with third parties. If financing is not available at adequate levels, the Company may need to reevaluate its operating plans. Management believes currently available resources, which includes the \$15.0 million in gross proceeds the Company received in connection with the October 2017 issuance of 7,763,975 shares of the Company’s Series A Preferred Stock, will provide sufficient funds to enable the Company to meet its operating plans for at least the next twelve months from the date these financial statements are issued. However, if the Company’s anticipated operating results are not achieved in future periods, planned expenditures may need to be reduced in order to extend the time period over which the then-available resources would be able to fund the Company’s operations.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation and Use of Estimates***

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”). The Company’s fiscal year end is December 31<sup>st</sup>. Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASUs”) of the Financial Accounting Standards Board (“FASB”). The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities, as of the date of the financial statements, and the reported amounts of any expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to accrued liabilities, fair value of tranche liabilities, fair value of common stock, income taxes, and stock-based compensation expense. Management bases its estimates on historical experience, and on various other market-specific relevant assumptions that management

believes to be reasonable, under the circumstances. Actual results may differ from those estimates or assumptions.

### ***Unaudited Interim Financial Information***

The accompanying interim statements of operations and statements of cash flows for the period from July 5, 2016 (inception) to September 30, 2016 and the related footnote disclosures are unaudited. These unaudited interim financial statements have been prepared in accordance with U.S. GAAP. In management's opinion, the unaudited interim financial statements have been prepared on the same basis as the audited financial statements and include all adjustments (including normal recurring adjustments) necessary for the fair presentation of the Company's results of operations and its cash flows for the period from July 5, 2016 (inception) to September 30, 2016. The results for the period from July 5, 2016 (inception) to September 30, 2016 are not necessarily indicative of the results expected for the full fiscal year or any other interim period.

### ***Unaudited Pro Forma Financial Information***

On October 26, 2017, the Company's board of directors authorized the Company to file a registration statement with the Securities and Exchange Commission ("SEC") permitting the Company to sell shares of its common stock to the public. Upon the closing of a qualified (as defined in the Company's Certificate of Incorporation) initial public offering ("IPO"), all of the Company's redeemable convertible preferred stock will automatically convert into common stock and all unvested restricted shares will become vested. The unaudited pro forma balance sheet and statement of redeemable convertible preferred stock and stockholders' equity as of September 30, 2017 reflect the assumed conversion of all of the outstanding shares of Series A Redeemable Convertible Preferred Stock ("Series A Preferred Stock") into shares of common stock as well as the accelerated vesting of all restricted stock. In addition, the pro forma financials give effect to (i) the sale and issuance of \$15.0 million (7,763,976 shares) of the Company's Series A Preferred Stock and (ii) the automatic conversion of all of the shares of preferred stock into an aggregate of 15,527,951 shares of common stock. See Note 14 "Subsequent Events."

Unaudited pro forma net loss per share is computed using the weighted-average number of common shares outstanding after giving effect to the conversion of all Series A Preferred Stock into shares of the common stock, as well as the vesting of the unvested restricted shares, as if such conversion had occurred at the beginning of the period presented, or the date of original issuance, if later. The conversion of Series A Preferred Stock has been reflected assuming shares of Series A Preferred Stock convert into shares of fully paid common stock at the applicable conversion ratio. The pro forma basic and diluted net loss per share attributable to common stockholders does not include the effects of extinguishment of Series A Preferred Stock or the vesting of the unvested restricted shares. As the period of July 5, 2016 (inception) through December 31, 2016 and the nine months ended September 30, 2017 resulted in net losses, there is no income allocation required under the two-class method or dilution attributed to pro forma weighted average shares outstanding in the calculation of pro forma diluted loss per share attributable to common stockholders.

See Note 7 for further discussion of the Series A Preferred Stock conversion features, as well as a discussion of the rights and preferences of the redeemable convertible preferred stock.

### ***Fair Value Measurements***

Fair value is defined as the price at which an asset could be exchanged in a current transaction between knowledgeable, willing parties. A liability's fair value is defined as the amount that would be paid to transfer the liability to a new obligor, not the amount that would be paid to settle the liability with the creditor. Where available, fair value is based on observable market prices, or parameters derived from such prices. Where observable prices or inputs are not available, valuation models are applied. These valuation techniques involve some level of management estimation and judgment. The degree of management estimation and judgment is

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dependent on the price transparency for the instruments, or market, and the instruments' complexity. The authoritative accounting guidance describes a fair value hierarchy based on three levels of inputs that may be used to measure fair value, of which the first two are considered observable and the last is considered unobservable. These levels of inputs are as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3—Unobservable inputs that reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Financial instruments measured at fair value on a recurring basis include the tranche liability associated with the redeemable convertible preferred stock (Note 7). The fair value of the financial liability was determined based on Level 3 inputs as described in Note 3. An entity may elect to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in net loss. The Company did not elect to measure any additional financial instruments or other items at fair value.

There have been no changes to the valuation methods utilized by the Company during the period from July 5, 2016 (inception) to December 31, 2016, the period from July 5, 2016 (inception) through September 30, 2016, or the nine months ended September 30, 2017. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of financial instruments between levels during the period from July 5, 2016 (inception) to December 31, 2016, the period from July 5, 2016 (inception) to September 30, 2016, or the nine months ended September 30, 2017.

### ***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash. The Company's cash is held by financial institutions in the United States. Amounts on deposit may at times exceed federally insured limits. Management believes that the financial institution is financially sound, and accordingly, minimal credit risk exists with respect to the financial institution.

### ***Concentration of Manufacturing Risk***

As of September 30, 2017, the Company had manufacturing arrangements with vendors for the supply of materials for use in preclinical and clinical studies. If the Company were to experience any disruptions in either party's ability or willingness to continue to provide manufacturing services, the Company may experience significant delays in its product development timelines and may incur substantial costs to secure alternative sources of manufacturing.



### ***Property and Equipment***

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is recorded using the straight-line method over the estimated useful lives of the respective assets. Depreciation begins at the time the asset is placed in service. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in the statement of operations.

The estimated useful lives of property and equipment are as follows:

	<u>Useful Life (in years)</u>
Laboratory and manufacturing equipment	2-8 years
Computer equipment and software	1-5 years

### ***Impairment of Long-Lived Assets***

The Company evaluates its long-lived assets, including property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying value of these assets may not be recoverable. Recoverability of these assets is measured by comparison of the carrying amount of each asset to the future undiscounted cash flows the asset is expected to generate over its remaining life. If the asset is considered to be impaired, the amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset. The Company has recorded no impairment of any long-lived assets during any of the periods presented.

### ***Accrued Research and Development Costs***

The Company accrues for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided, and includes these costs in accrued liabilities in the balance sheets and within research and development expense in the statements of operations. These costs are a significant component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers. The Company makes judgments and estimates in determining the accrued liabilities balance in each reporting period.

### ***Research and Development Costs***

Research and development costs are expensed as incurred and consist of personnel costs, lab supplies and other costs, as well as fees paid to third parties to conduct research and development activities on the Company's behalf. Amounts incurred in connection with license agreements are also included in research and development expenses. The Company records payments made to outside vendors for services performed or goods being delivered for use in research and development activities as either prepaid expenses or accrued expenses, depending on the timing of when services are performed or goods are delivered.

### ***Equity-Based Compensation Expense***

The Company recognizes equity-based compensation expense for awards of equity instruments to employees and non-employees based on the grant date fair value of those awards in accordance with FASB ASC Topic 718, *Stock Compensation* ("ASC 718"). ASC 718 requires all equity-based compensation awards to

employees and nonemployee directors, including grants of restricted shares and stock options, to be recognized as expense in the Statements of Operations based on their grant date fair values. The Company estimates the fair value of stock options using the Black-Scholes option pricing model. The Company uses the value of its common stock to determine the fair value of restricted shares.

The Company accounts for restricted stock and common stock options issued to nonemployees under FASB ASC Topic 505-50, *Equity-Based Payments to Non-Employees* (“ASC 505-50”). As such, the value of such options is periodically remeasured and income or expense is recognized over their vesting terms. Compensation cost related to awards with service-based vesting schedules is recognized using the straight-line method. The Company determines the fair value of the restricted stock and common stock granted to nonemployees as either the fair value of the consideration received or the fair value of the equity instruments issued.

The Black-Scholes option pricing model requires the input of certain subjective assumptions, including (i) the expected share price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) the expected dividend yield. Due to the lack of a public market for the trading of the Company’s common stock and a lack of company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The group of representative companies have characteristics similar to the Company, including stage of product development and focus on the life science industry. The Company uses the simplified method, which is the average of the final vesting tranche date and the contractual term, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For options granted to non-employees, the Company utilizes the contractual term of the arrangement as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The Company uses an assumed dividend yield of zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

The Company expenses the fair value of its equity-based compensation awards granted to employees on a straight-line basis over the associated service period, which is generally the period in which the related services are received. The Company measures equity-based compensation awards granted to nonemployees at fair value as the awards vest and recognizes the resulting value as compensation expense at each financial reporting period. The Company accounts for award forfeitures as they occur.

#### ***Determination of Fair Value of Common and Preferred Shares and Tranche Rights Liability***

As there has been no public market for our equity instruments to date, the estimated fair value of the Company’s common and preferred shares has been determined by the board of directors as of the grant date, with input from management, considering the Company’s most recently available third-party valuations of common shares and the board of directors’ assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants’ Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Our common and preferred share valuations were prepared using either an option-pricing method, or OPM, or a probability-weighted expected return method, or PWERM, which used a combination of market approaches and an income approach to estimate the Company’s enterprise value. The OPM treats common securities and preferred securities as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company’s securities changes. Under this method, the common and preferred shares have value only if the funds available for distribution to members are expected to exceed the value of the preferred security liquidation preference at the time of the liquidity event, such as a strategic sale or a merger. The PWERM is a scenario-based

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methodology that estimates the fair value of common and preferred shares based upon an analysis of future values for the enterprise, assuming various outcomes. The common and preferred share values are based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of common and preferred securities. The future value of the common and preferred shares under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common and preferred shares. The estimated fair value of the tranche liability was determined using the difference between the total purchase price of the Company's Series A Preferred Stock and the total fair value of the Series A Preferred Stock using a risk-adjusted forward contract model.

### ***Income Taxes***

The Company uses the asset and liability method of accounting for income taxes in accordance with FASB ASC Topic 740, *Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax basis of assets and liabilities, and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company must then assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion, or all of a deferred tax asset will not be realized. Due to the Company's lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes benefits of uncertain tax positions if it is more likely than not that such positions will be sustained upon examination based solely on their technical merits, as the largest amount of benefit that is more likely than not to be realized upon the ultimate settlement. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, the Company has no uncertain tax positions and there have been no interest charges or penalties related to unrecognized tax benefits.

### ***Net Loss per Share***

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding during the period without consideration of common stock equivalents. Diluted net loss per common share is the same as basic net loss per common share for all periods presented, since the effects of potentially dilutive securities are antidilutive.

### ***Recently Adopted Accounting Pronouncements***

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"). ASU 2014-15 requires management to evaluate relevant conditions, events, and certain management plans that are known or reasonably knowable that, when considered in the aggregate, raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued, for both annual and interim periods. ASU 2014-15 also requires certain disclosures around management's plans and evaluation, as well as the plans, if any, that are intended to mitigate those conditions or events that will alleviate the substantial doubt. ASU 2014-15 is effective for fiscal years ending after December 15, 2016. The Company adopted this guidance on July 5, 2016 (inception).

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718)* ("ASU 2016-09"). The guidance changes how companies account for certain aspects of equity-based payments to employees. Entities will be required to recognize income tax effects of awards in the income statement when the awards vest or are settled. The guidance also allows an employer to repurchase more of an employee's shares than it can under current guidance for tax withholding purposes providing for withholding at the employee's

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maximum rate as opposed to the minimum rate without triggering liability accounting and to make a policy election to account for forfeitures as they occur. The updated guidance is effective for annual periods beginning after December 15, 2017. Early adoption is permitted. The Company adopted this guidance on July 5, 2016 (inception) and made the policy election to account for forfeitures as they occur. No awards have been forfeited as of September 30, 2017.

### **Recently Issued Accounting Pronouncements**

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows* (“ASU 2016-18”), which requires that amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2018 and should be applied using a retrospective transition method to each period presented. Early adoption is permitted. The Company does not expect the impact of ASU 2016-18 to be material to its financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation* (Topic 718): Scope of Modification Accounting (“ASU 2017-09”). ASC 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The guidance is effective for annual periods beginning after December 15, 2017, with early adoption permitted, including adoption in any interim period for which financial statements have not yet been issued. The Company is currently evaluating the potential effects of adopting the provisions of ASU 2017-09.

In July 2017, the FASB issued ASU 2017-11, *Accounting for Certain Financial Instruments with Down Round Features* (“ASU 2017-11”), which updates the guidance related to the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. Under ASU 2017-11, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity’s own stock. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. ASU 2017-11 is effective for public entities for all annual and interim periods beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2017-11 will have on its financial statements.

### **3. Financial Instruments**

There were no assets or liabilities measured at fair value as of December 31, 2016. Below is a summary of liabilities measured at fair value as of September 30, 2017:

	<u>As of September 30, 2017</u> (In thousands)			
	<u>Quoted Prices in Active Markets (Level 1)</u>	<u>Significant Observable Inputs (Level 2)</u>	<u>Significant Unobservable Inputs (Level 3)</u>	<u>Total</u>
Tranche rights liability	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,379</u>	<u>\$1,379</u>

The tranche rights liability is considered a Level 3 liability because its fair value measurement is based, in part, on significant inputs not observed in the market. The Company determined the fair value of the liability as described in Note 7. Any reasonable changes in the assumptions used in the valuation could materially affect the financial results of the Company.

#### 4. Property and equipment, net

Property and equipment, net consists of the following:

	December 31, 2016	<u>As of</u> (In thousands)	September 30, 2017
Laboratory and manufacturing equipment	\$ —		\$ 38
Computer equipment and software	—		1
Total property and equipment	—		39
Less: accumulated depreciation	—		(3)
Property and equipment, net	<u>\$ —</u>		<u>\$ 36</u>

Depreciation expense was \$0, \$0 and \$2,738, for the period from July 5, 2016 (inception) to December 31, 2016, the period from July 5, 2016 (inception) through September 30, 2016, and the nine months ended September 30, 2017, respectively.

#### 5. Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2016	<u>As of</u> (In thousands)	September 30, 2017
Accrued payroll and related expenses	\$ —		\$ 245
Accrued research and development expenses	—		525
Other	—		252
Total accrued liabilities	<u>\$ —</u>		<u>\$ 1,022</u>

#### 6. License Agreements

##### *Novartis License Agreement*

On March 23, 2017, the Company entered into an exclusive license agreement with Novartis International Pharmaceutical Ltd. (“Novartis”). Under the agreement, Novartis granted the Company an exclusive, field-restricted, worldwide license, to certain intellectual property rights owned or controlled by Novartis, to develop, commercialize and sell one or more therapeutic products comprising RTB101 or RTB101 in combination with everolimus in a fixed dose combination. The exclusive field under the license agreement is for the treatment, prevention and diagnosis of disease and other conditions in all indications in humans and animals.

As initial consideration for the licensed rights, the Company issued Novartis Institutes for Biomedical Research (“NIBR”) 2,587,992 shares of the Company’s Series A Preferred Stock. The fair value of the Novartis license was \$3.2 million based on the fair value of the Series A Preferred Stock which was determined to be \$1.22 per share based on an independent third-party valuation, and is recorded as research and development expenses in the statements of operations.

The agreement may be terminated by either party upon a material breach by the other party that is not cured within 60 days after written notice. The Company may terminate the agreement in its entirety or on a product-by-product or country-by-country basis with or without cause with 60 days’ prior written notice.

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Novartis may terminate the portion of the agreement related to everolimus if the Company fails to use commercially reasonable efforts to research, develop and commercialize a product utilizing everolimus for a period of three years. Novartis may terminate the license agreement upon the Company's bankruptcy, insolvency, dissolution or winding up.

As additional consideration for the license, the Company is required to pay up to an aggregate of \$4.3 million upon the satisfaction of clinical milestones, up to an aggregate of \$24 million upon the satisfaction of regulatory milestones for the first indication approved, and up to an aggregate of \$18 million upon the satisfaction of regulatory milestones for the second indication approved. In addition, the Company is required to pay up to an aggregate of \$125 million upon the satisfaction of commercial milestones, based on the amount of annual net sales. The Company is also required to pay tiered royalties ranging from a mid single-digit percentage to a low teen-digit percentage on annual net sales of products. These royalty obligations last on a product-by-product and country-by-country basis until the latest of (i) the expiration of the last valid claim of a Novartis patent covering a subject product, (ii) the expiration of any regulatory exclusivity for the subject product in a country, or (iii) the 10<sup>th</sup> anniversary of the first commercial sale in the country, and are subject to a reduction after the expiration of the last valid claim of a Novartis patent or the introduction of a generic equivalent of a product in a country. In addition, if the Company sublicenses the rights under the license agreement, the Company is required to pay a certain percentage of sublicense revenue to Novartis. Novartis will no longer be entitled to sublicense revenue following the last visit of the 400<sup>th</sup> subject in any human clinical trial conducted by the Company or a sublicensee of the Company.

Milestone payments to Novartis will be recorded as research and development expenses in the statements of operations once achievement of each associated milestone has occurred or the achievement is considered probable. In May 2017, the Company initiated a Phase 2b clinical trial for a first indication, triggering the first milestone payment under the agreement. Accordingly, the Company paid the related \$0.3 million payment in May 2017. As of September 30, 2017, none of the remaining development milestones, regulatory milestones, sales milestones, or royalties had been reached or were probable of achievement.

### **7. Redeemable Convertible Preferred Stock**

As of September 30, 2017, the Company had 10,351,968 shares of preferred stock authorized, of which 7,763,976 shares were issued and outstanding and were designated as \$0.0001 par value Series A Preferred Stock.

The Company's redeemable convertible preferred shares have been classified as temporary or mezzanine equity on the accompanying balance sheets in accordance with U.S. GAAP for the classification and measurement of redeemable securities as the Series A Preferred Stock are contingently redeemable at the option of the holder for reasons outside of the Company's control. As of September 30, 2017, there has been no accretion of the redeemable convertible preferred shares to redemption value as at that date the shares are not redeemable or probable of being redeemed.

On March 23, 2017, the Company entered into a Series A Preferred Stock Purchase Agreement with PureTech Health LLC ("PureTech") and NIBR. Under the agreement, in the initial March 2017 closing, PureTech purchased 2,846,791 shares of Series A Preferred Stock at a purchase price of \$1.932 per share, resulting in aggregate gross proceeds of \$5.5 million, and NIBR was issued 2,587,992 shares of Series A Preferred Stock as consideration for an exclusive, field-restricted, worldwide license, to certain intellectual property rights owned or controlled by Novartis, to develop, commercialize and sell one or more therapeutic products comprising RTB101, alone or in combination with everolimus in a fixed dose combination. PureTech also agreed to purchase up to 4,917,185 additional shares (the "Tranche Rights"), at \$1.932 per share at future dates based on the occurrence of certain events as specified under the agreement. The fair value of the Series A Preferred Stock on the date of issuance was determined to be \$1.22 per share based on an independent third-party valuation.

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On March 23, 2017, the Company also entered into a side letter with PureTech under which PureTech agreed to purchase up to 5,175,984 additional shares at \$1.932 per share at a future date based on the occurrence of certain events as specified under the letter. The Tranche Rights were evaluated under ASC 480 – *Distinguishing Liabilities from Equity* and it was determined that they met the requirements for separate accounting from the initial issuance of Series A Preferred Stock as freestanding financial instruments and are accounted for as liabilities. The Company adjusts the carrying value of the Tranche Rights to its estimated fair value at each reporting date up to the closing of each tranche financing. Increases or decreases in fair value of the Tranche Rights are recorded as other income (expense) in the statements of operations.

At the date of issuance, the Tranche Rights liability was recorded at fair value of \$2.0 million as a liability on the balance sheet. From the date of issuance to September 30, 2017, the change in fair value of the Tranche Rights was \$0.6 million and was recorded as other income in the statements of operations.

In September 2017, the Company received gross proceeds of \$4.5 million in exchange for the issuance of 2,329,193 shares of Series A Preferred Stock at \$1.932 per share pursuant to the second closing on August 29, 2017. The fair value of the Series A Preferred Stock on the date of issuance was determined to be \$1.34 per share based on an independent third-party valuation.

The rights, privileges, and preferences of convertible preferred stock are summarized as follows:

### ***Liquidation Preference***

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, or Deemed Liquidation Event (as defined below), the holders of shares of Series A Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders before any payment shall be made to the holders of common stock, an amount per share equal to the Series A Original Issue Price of \$1.932, plus any dividends declared and unpaid thereon.

If upon any liquidation, dissolution, winding up of the Company or Deemed Liquidation Event, the assets of the Company available for distribution to shareholders is insufficient to pay the holders of shares of Series A Preferred Stock the full amount to which they shall be entitled, the holders of Series A Preferred Stock will share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

After payment of all preferential amounts required to be paid to the holders of preferred stock, the remaining funds and assets available for distribution to the shareholders of the Company will be distributed among the holders of Series A Preferred Stock and common stock, pro rata based on the number of shares held by each such holder, provided, however, that if the aggregate amount which the holders of Series A Preferred Stock are entitled to receive exceeds \$3.864 per share, each holder of Series A Preferred Stock shall be entitled to receive the greater of (i) \$3.864 or (ii) the amount such holder would have received if all shares of Series A Preferred Stock had been converted into common stock immediately prior.

The following events are defined as Deemed Liquidation Events unless the holders of a majority of the then outstanding shares of Series A Preferred Stock elect otherwise by written notice to the Company:

- (i) a merger or consolidation; or
- (ii) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Company of all or substantially all the assets or intellectual property of the Company.

### **Voting**

Each holder of shares of Series A Preferred Stock is entitled to the number of votes equal to the number of whole shares of common stock into which such shares of Series A Preferred Stock could be converted and has voting rights and powers equal to the voting rights and powers of the common stock, and except as provided by law or by other provisions of the Certificate of Incorporation, shall vote together with the common stock as a single class on an as-converted basis on all matters as to which holders of common stock have the right to vote.

The holders of Series A Preferred Stock, voting together as a single class, are entitled to elect three members of the Company's board of directors. The holders of common stock, exclusively and as a separate class, are entitled to elect two members of the Company's board of directors.

### **Redemption**

The Series A Preferred Stock may be redeemed upon a Deemed Liquidation Event. The Series A Preferred Stock may be redeemed at \$1.932 per share, or the holders of Series A Preferred Stock may receive an amount equal to the amount entitled if the Series A Preferred Stock converted into shares of common stock on a one-for-one basis on the redemption date. At September 30, 2017, the shares of Series A Preferred Stock were not redeemable and the likelihood of an occurrence of a Deemed Liquidation Event was not deemed to be probable.

### **Conversion**

The holders of Series A Preferred Stock are subject to certain optional and mandatory conversion rights.

- (i) *Optional Conversion Rights:* Each share of convertible preferred stock is convertible, at the option of the holder, into such number of fully paid shares of common stock as is determined by dividing the original issuance price by the conversion price in effect at the time of conversion. As of September 30, 2017, the conversion ratio was 1:1 for the Series A Preferred Stock.
- (ii) *Mandatory Conversion Rights:* Upon either (a) the closing of the sale of shares of common stock to the public at a price of at least \$5.796 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement resulting in at least \$25 million of gross proceeds to the Company or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of a majority of the then outstanding shares of Series A Preferred Stock, then all outstanding shares of Series A Preferred Stock shall automatically be converted into shares of common stock, at the then effective conversion rate.

The conversion price for Series A Preferred Stock is subject to adjustment upon certain events including certain dilutive issuances of shares, share subdivisions such as stock splits and stock dividends, combinations or other similar recapitalizations with respect to the common stock, or other similar events. At September 30, 2017 the Series A Preferred Stock had a conversion price and original issuance price of \$1.932 per share.

### **Dividends**

If the Company declares or makes any dividends to holders of common stock of the Company, each holder of Series A Preferred Stock shall be entitled to receive such dividend on an as-converted basis. Such dividends shall not accrue and shall not accumulate. No dividends had been declared as of September 30, 2017.



## 8. Common Stock

### *General*

The voting, dividend and liquidation rights of the holders of common stock are subject to and qualified by the rights, powers, and preferences of the holders of the shares of Series A Preferred Stock. The common stock has the following characteristics:

### *Voting*

The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders and written actions in lieu of meetings, provided, however, that except as otherwise required by law, holders of common stock as such shall not be entitled to vote on any amendment to the Company's Certificate of Incorporation that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to the Company's Certificate of Incorporation or pursuant to Delaware General Corporation Law. There shall be no cumulative voting.

### *Dividends*

The holders of shares of common stock are entitled to receive dividends, if and when declared by the Board of Directors. Cash dividends may not be declared or paid to the holders of common stock until paid on the Series A Preferred Stock. As of September 30, 2017, no dividends have been declared or paid since the Company's inception.

### *Liquidation*

After payment to the holders of shares of Series A Preferred Stock of their liquidation preference, the holders of the common stock are entitled to share ratably in the Company's assets available for distribution to stockholders, in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or upon the occurrence of a Deemed Liquidation Event.

### *Reserve for future issuance*

As of December 31, 2016, the Company had not reserved any shares of common stock for future issuance. As of September 30, 2017, the Company has reserved the following number of shares of common stock for future issuance upon the conversion or exercise of preferred stock or options or grant of equity awards:

	<u>As of September 30,</u> <u>2017</u>
Redeemable convertible preferred stock, on an as-converted basis	7,763,976
Options issued and outstanding	142,535
Options available for future grants	546,212
Total	<u>8,452,723</u>

## 9. Stock-based Compensation

In 2017, the Company adopted the 2017 Stock Incentive Plan (the "Plan"). Under the Plan, shares of the Company's common stock have been reserved for the issuance of stock options to employees, directors, and consultants under terms and provisions established by the Board of Directors. A total of 688,747 shares were reserved for issuance under the Plan. Under the terms of the Plan, options may be granted at an exercise price not less than fair market value. The terms of options granted under the Plan may not exceed ten years. The Board shall determine the terms and conditions of a Restricted Stock Award, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

**Stock-based Compensation Expense**

Total stock-based compensation expense is recognized for stock options granted to employees and non-employees and has been reported in the Company's statements of operations as follows:

	July 5, 2016 (inception) through December 31, 2016	July 5, 2016 (inception) through September 30, 2016 (unaudited) (In thousands)	Nine Months Ended September 30, 2017
Research and development	\$ —	\$ —	\$ 152
General and administrative	—	—	149
Total stock-based compensation expense	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 301</u>

**Stock Options**

A following table summarizes stock option activity under the Plan:

	Shares Available for Grant	Number of Options Outstanding	Weighted- Average Exercise Price per Option	Weighted- Average Remaining Contract Term	Aggregate Intrinsic Value (In thousands)
Outstanding, December 31, 2016	—	—	\$ —		
Shares reserved for issuance	688,747				
Options granted <sup>(1)</sup>	<u>(142,535)</u>	<u>142,535</u>	0.63		
Outstanding, September 30, 2017	<u>546,212</u>	<u>142,535</u>	0.63	9.68	\$ 21
Exercisable, September 30, 2017		—	—		
Vested and expected to vest, September 30, 2017		142,535	0.63	9.68	\$ 21

(1) The Company granted 60,000 stock options to non-employees during the nine months ended September 30, 2017.

The aggregate intrinsic values of options outstanding, exercisable, vested and expected to vest were calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock, as determined by the board of directors, as of September 30, 2017. No options were exercised during the nine months ended September 30, 2017.

There were no stock options granted to employees or non-employees during the period from July 5, 2016 (inception) to December 31, 2016 or the period from July 5, 2016 (inception) to September 30, 2016. During the nine months ended September 30, 2017, the Company granted options to employees to purchase an aggregate of 82,535 common shares with a grant date fair value of \$0.41. During the nine months ended September 30, 2017, the Company granted options to non-employees to purchase an aggregate of 60,000 common shares with a weighted-average grant date fair value of \$0.52. The expense related to options granted to employees and non-employees was \$2,606 and \$2,352, respectively, for the nine months ended September 30, 2017.

As of September 30, 2017, the total unrecognized compensation expense related to unvested employee options was \$31,339 which the Company expects to recognize over an estimated weighted-average period of 3.62 years. As of September 30, 2017, the total unrecognized compensation expense related to unvested nonemployee options was \$35,774 which the Company expects to recognize over an estimated weighted-average period of 3.76 years.

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The fair value of stock options for employees and non-employees was estimated using a Black-Scholes option pricing model with the following assumptions:

	<b>Nine Months Ended September 30, 2017</b>
<b>Employees:</b>	
Fair value of common stock	\$ 0.62
Expected term (in years)	6.1
Expected volatility	74.4%
Risk-free interest rate	1.9%
Expected dividend yield	0.0%
<b>Non-employees:</b>	
Fair value of common stock	\$ 0.62 - \$0.78
Expected term (in years)	10.0
Expected volatility	74.6% - 76.9%
Risk-free interest rate	2.3%
Expected dividend yield	0.0%

*Fair Value of Common Stock:* Given the absence of a public trading market, the Board of Directors considered numerous objective and subjective factors to determine the fair value of common stock at each grant date. These factors included, but were not limited to, (i) contemporaneous valuations of common stock performed by independent third-party specialists; (ii) the prices for preferred stock sold to outside investors; (iii) the rights, preferences and privileges of preferred stock relative to common stock; (iv) the lack of marketability of common stock; (v) developments in the business; and (vi) the likelihood of achieving a liquidity event, such as an initial public offering or a merger or acquisition of the Company, given prevailing market conditions.

### **Restricted Stock**

On July 11, 2016, certain founding non-employee directors purchased 4,830,600 common shares that are subject to a repurchase right upon termination or cessation of services at the original purchase price of \$0.0001 per share, or \$483. On April 4, 2017, the non-employee directors became employees of the Company. Compensation expense of such unvested shares was remeasured at fair value until vested at each reporting date. On April 4, 2017, compensation expense of such unvested shares was remeasured at fair value and fixed and is being recognized over the remaining period. The repurchase right lapses as vesting occurs.

A summary of restricted stock activity and related information follows:

	<b>Number of Restricted Shares Outstanding</b>
Unvested shares — July 5, 2016 (inception)	—
Issued	4,830,600
Vested	<u>(2,666,894)</u>
Unvested shares — December 31, 2016	2,163,706
Vested	<u>(623,952)</u>
Unvested shares — September 30, 2017	<u>1,539,754</u>

The Company recognized \$0, \$0, and \$0.3 million of stock based compensation expense related to restricted shares during the period from July 5, 2016 (inception) to December 31, 2016, the period from July 5,

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2016 (inception) to September 30, 2016, and the nine months ended September 30, 2017, respectively. As of September 30, 2017, there was \$1.0 million of unrecognized stock based compensation expense related to unvested restricted stock. This amount is expected to be recognized over a remaining weighted-average period of 2.78 years.

## 10. Income Taxes

### *Provision (Benefit) for Income Taxes*

For the period from July 5, 2016 (inception) to December 31, 2016, the period from July 5, 2016 (inception) to September 30, 2016, and the nine months ended September 30, 2017, the Company did not record a current or deferred income tax expense or benefit. The Company's loss before income taxes consists solely of a domestic loss.

A reconciliation of income tax expense computed at the statutory federal income tax rate to income taxes as reflected in the financial statements is as follows:

	July 5, 2016 (inception) through December 31, 2016	July 5, 2016 (inception) through September 30, 2016 (unaudited) (In thousands)	Nine Months Ended September 30, 2017
Income tax expense at federal statutory rate	\$ —	\$ —	\$ (3,646)
State taxes	—	—	(612)
Tax credits	—	—	(110)
Stock-based compensation	—	—	102
Other	—	—	(215)
Change in valuation allowance	—	—	4,481
Income tax expense	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>
Effective tax rate	<u>0.0%</u>	<u>0.0%</u>	<u>0.0%</u>

### ***Deferred Tax Assets and Liabilities***

Deferred income taxes reflect the net tax effects of loss and credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of deferred income taxes were as follows as of December 31, 2016 and September 30, 2017:

	<u>December 31,</u> <u>2016</u>	<u>As of</u> <u>September 30,</u> <u>2017</u>
	(In thousands)	
Deferred tax assets:		
Operating tax losses	\$ —	\$ 2,934
Capitalized license	—	1,358
Research credits	—	140
Accruals	—	96
Stock-based compensation	—	1
Total gross deferred tax assets	—	4,529
Less valuation allowance	—	(4,482)
Total deferred tax assets	—	47
Deferred tax liabilities:		
Depreciation and Amortization	—	(47)
Total gross deferred tax liability	—	(47)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Due to the lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance.

### ***Net Operating Loss and Tax Credit Carryforwards***

As of December 31, 2016 and September 30, 2017, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$1,000 and \$7.5 million, respectively which will begin to expire in 2036. As of December 31, 2016 and September 30, 2017, the Company had total state net operating loss carryforwards of approximately \$1,000 and \$7.4 million, respectively which will begin to expire in 2036. Utilization of some of the federal and state net operating loss and credit carryforwards are subject to annual limitations due to the “change of ownership” provisions under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitations may result in the expiration of net operating losses and credits before utilization. The Company has not performed an ownership change analysis.

As of December 31, 2016 and September 30, 2017, the Company had federal research credits of \$0 and \$0.1 million, respectively which will begin to expire in 2037 and state research credits of \$0 and approximately \$45,000, respectively which will begin to expire in 2032. These tax credits are subject to the same limitations discussed above.

### ***Unrecognized Tax Benefits***

The Company has incurred net operating losses since inception and has no significant unrecognized tax benefits. The Company’s policy is to include interest and penalties related to unrecognized tax benefits, if any, within the provision for taxes in the statements of operations. If in the future the Company recognizes uncertain tax positions, the Company’s effective tax rate will be reduced. Currently, the Company has a full valuation

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allowance against its net deferred tax asset which would impact the timing of the effective tax rate benefit should any of these uncertain tax positions be favorably settled in the future. Any adjustments to uncertain tax positions would result in an adjustment of net operating loss or tax credit carry forwards rather than resulting in a cash outlay. As of September 30, 2017, the Company had no unrecognized tax benefits and no accrued interest or penalties related to uncertain tax positions.

Income tax returns are filed in the U.S. and Massachusetts. The Company is not currently under examination. Due to net operating losses and research credit carryovers, all of the tax years remain open to examination.

### **11. Commitments and Contingences**

#### ***Litigation***

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities as of September 30, 2017.

### **12. Net Loss per Share**

As described in Note 2, the Company computes basic and diluted earnings (losses) per share using a methodology that gives effect to the impact of outstanding participating securities (the “two-class” method). Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period and excludes any dilutive effects of share-based awards. Diluted net loss per share is computed giving effect to all potential dilutive common shares, including common stock issuable upon exercise of stock options, convertible preferred stock, and unvested restricted common stock. As the Company had net losses for the period from July 5, 2016 (inception) to December 31, 2016, the nine months ended September 30, 2017, and the period from July 5, 2016 (inception) to September 30, 2016, there is no income allocation required under the two-class method or dilution attributed to weighted average shares outstanding in the calculation of diluted loss per share.

### **13. Related Party Transactions**

Since the Company’s incorporation in July 2016, the Company has engaged in transactions with related parties. The transactions were on terms comparable to terms that could have been obtained from unrelated third parties.

During the nine months ended September 30, 2017, the Company issued 2,415,300 shares of common stock and made payments to PureTech for certain founding services and cost reimbursements. PureTech is a founder of the Company and holds shares of common stock and preferred stock of the Company. See Note 7.

The Company is a party to an intellectual property license agreement with Novartis. In addition, NIBR is a preferred stock shareholder of the Company. See Note 6. During the nine months ended September 30, 2017, the Company made payments to Novartis for milestones achieved pursuant to the license agreement and for the purchases of materials for use in the Company’s clinical trials.

Aggregate payments for the above related party transactions totaled \$0.9 million for the nine months ended September 30, 2017. No payments were made to related parties during the periods from July 5, 2016 (inception) to December 31, 2016 or from July 5, 2016 (inception) to September 30, 2016.

### **14. Subsequent Events**

For the purposes of the financial statements as of December 31, 2016 and September 30, 2017, and the period from July 5, 2016 (inception) to December 31, 2016, the period from July 5, 2016 (inception) to September 30, 2016, and the nine months ended September 30, 2017, the Company has evaluated subsequent events through October 26, 2017, the date the financial statements were issued.

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On October 11, 2017, the Company increased the number of authorized shares of common stock from 19,000,000 shares to 24,000,000 shares, and increased the number of authorized shares of Series A Preferred Stock from 10,351,968 shares to 15,527,951 shares. In addition, the Company increased the number of shares of common stock available for issuance under the Plan from 688,747 shares to 807,500 shares.

On October 12, 2017, the Company amended the Series A Preferred Stock Purchase Agreement to accelerate the third and fourth closings under the original agreement (as discussed in Note 7). The Company issued 7,763,975 shares of Series A Preferred Stock at \$1.932 per share for aggregate gross proceeds of \$15.0 million, of which \$9.0 million was from PureTech and \$6.0 million from a new investor. These amounts have been included in the pro forma balance sheet.

Through and including \_\_\_\_\_, 2018 (the 25th day after the date of this prospectus), all dealers effecting transactions in the common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

## Shares



## Common Stock

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PROSPECTUS

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**BofA Merrill Lynch**

**Leerink Partners**

**Wedbush PacGrow**

, 2018

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**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. Other Expenses of Issuance and Distribution**

The following table sets forth the expenses to be incurred in connection with the offering described in this Registration Statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimates except the Securities and Exchange Commission's registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the Nasdaq listing fee.

	<u>Amount</u>	
Securities and Exchange Commission registration fee	\$	*
FINRA filing fee		*
Nasdaq listing fee		*
Accountants' fees and expenses		*
Legal fees and expenses		*
Transfer Agent's fees and expenses		*
Printing and engraving expenses		*
Miscellaneous fees and expenses		*
Total expenses	<u>\$</u>	<u>*</u>

\* To be filed by amendment.

**Item 14. Indemnification of Directors and Officers**

Section 102 of the General Corporation Law of the State of Delaware permits a corporation to eliminate the personal liability of its directors for monetary damages for a breach of fiduciary duty as a director, except where the director breached his or her duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Upon completion of this offering, our certificate of incorporation will provide that none of our directors shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he or she is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Upon the completion of this offering, our certificate of incorporation will provide that we will indemnify each person who was or is a party or is threatened to be made a party or is involved in any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other

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than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our certificate of incorporation that will be effective as of the closing date of this offering also provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred by him or her or on his or her behalf in connection therewith. If we do not assume the defense, expenses must be advanced to an Indemnitee under certain circumstances.

We plan to enter into indemnification agreements with each of our executive officers and directors. In general, these agreements provide that we will indemnify the director or executive officer to the fullest extent permitted by law for claims arising in his or her capacity as a director or executive officer of our company or in connection with their service at our request for another corporation or entity. The indemnification agreements also provide for procedures that will apply in the event that a director or executive officer makes a claim for indemnification and establish certain presumptions that are favorable to the director or executive officer.

We maintain a general liability insurance policy that covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

The underwriting agreement we will enter into in connection with the offering of common stock being registered hereby provides that the underwriters will indemnify, under certain conditions, our directors and officers (as well as certain other persons) against certain liabilities arising in connection with such offering.

Insofar as the forgoing provisions permit indemnification of directors, executive officers, or persons controlling us for liability arising under the Securities Act of 1933, as amended, or the Securities Act, we have been informed that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

### **Item 15. Recent Sales of Unregistered Securities**

Set forth below is information regarding shares of our common stock and shares of our preferred stock issued, and stock options granted, by us within the past three years that were not registered under the Securities Act. Included is the consideration, if any, we received for such shares and options and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

**(a) Issuance of Capital Stock**

In July 2016, we issued and sold 2,415,300 shares of restricted common stock to each of Chen Schor and Joan Mannick at a price per share of \$0.0001. In March 2017, we issued 2,415,300 shares of our common stock to PureTech Health in exchange for its provision of founding strategic medical, clinical and scientific advice, as well as shared administrative support and offices pursuant to a business services, personnel and information management agreement.

In March 2017, we issued and sold an aggregate of 5,434,783 shares of our Series A preferred stock in the first closing of our Series A preferred stock financing to PureTech Health and Novartis Institutes for BioMedical Research, Inc., or NIBR, at a price per share of \$1.932. PureTech Health paid approximately \$5.0 million for such Series A shares, and the remaining \$482,011 of the purchase price was net settled against invoices paid by PureTech Health on our behalf prior to the closing of our Series A financing and as reimbursement for certain due diligence costs incurred in connection with the financing. The remaining shares were issued in consideration to NIBR for our entry into a license agreement with Novartis International Pharmaceutical Ltd, or Novartis.

In August 2017, we issued and sold 2,329,193 shares of our Series A preferred stock at a price per share of \$1.932 in the second closing of our Series A preferred stock financing for an aggregate purchase price of approximately \$4.5 million.

In October 2017, we issued and sold 7,763,95 shares of our Series A preferred stock at a price per share of \$1.932 in the third closing of our Series A preferred stock financing for an aggregate purchase price of approximately \$15.0 million.

In November 2017, we issued and sold 4,792,716 shares of our Series B preferred stock at a price per share of \$8.346 for an aggregate purchase price of approximately \$40.0 million.

No underwriters were involved in the foregoing issuances of securities. The securities described in this section (a) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. The recipients of securities in the transactions described above represented that they were accredited investors and were acquiring the securities for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time and appropriate legends were affixed to the instruments representing such securities issued in such transactions.

**(b) Stock Option Grants and Option Exercises**

From inception to September 30, 2017, we granted options to purchase an aggregate of 142,535 shares of common stock, with exercise prices ranging from \$0.62 to \$0.78 per share, to employees and consultants pursuant to our 2017 stock incentive plan. None of these options have been exercised.

No underwriters were involved in the foregoing issuances of securities. The issuances of stock options described in this paragraph (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with our employees, directors, consultants and advisors, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act, or pursuant to Section 4(a)(2) under the Securities Act, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

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All of the securities described in paragraphs (a) and (b) of this Item 15 are deemed restricted securities for purposes of the Securities Act. All of the certificates representing such securities included appropriate legends setting forth that the securities have not been registered and the applicable restrictions on transfer.

**Item 16. Exhibits and Financial Statement Schedules**

***(a) Exhibits***

The exhibits to the registration statement are listed in the Exhibit Index attached hereto and incorporated by reference herein.

***(b) Financial Statement Schedules***

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or the related notes.

**EXHIBIT INDEX**

<b><u>Exhibit Number</u></b>	<b><u>Description of Exhibit</u></b>
1.1*	Form of Underwriting Agreement
3.1	Second Amended and Restated Certificate of Incorporation of the Registrant (as currently in effect).
3.2*	Bylaws of the Registrant (as currently in effect)
3.3*	Form of Restated Certificate of Incorporation of the Registrant (to be effective upon the closing of this offering)
3.4*	Form of Amended and Restated Bylaws of the Registrant (to be effective upon the closing of this offering)
4.1*	Specimen stock certificate evidencing the shares of common stock
4.2	Amended and Restated Investors' Rights Agreement, dated as of November 29, 2017, among the Registrant and the other parties thereto
5.1*	Opinion of Goodwin Procter LLP
10.1#	2017 Stock Incentive Plan and forms of award agreements thereunder
10.2#*	2018 Stock Incentive Plan and forms of award agreements thereunder
10.3#*	Form of Director and Officer Indemnification Agreement
10.4+	License Agreement, dated as of March 23, 2017, by and between the Registrant and Novartis International Pharmaceutical Ltd.
10.5+*	First Amendment to the License Agreement, dated as of October 3, 2017, by and among Novartis International Pharmaceutical Ltd. and the Registrant
10.6	Business Services, Personnel and Information Management Agreement, dated as of August 1, 2016, by and among the Registrant, PureTech Management, Inc., PureTech Health LLC and PureTech Health plc
10.7#	Offer Letter, dated as of March 31, 2017, between the Registrant and Chen Schor
10.8#	Offer Letter, dated as of March 31, 2017, between the Registrant and Joan Mannick
10.9#	Offer Letter, dated as of October 5, 2017, between the Registrant and John McCabe
21.1*	Subsidiaries of the Registrant
23.1*	Consent of KPMG LLP, independent registered public accounting firm
23.2*	Consent of Goodwin Procter LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included on signature page)

\* To be filed by amendment.

+ Confidential treatment requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

# Indicates a management contract or any compensatory plan, contract or arrangement.

**Item 17. Undertakings**

- (a) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

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- (b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.
- (c) The undersigned registrant hereby undertakes that:
- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
  - (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boston, Commonwealth of Massachusetts, on this \_\_\_\_\_ day of \_\_\_\_\_, 2017.

RESTORBIO, INC.

By: \_\_\_\_\_  
Chen Schor  
*President and Chief Executive Officer*

## Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Chen Schor and John McCabe and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and any subsequent registration statements pursuant to Rule 462 of the Securities Act and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that each of said attorney-in-fact or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ Chen Schor	President, Chief Executive Officer and Director (principal executive officer)	, 2017
_____ John McCabe	Vice President, Finance (principal financial officer and principal accounting officer)	, 2017
_____ Raju Kucherlapati, Ph.D.	Director	, 2017
_____ David Steinberg	Director	, 2017
_____ Jonathan Silverstein	Director	, 2017

SECOND AMENDED AND RESTATED  
CERTIFICATE OF INCORPORATION  
OF  
RESTORBIO, INC.

(Pursuant to Sections 242 and 245 of the  
General Corporation Law of the State of Delaware)

resTORbio, Inc., a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the “**General Corporation Law**”),

**DOES HEREBY CERTIFY:**

**1.** That the name of this corporation is resTORbio, Inc., and that this corporation was originally incorporated pursuant to the General Corporation Law on July 5, 2016 under the name resTORbio, Inc.

**2.** That the Board of Directors duly adopted resolutions proposing to amend and restate the Amended and Restated Certificate of Incorporation of this corporation, declaring said amendment and restatement to be advisable and in the best interests of this corporation and its stockholders, and authorizing the appropriate officers of this corporation to solicit the consent of the stockholders therefor, which resolution setting forth the proposed amendment and restatement is as follows:

**RESOLVED**, that the Amended and Restated Certificate of Incorporation of this corporation be amended and restated (as amended and restated, the “Certificate of Incorporation”) in its entirety to read as follows:

**FIRST:** The name of this corporation is resTORbio, Inc. (the “**Corporation**”).

**SECOND:** The address of the registered office of the Corporation in the State of Delaware is 1209 Orange St., the County of New Castle, Wilmington, Delaware 19801. The name of its registered agent at such address is The Corporation Trust Company.

**THIRD:** The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law.

**FOURTH:** The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 30,000,000 shares of Common Stock, \$0.0001 par value per share (“**Common Stock**”) and (ii) 20,320,667 shares of Preferred Stock, \$0.0001 par value per share (“**Preferred Stock**”).

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.



## A. COMMON STOCK

1. General. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth herein.

2. Voting. The holders of the Common Stock are entitled to one vote for each share of Common Stock held at all meetings of stockholders (and written actions in lieu of meetings); provided, however, that, except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to the Certificate of Incorporation that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to the Certificate of Incorporation or pursuant to the General Corporation Law. There shall be no cumulative voting. The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by (in addition to any vote of the holders of one or more series of Preferred Stock that may be required by the terms of the Certificate of Incorporation) the affirmative vote of the holders of shares of capital stock of the Corporation representing a majority of the votes represented by all outstanding shares of capital stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law.

## B. PREFERRED STOCK

15,527,951 shares of the authorized Preferred Stock of the Corporation are hereby designated “**Series A Preferred Stock**” and 4,792,716 shares of the authorized and unissued Preferred Stock of the Corporation are hereby designated “**Series B Preferred Stock**.” The Series A Preferred Stock and the Series B Preferred Stock shall have the rights, preferences, powers, privileges and restrictions, qualifications and limitations set forth herein. Unless otherwise indicated, references to “sections” or “subsections” in this Part B of this Article Fourth refer to sections and subsections of Part B of this Article Fourth.

### 1. Dividends.

The Corporation shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Corporation (other than dividends on shares of Common Stock payable in shares of Common Stock) unless (in addition to the obtaining of any consents required elsewhere in the Certificate of Incorporation) the holders of the Preferred Stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of Preferred Stock in an amount at least equal to (i) in the case of a dividend on Common Stock or any class or series that is convertible into Common Stock, that dividend per share of such series of Preferred Stock as would equal the product of (A) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into Common Stock and (B) the number of shares of Common Stock issuable upon conversion of a share of such series of Preferred Stock, in each case calculated on the record date for determination of holders entitled to receive such dividend or (ii) in the case of a dividend on any class or series that is not convertible into Common Stock, at a rate per share of such series of Preferred Stock determined by (A) dividing the amount of the dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series of capital

stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such class or series) and (B) multiplying such fraction by an amount equal to the applicable Original Issue Price (as defined below); provided that, if the Corporation declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Corporation, the dividend payable to the holders of Preferred Stock pursuant to this Section 1 shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest dividend. The “**Series A Original Issue Price**” shall mean \$1.932 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock. The “**Series B Original Issue Price**” shall mean \$8.346 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B Preferred Stock. The Series A Original Issue Price and Series B Original Issue Price, together are hereby designated as the “**Original Issue Price**.”

2. Liquidation, Dissolution or Winding Up; Certain Mergers, Consolidations and Asset Sales.

2.1 Preferential Payments to Holders of Series B Preferred Stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, the holders of shares of Series B Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Corporation available for distribution to its stockholders before any payment shall be made to the holders of Series A Preferred Stock or Common Stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the Series B Original Issue Price, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Preferred Stock been converted into Common Stock pursuant to Section 4 immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event (the amount payable pursuant to this sentence is hereinafter referred to as the “**Series B Liquidation Amount**”). If upon any such liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, the assets of the Corporation available for distribution to its stockholders shall be insufficient to pay the holders of shares of Series B Preferred Stock the full amount to which they shall be entitled under this Subsection 2.1, the holders of shares of Series B Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

2.2 Preferential Payments to Holders of Series A Preferred Stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, after the payment of all preferential amounts required to be paid to the holders of shares of Series B Preferred Stock as set forth in Section 2.1 above, the holders of shares of Series A Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Corporation available for distribution to its stockholders before any payment shall be made to the holders of Common Stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the Series A Original Issue Price, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Preferred Stock been converted into Common Stock pursuant to Section 4 immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event (the amount payable

pursuant to this sentence is hereinafter referred to as the “**Series A Liquidation Amount**”). If upon any such liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, the assets of the Corporation available for distribution to its stockholders after giving effect to the payment of the Series B Liquidation Amount shall be insufficient to pay the holders of shares of Series A Preferred Stock the full amount to which they shall be entitled under this Subsection 2.2, the holders of shares of Series A Preferred Stock shall share ratably in any distribution of the remaining assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

2.3 Payments to Holders of Common Stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, after the payment of all preferential amounts required to be paid to the holders of shares of Preferred Stock as set forth in Section 2.1 and Section 2.2 above, the remaining assets of the Corporation available for distribution to its stockholders shall be distributed among the holders of shares of Common Stock, pro rata based on the number of shares held by each such holder.

#### 2.4 Deemed Liquidation Events.

2.4.1 Definition. Each of the following events shall be considered a “**Deemed Liquidation Event**” unless (i) the holders of a majority of the then outstanding shares of Series A Preferred Stock, and (ii) the holders of a majority of the then outstanding shares of Series B Preferred Stock, each voting as a separate class (clauses (i) and (ii) together, the “**Requisite Holders**”) elect otherwise by written notice sent to the Corporation at least ten (10) days prior to the effective date of any such event:

(a) a merger, consolidation, sale or reorganization in which

- (i) the Corporation is a constituent party or
- (ii) a subsidiary of the Corporation is a constituent party and the Corporation issues shares of its capital stock pursuant to such merger or consolidation,

except any such merger, consolidation, sale or reorganization involving the Corporation or a subsidiary in which the shares of capital stock of the Corporation outstanding immediately prior to such merger, consolidation, sale or reorganization continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger, consolidation, sale or reorganization, at least a majority, by voting power, in substantially the same relative proportions as among such stockholders prior to such transaction, of the capital stock of (1) the surviving or resulting corporation; or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation; or

(b) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Corporation or any subsidiary of the Corporation of all or substantially all the assets or intellectual property of the Corporation and its subsidiaries taken as a whole, or the sale or disposition (whether by merger, consolidation or otherwise) of one or more subsidiaries of the Corporation if substantially all of the assets or intellectual property of the Corporation and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Corporation.

#### 2.4.2 Effecting a Deemed Liquidation Event.

(a) The Corporation shall not have the power to effect a Deemed Liquidation Event referred to in Subsection 2.4.1(a)(i) unless the agreement or plan of merger or consolidation for such transaction (the “**Merger Agreement**”) provides that the consideration payable to the stockholders of the Corporation shall be allocated among the holders of capital stock of the Corporation in accordance with Subsections 2.1, 2.2 and 2.3.

(b) In the event of a Deemed Liquidation Event referred to in Subsection 2.4.1(a)(ii) or 2.4.1(b), if the Corporation does not effect a dissolution of the Corporation under the General Corporation Law within ninety (90) days after such Deemed Liquidation Event, then (i) the Corporation shall send a written notice to each holder of Preferred Stock no later than the ninetieth (90<sup>th</sup>) day after the Deemed Liquidation Event advising such holders of their right (and the requirements to be met to secure such right) pursuant to the terms of the following clause; (ii) to require the redemption of such shares of Preferred Stock, and (iii) if the Requisite Holders so request in a written instrument delivered to the Corporation not later than one hundred twenty (120) days after such Deemed Liquidation Event, the Corporation shall use the consideration received by the Corporation for such Deemed Liquidation Event (net of any retained liabilities associated with the assets sold or technology licensed, as determined in good faith by the Board of Directors of the Corporation), together with any other assets of the Corporation available for distribution to its stockholders, all to the extent permitted by Delaware law governing distributions to stockholders (the “**Available Proceeds**”), on the one hundred fiftieth (150<sup>th</sup>) day after such Deemed Liquidation Event, to redeem all outstanding shares of Preferred Stock at a price per share equal to the Series A Liquidation Amount, in the case of Series A Preferred Stock, or the Series B Liquidation Amount, in the case of Series B Preferred Stock to the fullest extent of such Available Proceeds, in accordance with the payment priorities set forth in Subsections 2.1 and 2.2. Notwithstanding the foregoing, in the event of a redemption pursuant to the preceding sentence, if the Available Proceeds are not sufficient to redeem all outstanding shares of Preferred Stock, the Corporation shall ratably redeem each holder’s shares of Preferred Stock to the fullest extent of such Available Proceeds, and shall redeem the remaining shares as soon as it may lawfully do so under Delaware law governing distributions to stockholders; *provided however* that no shares of Series A Preferred Stock may be redeemed until all shares of Series B Preferred Stock have been redeemed (or the payment therefore has been set aside).

(c) The following provisions shall apply to the redemption of the Preferred Stock pursuant to this Subsection 2.4.2:

(i) Redemption Notice. The Corporation shall send written notice of redemption (the “**Redemption Notice**”) to each holder of record of Preferred Stock not less than forty (40) days prior to the Redemption Date. Each Redemption Notice shall state: (1) the number of shares of each series of Preferred Stock held by the holder

that the Corporation shall redeem on the Redemption Date specified in the Redemption Notice; (2) the Redemption Date and the redemption price for each series of Preferred Stock; (3) the date upon which the holder's right to convert such shares terminates (as determined in accordance with Subsection 4.1); and (4) for holders of shares in certificated form, that the holder is to surrender to the Corporation, in the manner and at the place designated, his, her or its certificate or certificates representing the shares of Preferred Stock to be redeemed.

(ii) Surrender of Certificates; Payment. On or before the Redemption Date, each holder of shares of Preferred Stock to be redeemed on the Redemption Date, unless such holder has exercised his, her or its right to convert such shares as provided in Section 4, shall, if a holder of shares in certificated form, surrender the certificate or certificates representing such shares (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation, in the manner and at the place designated in the Redemption Notice, and thereupon the redemption price for such shares shall be payable to the order of the person whose name appears on such certificate or certificates as the owner thereof. In the event less than all of the shares of Preferred Stock represented by a certificate are redeemed, a new certificate, instrument, or book entry representing the unredeemed shares of Preferred Stock shall promptly be issued to such holder.

(iii) Rights Subsequent to Redemption. If the Redemption Notice shall have been duly given, and if on the Redemption Date the redemption price of a series of Preferred Stock payable upon redemption of the shares of such series of Preferred Stock to be redeemed on the Redemption Date is paid or tendered for payment or deposited with an independent payment agent so as to be available therefor in a timely manner, then notwithstanding that any certificates evidencing any of the shares of Preferred Stock so called for redemption shall not have been surrendered, dividends with respect to such shares of Preferred Stock shall cease to accrue after the Redemption Date and all rights with respect to such shares shall forthwith after the Redemption Date terminate, except only the right of the holders to receive the redemption price of such series of Preferred Stock without interest upon surrender of any such certificate or certificates therefor.

(d) Prior to the distribution or redemption provided for in Subsection 2.4.2(b), the Corporation shall not expend or dissipate the consideration received for such Deemed Liquidation Event, except to discharge expenses incurred in connection with such Deemed Liquidation Event.

2.4.3 Amount Deemed Paid or Distributed. The amount deemed paid or distributed to the holders of capital stock of the Corporation upon any such merger, consolidation, sale, transfer, exclusive license, other disposition or redemption shall be the cash or the value of the property, rights or securities paid or distributed to such holders by the Corporation or the acquiring person, firm or other entity. The value of such property, rights or securities shall be determined in good faith by the Board of Directors of the Corporation.

2.4.4 Allocation of Escrow and Contingent Consideration. In the event of a Deemed Liquidation Event, if any portion of the consideration payable to the stockholders of the Corporation or the Corporation is payable only upon satisfaction of contingencies (the “**Additional Consideration**”), the Merger Agreement (or, as applicable, the Redemption Notice) shall provide that (a) the portion of such consideration that is not Additional Consideration (such portion, the “**Initial Consideration**”) shall be allocated among the holders of capital stock of the Corporation (or, as applicable, the redemption price shall be calculated) in accordance with Subsections 2.1, 2.2 and 2.3 as if the Initial Consideration were the only consideration payable in connection with such Deemed Liquidation Event; and (b) any Additional Consideration which becomes payable to the stockholders of the Corporation or the Corporation upon satisfaction of such contingencies shall be allocated among the holders of capital stock of the Corporation (or, as applicable, the redemption price shall be recalculated) in accordance with Subsections 2.1, 2.2 and 2.3 after taking into account the previous payment of the Initial Consideration as part of the same transaction. For the purposes of this Subsection 2.4.4, consideration placed into escrow or retained as holdback to be available for satisfaction of indemnification or similar obligations in connection with such Deemed Liquidation Event shall be deemed to be Additional Consideration.

### 3. Voting.

3.1 General. On any matter presented to the stockholders of the Corporation for their action or consideration at any meeting of stockholders of the Corporation (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Preferred Stock shall be entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Certificate of Incorporation, holders of Preferred Stock shall vote together with the holders of Common Stock as a single class.

3.2 Election of Directors. The holders of record of the shares of Series A Preferred Stock, exclusively and as a separate class, shall be entitled to elect two directors of the Corporation (the “**Series A Directors**”) and the holders of record of the shares of Series B Preferred Stock, exclusively and as a separate class, shall be entitled to elect one director of the Corporation (the “**Series B Director**”). Any director elected as provided in the preceding sentence may be removed without cause by, and only by, the affirmative vote of the holders of the shares of the class or series of capital stock entitled to elect such director or directors, given either at a special meeting of such stockholders duly called for that purpose or pursuant to a written consent of stockholders. If the holders of shares of Series A Preferred Stock or Series B Preferred Stock, as the case may be, fail to elect a sufficient number of directors to fill all directorships for which they are entitled to elect directors, voting exclusively and as a separate class, pursuant to the first sentence of this Subsection 3.2, then any directorship not so filled shall remain vacant until such time as the holders of the Series A Preferred Stock or Series B Preferred Stock, as the case may be, elect a person to fill such directorship by vote or written consent in lieu of a meeting; and no such directorship may be filled by stockholders of the Corporation other than by the stockholders of the Corporation that are entitled to elect a person to fill such directorship, voting exclusively and as a separate class. The holders of record of the shares of Common Stock and of any other class or series of voting stock (including the Preferred Stock), exclusively and voting together as a single class on an as converted basis, shall be entitled to elect the balance of the total number of directors of the Corporation. At any meeting held for the purpose of electing a director, the presence in person or by proxy of the holders of a majority of

the outstanding shares of the class or series entitled to elect such director shall constitute a quorum for the purpose of electing such director. Except as otherwise provided in this Subsection 3.2, a vacancy in any directorship filled by the holders of any class or series shall be filled only by vote or written consent in lieu of a meeting of the holders of such class or series or by any remaining director or directors elected by the holders of such class or series pursuant to this Subsection 3.2.

**3.3 Preferred Stock Protective Provisions.** At any time when shares of Preferred Stock are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following without (in addition to any other vote required by law or the Certificate of Incorporation) the written consent or affirmative vote of the Requisite Holders, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void *ab initio*, and of no force or effect.

3.3.1 liquidate, dissolve or wind-up the business and affairs of the Corporation, effect any merger or consolidation or any other Deemed Liquidation Event, or consent to any of the foregoing;

3.3.2 amend, alter or repeal any provision of the Certificate of Incorporation or Bylaws of the Corporation;

3.3.3 create (by reclassification or otherwise), or authorize the creation of, or issue or obligate itself to issue shares of, any additional class or series of capital stock unless the same ranks junior to the Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption, or increase the authorized number of shares of Preferred Stock or increase the authorized number of shares of any additional class or series of capital stock unless the same ranks junior to the Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption;

3.3.4 purchase or redeem (or permit any subsidiary to purchase or redeem) or pay or declare any dividend or make any distribution on, any shares of capital stock of the Corporation other than (i) redemptions of or dividends or distributions on the Preferred Stock or Common Stock as expressly authorized herein, (ii) dividends or other distributions payable on the Common Stock solely in the form of additional shares of Common Stock and (iii) repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for the Corporation or any subsidiary in connection with the cessation of such employment or service at the lower of the original purchase price or the then-current fair market value thereof;

3.3.5 create, or authorize the creation of, or issue, or authorize the issuance of any debt security, or permit any subsidiary to take any such action with respect to any debt security;

3.3.6 create, or hold capital stock in, any subsidiary that is not wholly owned (either directly or through one or more other subsidiaries) by the Corporation, or sell, transfer or otherwise dispose of any capital stock of any direct or indirect subsidiary of the Corporation, or permit any direct or indirect subsidiary to sell, lease, transfer, exclusively license or otherwise dispose (in a single transaction or series of related transactions) of all or substantially all of the assets of such subsidiary;

3.3.7 sell, assign, license, pledge or encumber any material technology or intellectual property of the Corporation, other than licenses granted in the ordinary course of business;

3.3.8 enter into any corporate strategic relationship involving the payment, contribution or assignment by the Corporation or to the Corporation of assets; or

3.3.9 increase or decrease the authorized number of directors constituting the Board of Directors.

#### 4. Optional Conversion.

The holders of the Preferred Stock shall have conversion rights as follows (the “**Conversion Rights**”):

##### 4.1 Right to Convert.

###### 4.1.1 Conversion Ratio.

(a) Each share of Series A Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of Common Stock as is determined by dividing the Series A Original Issue Price by the Series A Conversion Price (as defined below) in effect at the time of conversion. The “**Series A Conversion Price**” is currently equal to \$1.932. Such Series A Conversion Price, and the rate at which shares of Series A Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided below.

(b) Each share of Series B Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of Common Stock as is determined by dividing the Series B Original Issue Price by the Series B Conversion Price (as defined below) in effect at the time of conversion. The “**Series B Conversion Price**” shall initially be equal to \$8.346. Such initial Series B Conversion Price, and the rate at which shares of Series B Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided below. “**Conversion Price**” shall mean the Series A Conversion Price or the Series B Conversion Price, as applicable.

4.1.2 Termination of Conversion Rights. In the event of a liquidation, dissolution or winding up of the Corporation or a Deemed Liquidation Event, the Conversion Rights shall terminate at the close of business on the last full day preceding the date fixed for the payment of any such amounts distributable on such event to the holders of Preferred Stock.



4.2 Fractional Shares. No fractional shares of Common Stock shall be issued upon conversion of the Preferred Stock. In lieu of any fractional shares to which the holder would otherwise be entitled, the Corporation shall pay cash equal to such fraction multiplied by the fair market value of a share of Common Stock as determined in good faith by the Board of Directors of the Corporation. Whether or not fractional shares would be issuable upon such conversion shall be determined on the basis of the total number of shares of Preferred Stock the holder is at the time converting into Common Stock and the aggregate number of shares of Common Stock issuable upon such conversion.

#### 4.3 Mechanics of Conversion.

4.3.1 Notice of Conversion. In order for a holder of Preferred Stock to voluntarily convert shares of Preferred Stock into shares of Common Stock, such holder shall (a) provide written notice to the Corporation's transfer agent at the office of the transfer agent for the Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent) that such holder elects to convert all or any number of such holder's shares of any series of Preferred Stock and, if applicable, any event on which such conversion is contingent and (b), if such holder's shares are certificated, surrender the certificate or certificates for such shares of Preferred Stock (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate), at the office of the transfer agent for the Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent). Such notice shall state such holder's name or the names of the nominees in which such holder wishes the shares of Common Stock to be issued. If required by the Corporation, any certificates surrendered for conversion shall be endorsed or accompanied by a written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or his, her or its attorney duly authorized in writing. The close of business on the date of receipt by the transfer agent (or by the Corporation if the Corporation serves as its own transfer agent) of such notice and, if applicable, certificates (or lost certificate affidavit and agreement) shall be the time of conversion (the "**Conversion Time**"), and the shares of Common Stock issuable upon conversion of the specified shares shall be deemed to be outstanding of record as of such date. The Corporation shall, as soon as practicable after the Conversion Time (i) issue and deliver to such holder of Preferred Stock, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable upon such conversion in accordance with the provisions hereof and a certificate for the number (if any) of the shares of the series of Preferred Stock represented by the surrendered certificate that were not converted into Common Stock, (ii) pay in cash such amount as provided in Subsection 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion and (iii) pay all declared but unpaid dividends on the shares of Preferred Stock converted.

4.3.2 Reservation of Shares. The Corporation shall at all times when any Preferred Stock shall be outstanding, reserve and keep available out of its authorized but unissued capital stock, for the purpose of effecting the conversion of the Preferred Stock, such number of its duly authorized shares of Common Stock as shall from time to time be sufficient to effect the conversion of all outstanding Preferred Stock; and if at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the

conversion of all then outstanding shares of the Preferred Stock, the Corporation shall take such corporate action as may be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purposes, including, without limitation, engaging in best efforts to obtain the requisite stockholder approval of any necessary amendment to the Certificate of Incorporation. Before taking any action which would cause an adjustment reducing the Conversion Price of a series of Preferred Stock below the then par value of the shares of Common Stock issuable upon conversion of such series of Preferred Stock, the Corporation will take any corporate action which may, in the opinion of its counsel, be necessary in order that the Corporation may validly and legally issue fully paid and non-assessable shares of Common Stock at such adjusted Conversion Price.

4.3.3 Effect of Conversion. All shares of Preferred Stock which shall have been surrendered for conversion as herein provided shall no longer be deemed to be outstanding and all rights with respect to such shares shall immediately cease and terminate at the Conversion Time, except only the right of the holders thereof to receive shares of Common Stock in exchange therefor, to receive payment in lieu of any fraction of a share otherwise issuable upon such conversion as provided in Subsection 4.2 and to receive payment of any dividends declared but unpaid thereon. Any shares of Preferred Stock so converted shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Preferred Stock and the associated series of Preferred Stock accordingly.

4.3.4 No Further Adjustment. Upon any such conversion, no adjustment to the Conversion Price of a series of Preferred Stock shall be made for any declared but unpaid dividends on such series of Preferred Stock surrendered for conversion or on the Common Stock delivered upon conversion.

4.3.5 Taxes. The Corporation shall pay any and all issue and other similar taxes that may be payable in respect of any issuance or delivery of shares of Common Stock upon conversion of shares of Preferred Stock pursuant to this Section 4. The Corporation shall not, however, be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of shares of Common Stock in a name other than that in which the shares of Preferred Stock so converted were registered, and no such issuance or delivery shall be made unless and until the person or entity requesting such issuance has paid to the Corporation the amount of any such tax or has established, to the satisfaction of the Corporation, that such tax has been paid.

#### 4.4 Adjustments to Conversion Price for Diluting Issues.

4.4.1 Special Definitions. For purposes of this Article Fourth, the following definitions shall apply:

- (a) “**Option**” shall mean rights, options or warrants to subscribe for, purchase or otherwise acquire Common Stock or Convertible Securities.
- (b) “**Series B Original Issue Date**” shall mean the date on which the first share of Series B Preferred Stock was issued.

(c) “**Convertible Securities**” shall mean any evidences of indebtedness, shares or other securities directly or indirectly convertible into or exchangeable for Common Stock, but excluding Options.

(d) “**Additional Shares of Common Stock**” shall mean all shares of Common Stock issued (or, pursuant to Subsection 4.4.3 below, deemed to be issued) by the Corporation after the Series B Original Issue Date, other than (1) the following shares of Common Stock and (2) shares of Common Stock deemed issued pursuant to the following Options and Convertible Securities (clauses (1) and (2), collectively, “**Exempted Securities**”):

- (i) shares of Common Stock, Options or Convertible Securities issued as a dividend or distribution on Preferred Stock;
- (ii) shares of Common Stock, Options or Convertible Securities issued by reason of a dividend, stock split, split-up or other distribution on shares of Common Stock that is covered by Subsection 4.5, 4.6, 4.7 or 4.8;
- (iii) shares of Common Stock or Options issued to employees or directors of, or consultants or advisors to, the Corporation or any of its subsidiaries pursuant to a plan, agreement or arrangement approved by the Board of Directors of the Corporation; or
- (iv) shares of Common Stock or Convertible Securities actually issued upon the exercise of Options or shares of Common Stock actually issued upon the conversion or exchange of Convertible Securities, in each case provided such issuance is pursuant to the terms of such Option or Convertible Security.

4.4.2 No Adjustment of Conversion Price. No adjustment in the Series A Conversion Price shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the holders of a majority of the then outstanding shares of Series A Preferred Stock agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock. No adjustment in the Series B Conversion Price shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the holders of a majority of the then outstanding shares of Series B Preferred Stock agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock.

#### 4.4.3 Deemed Issue of Additional Shares of Common Stock.

(a) If the Corporation at any time or from time to time after the Series B Original Issue Date shall issue any Options or Convertible Securities (excluding Options or Convertible Securities which are themselves Exempted Securities) or shall fix a record date for the determination of holders of any class of securities entitled to receive any such Options or Convertible Securities, then the maximum number of shares of Common Stock (as set forth in the instrument relating thereto, assuming the satisfaction of any conditions to exercisability, convertibility or exchangeability but without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or, in the case of Convertible Securities and Options therefor, the conversion or exchange of such Convertible Securities, shall be deemed to be Additional Shares of Common Stock issued as of the time of such issue or, in case such a record date shall have been fixed, as of the close of business on such record date.

(b) If the terms of any Option or Convertible Security, the issuance of which resulted in an adjustment to the Conversion Price of a series of Preferred Stock pursuant to the terms of Subsection 4.4.4, are revised as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase or decrease in the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any such Option or Convertible Security or (2) any increase or decrease in the consideration payable to the Corporation upon such exercise, conversion and/or exchange, then, effective upon such increase or decrease becoming effective, the applicable Conversion Price computed upon the original issue of such Option or Convertible Security (or upon the occurrence of a record date with respect thereto) shall be readjusted to such Conversion Price for such series of Preferred Stock as would have been obtained had such revised terms been in effect upon the original date of issuance of such Option or Convertible Security. Notwithstanding the foregoing, no readjustment pursuant to this clause (b) shall have the effect of increasing the Conversion Price of a series of Preferred Stock to an amount which exceeds the lower of (i) the Conversion Price of such series of Preferred Stock in effect immediately prior to the original adjustment made as a result of the issuance of such Option or Convertible Security, or (ii) the Conversion Price of such series of Preferred Stock that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date.

(c) If the terms of any Option or Convertible Security (excluding Options or Convertible Securities which are themselves Exempted Securities), the issuance of which did not result in an adjustment to the Conversion Price of a series of Preferred Stock pursuant to the terms of Subsection 4.4.4 (either because the consideration per share (determined pursuant to Subsection 4.4.5) of the Additional Shares of Common Stock subject thereto was equal to or greater than the Conversion Price of such series of Preferred Stock then in effect, or because such Option or Convertible Security was issued before the Series B Original Issue Date), are revised after the Series B Original Issue Date as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar

provisions of such Option or Convertible Security) to provide for either (1) any increase in the number of shares of Common Stock issuable upon the exercise, conversion or exchange of any such Option or Convertible Security or (2) any decrease in the consideration payable to the Corporation upon such exercise, conversion or exchange, then such Option or Convertible Security, as so amended or adjusted, and the Additional Shares of Common Stock subject thereto (determined in the manner provided in Subsection 4.4.3(a)) shall be deemed to have been issued effective upon such increase or decrease becoming effective.

(d) Upon the expiration or termination of any unexercised Option or unconverted or unexchanged Convertible Security (or portion thereof) which resulted (either upon its original issuance or upon a revision of its terms) in an adjustment to the Conversion Price of a series of Preferred Stock pursuant to the terms of Subsection 4.4.4, the Conversion Price of such series of Preferred Stock shall be readjusted to such Conversion Price as would have been obtained had such Option or Convertible Security (or portion thereof) never been issued.

(e) If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, is calculable at the time such Option or Convertible Security is issued or amended but is subject to adjustment based upon subsequent events, any adjustment to the Conversion Price of a series of Preferred Stock provided for in this Subsection 4.4.3 shall be effected at the time of such issuance or amendment based on such number of shares or amount of consideration without regard to any provisions for subsequent adjustments (and any subsequent adjustments shall be treated as provided in clauses (b) and (c) of this Subsection 4.4.3). If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, cannot be calculated at all at the time such Option or Convertible Security is issued or amended, any adjustment to the Conversion Price of a series of Preferred Stock that would result under the terms of this Subsection 4.4.3 at the time of such issuance or amendment shall instead be effected at the time such number of shares and/or amount of consideration is first calculable (even if subject to subsequent adjustments), assuming for purposes of calculating such adjustment to the Conversion Price of such series of Preferred Stock that such issuance or amendment took place at the time such calculation can first be made.

4.4.4 Adjustment of Conversion Price Upon Issuance of Additional Shares of Common Stock. In the event the Corporation shall at any time after the Series B Original Issue Date issue Additional Shares of Common Stock (including Additional Shares of Common Stock deemed to be issued pursuant to Subsection 4.4.3), without consideration or for a consideration per share less than the Conversion Price of a series of Preferred Stock in effect immediately prior to such issue, then the Conversion Price of such series of Preferred Stock shall be reduced, concurrently with such issue, to a price (calculated to the nearest one-hundredth of a cent) determined in accordance with the following formula:

$$CP_2 = CP_1 * (A + B) \div (A + C).$$

For purposes of the foregoing formula, the following definitions shall apply:

(a) “CP<sub>2</sub>” shall mean the Conversion Price of such series of Preferred Stock in effect immediately after such issue of Additional Shares of Common Stock

(b) “CP<sub>1</sub>” shall mean the Conversion Price of such series of Preferred Stock in effect immediately prior to such issue of Additional Shares of Common Stock;

(c) “A” shall mean, (i) with respect to adjustments to the Series A Conversion Price, the number of shares of Common Stock outstanding immediately prior to such issue of Additional Shares of Common Stock (treating for this purpose as outstanding all shares of Common Stock issuable upon exercise of Options outstanding immediately prior to such issue or upon conversion or exchange of Convertible Securities (including the Preferred Stock) outstanding (assuming exercise of any outstanding Options therefor) immediately prior to such issue), and (ii) with respect to adjustments to the Series B Conversion Price, the number of shares of Common Stock outstanding immediately prior to such issue of Additional Shares of Common Stock (treating for this purpose as outstanding all shares of Common Stock issuable upon conversion of the Preferred Stock outstanding immediately prior to such issue);

(d) “B” shall mean the number of shares of Common Stock that would have been issued if such Additional Shares of Common Stock had been issued at a price per share equal to CP<sub>1</sub> (determined by dividing the aggregate consideration received by the Corporation in respect of such issue by CP<sub>1</sub>); and

(e) “C” shall mean the number of such Additional Shares of Common Stock issued in such transaction.

4.4.5 Determination of Consideration. For purposes of this Subsection 4.4, the consideration received by the Corporation for the issue of any Additional Shares of Common Stock shall be computed as follows:

(a) Cash and Property: Such consideration shall:

- (i) insofar as it consists of cash, be computed at the aggregate amount of cash received by the Corporation, excluding amounts paid or payable for accrued interest;
- (ii) insofar as it consists of property other than cash, be computed at the fair market value thereof at the time of such issue, as determined in good faith by the Board of Directors of the Corporation; and
- (iii) in the event Additional Shares of Common Stock are issued together with other shares or securities or other assets of the Corporation for consideration which covers

both, be the proportion of such consideration so received, computed as provided in clauses (i) and (ii) above, as determined in good faith by the Board of Directors of the Corporation.

(b) Options and Convertible Securities. The consideration per share received by the Corporation for Additional Shares of Common Stock deemed to have been issued pursuant to Subsection 4.4.3, relating to Options and Convertible Securities, shall be determined by dividing:

- (i) The total amount, if any, received or receivable by the Corporation as consideration for the issue of such Options or Convertible Securities, plus the minimum aggregate amount of additional consideration (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such consideration) payable to the Corporation upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities, by
- (ii) the maximum number of shares of Common Stock (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities.

4.4.6 Multiple Closing Dates. In the event the Corporation shall issue on more than one date Additional Shares of Common Stock that are a part of one transaction or a series of related transactions and that would result in an adjustment to the Conversion Price of a series of Preferred Stock pursuant to the terms of Subsection 4.4.4, and such issuance dates occur within a period of no more than ninety (90) days from the first such issuance to the final such issuance, then, upon the final such issuance, the Conversion Price of such series of Preferred Stock shall be readjusted to give effect to all such issuances as if they occurred on the date of the first such issuance (and without giving effect to any additional adjustments as a result of any such subsequent issuances within such period).

4.5 Adjustment for Stock Splits and Combinations. If the Corporation shall at any time or from time to time after the Series B Original Issue Date effect a subdivision of the outstanding Common Stock, the Conversion Price of each series of Preferred Stock in effect immediately before that subdivision shall be proportionately decreased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be increased in proportion to such increase in the aggregate number of shares of Common Stock outstanding. If the Corporation shall at any time or from time to time after the Series B Original Issue Date combine the outstanding shares of Common Stock, the Conversion Price of each series of Preferred Stock in effect immediately before the combination shall be proportionately increased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be decreased in proportion to such decrease in the aggregate number of shares of Common Stock outstanding. Any adjustment under this subsection shall become effective at the close of business on the date the subdivision or combination becomes effective.

4.6 Adjustment for Certain Dividends and Distributions. In the event the Corporation at any time or from time to time after the Series B Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable on the Common Stock in additional shares of Common Stock, then and in each such event the Conversion Price of each series of Preferred Stock in effect immediately before such event shall be decreased as of the time of such issuance or, in the event such a record date shall have been fixed, as of the close of business on such record date, by multiplying the Conversion Price of the applicable series of Preferred Stock then in effect by a fraction:

(1) the numerator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date, and

(2) the denominator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date plus the number of shares of Common Stock issuable in payment of such dividend or distribution.

Notwithstanding the foregoing (a) if such record date shall have been fixed and such dividend is not fully paid or if such distribution is not fully made on the date fixed therefor, the Conversion Price of each series of Preferred Stock shall be recomputed accordingly as of the close of business on such record date and thereafter the Conversion Price of each series of Preferred Stock shall be adjusted pursuant to this subsection as of the time of actual payment of such dividends or distributions; and (b) that no such adjustment shall be made to a series of Preferred Stock if the holders of such series of Preferred Stock simultaneously receive a dividend or other distribution of shares of Common Stock in a number equal to the number of shares of Common Stock as they would have received if all outstanding shares of such series of Preferred Stock had been converted into Common Stock on the date of such event.



4.7 Adjustments for Other Dividends and Distributions. In the event the Corporation at any time or from time to time after the Series B Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable in securities of the Corporation (other than a distribution of shares of Common Stock in respect of outstanding shares of Common Stock) or in other property and the provisions of Section 1 do not apply to such dividend or distribution, then and in each such event the holders of Preferred Stock shall receive, simultaneously with the distribution to the holders of Common Stock, a dividend or other distribution of such securities or other property in an amount equal to the amount of such securities or other property as they would have received if all outstanding shares of Preferred Stock had been converted into Common Stock on the date of such event.

4.8 Adjustment for Merger or Reorganization, etc. Subject to the provisions of Subsection 2.3, if there shall occur any reorganization, recapitalization, reclassification, consolidation or merger involving the Corporation in which the Common Stock (but not a given series of Preferred Stock) is converted into or exchanged for securities, cash or other property (other than a transaction covered by Subsections 4.4, 4.6 or 4.7), then, following any such reorganization, recapitalization, reclassification, consolidation or merger, each share of such applicable series of Preferred Stock shall thereafter be convertible in lieu of the Common Stock into which it was convertible prior to such event into the kind and amount of securities, cash or other property which a holder of the number of shares of Common Stock of the Corporation issuable upon conversion of one share of such series of Preferred Stock immediately prior to such reorganization, recapitalization, reclassification, consolidation or merger would have been entitled to receive pursuant to such transaction; and, in such case, appropriate adjustment (as determined in good faith by the Board of Directors of the Corporation) shall be made in the application of the provisions in this Section 4 with respect to the rights and interests thereafter of the holders of such series of Preferred Stock, to the end that the provisions set forth in this Section 4 (including provisions with respect to changes in and other adjustments of the Conversion Price of each series of Preferred Stock) shall thereafter be applicable, as nearly as reasonably may be, in relation to any securities or other property thereafter deliverable upon the conversion of the Preferred Stock. For the avoidance of doubt, nothing in this Subsection 4.8 shall be construed as preventing the holders of Preferred Stock from seeking any appraisal rights to which they are otherwise entitled under the DGCL in connection with a merger triggering an adjustment hereunder, nor shall this Subsection 4.8 be deemed conclusive evidence of the fair value of the shares of Preferred Stock in any such appraisal proceeding.

4.9 Certificate as to Adjustments. Upon the occurrence of each adjustment or readjustment of the Conversion Price of a series of Preferred Stock pursuant to this Section 4, the Corporation at its expense shall, as promptly as reasonably practicable but in any event not later than ten (10) days thereafter, compute such adjustment or readjustment in accordance with the terms hereof and furnish to each holder of Preferred Stock that has been subject to an adjustment or readjustment a certificate setting forth such adjustment or readjustment (including the kind and amount of securities, cash or other property into which such series of Preferred Stock is convertible) and showing in detail the facts upon which such adjustment or readjustment is based. The Corporation shall, as promptly as reasonably practicable after the written request at any time of any holder of Preferred Stock (but in any event not later than ten (10) days thereafter), furnish or cause to be furnished to such holder a certificate setting forth (i) the Conversion Price of each series of Preferred Stock then in effect, and (ii) the number of shares of Common Stock and the amount, if any, of other securities, cash or property which then would be received upon the conversion of each series of Preferred Stock.

4.10 Notice of Record Date. In the event:

- (a) the Corporation shall take a record of the holders of its Common Stock (or other capital stock or securities at the time issuable upon conversion of the Preferred Stock) for the purpose of entitling or enabling them to receive any dividend or other distribution, or to receive any right to subscribe for or purchase any shares of capital stock of any class or any other securities, or to receive any other security; or
- (b) of any capital reorganization of the Corporation, any reclassification of the Common Stock of the Corporation, or any Deemed Liquidation Event; or
- (c) of the voluntary or involuntary dissolution, liquidation or winding-up of the Corporation,

then, and in each such case, the Corporation will send or cause to be sent to the holders of the Preferred Stock a notice specifying, as the case may be, (i) the record date for such dividend, distribution or right, and the amount and character of such dividend, distribution or right, or (ii) the effective date on which such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up is proposed to take place, and the time, if any is to be fixed, as of which the holders of record of Common Stock (or such other capital stock or securities at the time issuable upon the conversion of any Preferred Stock) shall be entitled to exchange their shares of Common Stock (or such other capital stock or securities) for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up, and the amount per share and character of such exchange applicable to the Preferred Stock and the Common Stock. Such notice shall be sent at least ten (10) days prior to the record date or effective date for the event specified in such notice.

5. Mandatory Conversion.

5.1 Trigger Events. Upon either (a) the closing of the sale of shares of Common Stock to the public at a price of at least \$8.346 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement resulting in at least \$50 million of gross proceeds to the Corporation or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the Requisite Holders (the time of such closing or the date and time specified or the time of the event specified in such vote or written consent is referred to herein as the “**Mandatory Conversion Time**”), then (i) all outstanding shares of Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rate as calculated pursuant to Subsection 4.1.1, and (ii) such shares may not be reissued by the Corporation.

5.2 Procedural Requirements. All holders of record of shares of Preferred Stock shall be sent written notice of the Mandatory Conversion Time and the place designated for mandatory conversion of all shares of Preferred Stock being converted pursuant to this Section 5. Such notice need not be sent in advance of the occurrence of the Mandatory Conversion Time. Upon receipt of such notice, each holder of shares of Preferred Stock in certificated form shall surrender his, her or its certificate or certificates for all such shares being

converted (or, if such holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation at the place designated in such notice. If so required by the Corporation, any certificates surrendered for conversion shall be endorsed or accompanied by written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or by his, her or its attorney duly authorized in writing. All rights with respect to the Preferred Stock converted pursuant to Subsection 5.1, including the rights, if any, to receive notices and vote (other than as a holder of Common Stock), will terminate at the Mandatory Conversion Time (notwithstanding the failure of the holder or holders thereof to surrender any certificates at or prior to such time), except only the rights of the holders thereof, upon surrender of any certificate or certificates of such holders (or lost certificate affidavit and agreement) therefor, to receive the items provided for in the next sentence of this Subsection 5.2. As soon as practicable after the Mandatory Conversion Time and, if applicable, the surrender of any certificate or certificates (or lost certificate affidavit and agreement) for Preferred Stock being converted, the Corporation shall (a) issue and deliver to such holder, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable on such conversion in accordance with the provisions hereof and (b) pay cash as provided in Subsection 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion and the payment of any declared but unpaid dividends on the shares of Preferred Stock converted. Such converted Preferred Stock shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Preferred Stock accordingly.

6. Redeemed or Otherwise Acquired Shares. Any shares of Preferred Stock that are redeemed or otherwise acquired by the Corporation or any of its subsidiaries shall be automatically and immediately cancelled and retired and shall not be reissued, sold or transferred. Neither the Corporation nor any of its subsidiaries may exercise any voting or other rights granted to the holders of Preferred Stock following redemption.

7. Waiver. Any of the rights, powers, preferences and other terms of the Series A Preferred Stock set forth herein may be waived on behalf of all holders of Series A Preferred Stock by the affirmative written consent or vote of the holders of a majority of the shares of Series A Preferred Stock then outstanding. Any of the rights, powers, preferences and other terms of the Series B Preferred Stock set forth herein may be waived on behalf of all holders of Series B Preferred Stock by the affirmative written consent or vote of the holders of a majority of the shares of Series B Preferred Stock then outstanding. Any of the rights, powers, preferences and other terms of the Preferred Stock set forth herein may be waived on behalf of all holders of Preferred Stock by the affirmative written consent or vote of the Requisite Holders.

8. Notices. Any notice required or permitted by the provisions of this Article Fourth to be given to a holder of shares of Preferred Stock shall be mailed, postage prepaid, to the post office address last shown on the records of the Corporation, or given by electronic communication in compliance with the provisions of the General Corporation Law, and shall be deemed sent upon such mailing or electronic transmission.

**FIFTH:** Subject to any additional vote required by the Certificate of Incorporation or Bylaws, in furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to make, repeal, alter, amend and rescind any or all of the Bylaws of the Corporation.

**SIXTH:** Subject to any additional vote required by the Certificate of Incorporation, the number of directors of the Corporation shall be determined in the manner set forth in the Bylaws of the Corporation.

**SEVENTH:** Elections of directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

**EIGHTH:** Meetings of stockholders may be held within or without the State of Delaware, as the Bylaws of the Corporation may provide. The books of the Corporation may be kept outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws of the Corporation.

**NINTH:** To the fullest extent permitted by law, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the General Corporation Law or any other law of the State of Delaware is amended after approval by the stockholders of this Article Ninth to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law as so amended.

Any repeal or modification of the foregoing provisions of this Article Ninth by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director occurring prior to, such repeal or modification.

**TENTH:** To the fullest extent permitted by applicable law, the Corporation is authorized to provide indemnification of (and advancement of expenses to) directors, officers and agents of the Corporation (and any other persons to which General Corporation Law permits the Corporation to provide indemnification) through Bylaw provisions, agreements with such agents or other persons, vote of stockholders or disinterested directors or otherwise, in excess of the indemnification and advancement otherwise permitted by Section 145 of the General Corporation Law.

Any amendment, repeal or modification of the foregoing provisions of this Article Tenth shall not adversely affect any right or protection of any director, officer or other agent of the Corporation existing at the time of such amendment, repeal or modification.

**ELEVENTH:** The Corporation renounces, to the fullest extent permitted by law, any interest or expectancy of the Corporation in, or in being offered an opportunity to participate in, any Excluded Opportunity. An “**Excluded Opportunity**” is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of (i) any director of the Corporation who is not an employee of the Corporation or any of its subsidiaries, or (ii) any holder of Preferred Stock or any partner, member, director, stockholder, employee or agent of any such holder, other than someone who is an employee of the Corporation or any of its subsidiaries (collectively, “**Covered Persons**”), unless such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in such Covered Person’s capacity as a director of the Corporation.

**TWELFTH:** Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery in the State of Delaware shall be the sole and exclusive forum for any stockholder (including a beneficial owner) to bring (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim against the Corporation, its directors, officers or employees arising pursuant to any provision of the Delaware General Corporation Law or the Corporation's certificate of incorporation or bylaws or (iv) any action asserting a claim against the Corporation, its directors, officers or employees governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction. If any provision or provisions of this Article Twelfth shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law, the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Article Twelfth (including, without limitation, each portion of any sentence of this Article Twelfth containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) and the application of such provision to other persons or entities and circumstances shall not in any way be affected or impaired thereby.

\* \* \*

3. That the foregoing amendment and restatement was approved by the holders of the requisite number of shares of this corporation in accordance with Section 228 of the General Corporation Law.

4. That this Second Amended and Restated Certificate of Incorporation, which restates and integrates and further amends the provisions of this Corporation's Amended and Restated Certificate of Incorporation, has been duly adopted in accordance with Sections 242 and 245 of the General Corporation Law.

**IN WITNESS WHEREOF**, this Second Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of this corporation on this 29<sup>th</sup> day of November, 2017.

By: /s/ Chen Schor  
Chen Schor, President

**AMENDED AND RESTATED  
INVESTORS' RIGHTS AGREEMENT**

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Schedule A - Schedule of Investors



## AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT

THIS AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT (this "**Agreement**"), is made as of the 29<sup>th</sup> day of November, 2017, by and among resTORbio, Inc., a Delaware corporation (the "**Company**"), and each of the investors listed on Schedule A hereto, each of which is referred to in this Agreement as an "**Investor**" and any Additional Purchaser (as defined in the Purchase Agreement) that becomes a party to this Agreement in accordance with Section 6.9 hereof.

### RECITALS

**WHEREAS**, certain of the Investors (the "**Existing Investors**") hold shares of the Company's Series A Preferred Stock and/or shares of Common Stock issued upon conversion thereof and possess registration rights, information rights, rights of first offer, and other rights pursuant to an Investors' Rights Agreement dated as of March 23, 2017 between the Company and such Investors (the "**Prior Agreement**"); and

**WHEREAS**, the Existing Investors are holders of a majority of the Registrable Securities of the Company (as defined in the Prior Agreement), and desire to amend and restate the Prior Agreement in its entirety and to accept the rights created pursuant to this Agreement in lieu of the rights granted to the Investors under the Prior Agreement; and

**WHEREAS**, certain of the Investors are parties to that certain Series B Preferred Stock Purchase Agreement dated as of October 27, 2017 between the Company and certain of the Investors (the "**Purchase Agreement**"), under which certain of the Company's and such Investors' obligations are conditioned upon the execution and delivery of this Agreement by such Investors, Existing Investors holding a majority of the Registrable Securities, and the Company;

**WHEREAS**, in order to induce the Investors party thereto to invest funds in the Company pursuant to the Purchase Agreement, the Investors and the Company hereby agree that this Agreement shall govern the rights of the Investors to cause the Company to register shares of Common Stock issuable to the Investors, to receive certain information from the Company, and to participate in future equity offerings by the Company, and shall govern certain other matters as set forth in this Agreement;

**NOW, THEREFORE**, the Existing Investors hereby agree that the Prior Agreement shall be amended and restated and replaced in its entirety as set forth herein, and the parties to this Agreement further agree as follows:

1. Definitions. For purposes of this Agreement:

1.1 "**Affiliate**" means, with respect to any specified Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such Person, including without limitation any general partner, managing member, officer or director of such Person or any venture capital fund now or hereafter existing that is controlled by one or more general partners or managing members of, or shares the same management company with, such Person.

1.2 “**Common Stock**” means shares of the Company’s common stock, par value \$0.0001 per share.

1.3 “**Competitor**” means a Person engaged, directly or indirectly (including through any partnership, limited liability company, corporation, joint venture or similar arrangement (whether now existing or formed hereafter)), in the discovery and/or development of chemical entities with a primary mechanism of action modulating TORC1, S6K, 4EBP1 or Ulk1, but shall not include any financial investment firm or collective investment vehicle that, together with its Affiliates, holds less than twenty percent (20)% of the outstanding equity of any Competitor and does not, nor do any of its Affiliates, have a right to designate any members of the Board of Directors of any Competitor; provided, that, in no event shall PureTech, Novartis or OrbiMed be considered a Competitor.

1.4 “**Damages**” means any loss, damage, claim or liability (joint or several) to which a party hereto may become subject under the Securities Act, the Exchange Act, or other federal or state law, insofar as such loss, damage, claim or liability (or any action in respect thereof) arises out of or is based upon: (i) any untrue statement or alleged untrue statement of a material fact contained in any registration statement of the Company, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto; (ii) an omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading; or (iii) any violation or alleged violation by the indemnifying party (or any of its agents or Affiliates) of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act, or any state securities law.

1.5 “**Derivative Securities**” means any securities or rights convertible into, or exercisable or exchangeable for (in each case, directly or indirectly), Common Stock, including options and warrants.

1.6 “**Exchange Act**” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

1.7 “**Excluded Registration**” means (i) a registration relating to the sale of securities to employees of the Company or a subsidiary pursuant to a stock option, stock purchase, or similar plan; (ii) a registration relating to an SEC Rule 145 transaction; (iii) a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the Registrable Securities; or (iv) a registration in which the only Common Stock being registered is Common Stock issuable upon conversion of debt securities that are also being registered.

1.8 “**FOIA Party**” means a Person that, in the reasonable determination of the Board of Directors, may be subject to, and thereby required to disclose non-public information furnished by or relating to the Company under, the Freedom of Information Act, 5 U.S.C. 552 (“**FOIA**”), any state public records access law, any state or other jurisdiction’s laws similar in intent or effect to FOIA, or any other similar statutory or regulatory requirement.

1.9 “**Form S-1**” means such form under the Securities Act as in effect on the date hereof or any successor registration form under the Securities Act subsequently adopted by the SEC.

1.10 “**Form S-3**” means such form under the Securities Act as in effect on the date hereof or any registration form under the Securities Act subsequently adopted by the SEC that permits incorporation of substantial information by reference to other documents filed by the Company with the SEC.

1.11 “**GAAP**” means generally accepted accounting principles in the United States.

1.12 “**Holder**” means any holder of Registrable Securities who is a party to this Agreement.

1.13 “**Immediate Family Member**” means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including, adoptive relationships, of a natural person referred to herein.

1.14 “**Initiating Holders**” means, collectively, Holders who properly initiate a registration request under this Agreement.

1.15 “**IPO**” means the Company’s first underwritten public offering of its Common Stock under the Securities Act.

1.16 “**Key Employee**” means any executive-level employee (including, division director and vice president-level positions) as well as any employee who, either alone or in concert with others, develops, invents, programs, or designs any Company Intellectual Property (as defined in the Purchase Agreement).

1.17 “**Major Investor**” means any Investor that, individually or together with such Investor’s Affiliates, holds at least 1,000,000 shares of Registrable Securities (as adjusted for any stock split, stock dividend, combination, or other recapitalization or reclassification effected after the date hereof).

1.18 “**New Securities**” means, collectively, equity securities of the Company, whether or not currently authorized, as well as rights, options, or warrants to purchase such equity securities, or securities of any type whatsoever that are, or may become, convertible or exchangeable into or exercisable for such equity securities.

1.19 “**Novartis**” Novartis Institutes for BioMedical Research, Inc. and its Affiliates.

1.20 “**Person**” means any individual, corporation, partnership, trust, limited liability company, association or other entity.

1.21 “**Preferred Stock**” means, collectively, shares of the Company’s Series A Preferred Stock and Series B Preferred Stock.

1.22 “**Registrable Securities**” means (i) the Common Stock issuable or issued upon conversion of the Preferred Stock held from time to time by the Investors and their permitted assigns; (ii) any Common Stock, or any Common Stock issued or issuable (directly or indirectly) upon conversion and/or exercise of any other securities of the Company, acquired by the Investors after the date hereof; and (iii) any Common Stock issued as (or issuable upon the conversion or exercise of any warrant, right, or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the shares referenced in clauses (i) and (ii) above; excluding in all cases, however, any Registrable Securities sold by a Person in a transaction in which the applicable rights under this Agreement are not assigned pursuant to Subsection 6.1, and excluding for purposes of Section 2 any shares for which registration rights have terminated pursuant to Subsection 2.13 of this Agreement.

1.23 “**Registrable Securities then outstanding**” means the number of shares determined by adding the number of shares of outstanding Common Stock that are Registrable Securities and the number of shares of Common Stock issuable (directly or indirectly) pursuant to then exercisable and/or convertible securities that are Registrable Securities.

1.24 “**Restricted Securities**” means the securities of the Company required to be notated with the legend set forth in Subsection 2.12(b) hereof.

1.25 “**SEC**” means the Securities and Exchange Commission.

1.26 “**SEC Rule 144**” means Rule 144 promulgated by the SEC under the Securities Act.

1.27 “**SEC Rule 145**” means Rule 145 promulgated by the SEC under the Securities Act.

1.28 “**Securities Act**” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

1.29 “**Selling Expenses**” means all underwriting discounts, selling commissions, and stock transfer taxes applicable to the sale of Registrable Securities, and fees and disbursements of counsel for any Holder, except for the fees and disbursements of the Selling Holder Counsel borne and paid by the Company as provided in Subsection 2.6.

1.30 “**Series A Preferred Stock**” means shares of the Company’s Series A Preferred Stock, par value \$0.0001 per share.

1.31 “**Series B Preferred Stock**” means shares of the Company’s Series B Preferred Stock, par value \$0.0001 per share.

2. Registration Rights. The Company covenants and agrees as follows:

2.1 Demand Registration.

(a) Form S-1 Demand. If at any time after the earlier of (i) four (4) years after the date of this Agreement or (ii) one hundred eighty (180) days after the effective date of the registration statement for the IPO, the Company receives a request from Holders of at least twenty percent (20%) of the Registrable Securities then outstanding that the Company file a Form S-1 registration statement with respect to at least forty percent (40%) of the Registrable Securities then outstanding (or a lesser percent if the anticipated aggregate offering price, net of Selling Expenses, would exceed \$15 million), then the Company shall (x) within ten (10) days after the date such request is given, give notice thereof (the “**Demand Notice**”) to all Holders other than the Initiating Holders; and (y) as soon as practicable, and in any event within sixty (60) days after the date such request is given by the Initiating Holders, file a Form S-1 registration statement under the Securities Act covering all Registrable Securities that the Initiating Holders requested to be registered and any additional Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within twenty (20) days of the date the Demand Notice is given, and in each case, subject to the limitations of Subsections 2.1(c) and 2.3.

(b) Form S-3 Demand. If at any time when it is eligible to use a Form S-3 registration statement, the Company receives a request from Holders of at least ten percent (10%) of the Registrable Securities then outstanding that the Company file a Form S-3 registration statement with respect to outstanding Registrable Securities of such Holders having an anticipated aggregate offering price, net of Selling Expenses, of at least \$10 million, then the Company shall (i) within ten (10) days after the date such request is given, give a Demand Notice to all Holders other than the Initiating Holders; and (ii) as soon as practicable, and in any event within forty-five (45) days after the date such request is given by the Initiating Holders, file a Form S-3 registration statement under the Securities Act covering all Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within twenty (20) days of the date the Demand Notice is given, and in each case, subject to the limitations of Subsections 2.1(c) and 2.3.

(c) Notwithstanding the foregoing obligations, if the Company furnishes to Holders requesting a registration pursuant to this Subsection 2.1 a certificate signed by the Company’s chief executive officer stating that in the good faith judgment of the Company’s Board of Directors it would be materially detrimental to the Company and its stockholders for such registration statement to either become effective or remain effective for as

long as such registration statement otherwise would be required to remain effective, because such action would (i) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving the Company; (ii) require premature disclosure of material information that the Company has a bona fide business purpose for preserving as confidential; or (iii) render the Company unable to comply with requirements under the Securities Act or Exchange Act, then the Company shall have the right to defer taking action with respect to such filing, and any time periods with respect to filing or effectiveness thereof shall be tolled correspondingly, for a period of not more than one hundred twenty (120) days after the request of the Initiating Holders is given; provided, however, that the Company may not invoke this right more than once in any twelve (12) month period; and provided further that the Company shall not register any securities for its own account or that of any other stockholder during such one hundred twenty (120) day period other than an Excluded Registration.

(d) The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Subsection 2.1(a). (i) during the period that is sixty (60) days before the Company's good faith estimate of the date of filing of, and ending on a date that is one hundred eighty (180) days after the effective date of, a Company-initiated registration, provided that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; (ii) after the Company has effected two registrations pursuant to Subsection 2.1(a); or (iii) if the Initiating Holders propose to dispose of shares of Registrable Securities that may be immediately registered on Form S-3 pursuant to a request made pursuant to Subsection 2.1(b). The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Subsection 2.1(b). (i) during the period that is thirty (30) days before the Company's good faith estimate of the date of filing of, and ending on a date that is ninety (90) days after the effective date of, a Company-initiated registration, provided that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; or (ii) if the Company has effected two registrations pursuant to Subsection 2.1(b) within the twelve (12) month period immediately preceding the date of such request. A registration shall not be counted as "effected" for purposes of this Subsection 2.1(d) until such time as the applicable registration statement has been declared effective by the SEC, unless the Initiating Holders withdraw their request for such registration, elect not to pay the registration expenses therefor, and forfeit their right to one demand registration statement pursuant to Subsection 2.6, in which case such withdrawn registration statement shall be counted as "effected" for purposes of this Subsection 2.1(d).

2.2 Company Registration. If the Company proposes to register (including, for this purpose, a registration effected by the Company for stockholders other than the Holders) any of its Common Stock under the Securities Act in connection with the public offering of such securities solely for cash (other than in an Excluded Registration), the Company shall, at such time, promptly give each Holder notice of such registration. Upon the request of each Holder given within twenty (20) days after such notice is given by the Company, the Company shall, subject to the provisions of Subsection 2.3, cause to be registered all of the Registrable Securities that each such Holder has requested to be included in such registration. The Company shall have the right to terminate or withdraw any registration initiated by it under this Subsection 2.2 before the effective date of such registration, whether or not any Holder has elected to include Registrable Securities in such registration. The expenses (other than Selling Expenses) of such withdrawn registration shall be borne by the Company in accordance with Subsection 2.6.

### 2.3 Underwriting Requirements.

(a) If, pursuant to Subsection 2.1, the Initiating Holders intend to distribute the Registrable Securities covered by their request by means of an underwriting, they shall so advise the Company as a part of their request made pursuant to Subsection 2.1, and the Company shall include such information in the Demand Notice. The underwriter(s) will be selected by the Company and shall be reasonably acceptable to a majority in interest of the Initiating Holders. In such event, the right of any Holder to include such Holder's Registrable Securities in such registration shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting to the extent provided herein. All Holders proposing to distribute their securities through such underwriting shall (together with the Company as provided in Subsection 2.4(e)) enter into an underwriting agreement in customary form with the underwriter(s) selected for such underwriting. Notwithstanding any other provision of this Subsection 2.3, if the managing underwriter(s) advise(s) the Initiating Holders in writing that marketing factors require a limitation on the number of shares to be underwritten, then the Initiating Holders shall so advise all Holders of Registrable Securities that otherwise would be underwritten pursuant hereto, and the number of Registrable Securities that may be included in the underwriting shall be allocated among such Holders of Registrable Securities, including the Initiating Holders, in proportion (as nearly as practicable) to the number of Registrable Securities owned by each Holder or in such other proportion as shall mutually be agreed to by all such selling Holders; provided, however, that the number of Registrable Securities held by the Holders to be included in such underwriting shall not be reduced unless all other securities are first entirely excluded from the underwriting. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest one hundred (100) shares.

(b) In connection with any offering involving an underwriting of shares of the Company's capital stock pursuant to Subsection 2.2, the Company shall not be required to include any of the Holders' Registrable Securities in such underwriting unless the Holders accept the terms of the underwriting as agreed upon between the Company and its underwriters, and then only in such quantity as the underwriters in their sole discretion determine will not jeopardize the success of the offering by the Company. If the total number of securities, including Registrable Securities, requested by stockholders to be included in such offering exceeds the number of securities to be sold (other than by the Company) that the underwriters in their reasonable discretion determine is compatible with the success of the offering, then the Company shall be required to include in the offering only that number of such securities, including Registrable Securities, which the underwriters and the Company in their sole discretion determine will not jeopardize the success of the offering. If the underwriters determine that less than all of the Registrable Securities requested to be registered can be included in such offering, then the Registrable Securities that are included in such offering shall be allocated among the selling Holders in proportion (as nearly as practicable to) the number of Registrable Securities owned by each selling Holder or in such other proportions as shall mutually be agreed to by all

such selling Holders. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest one hundred (100) shares. Notwithstanding the foregoing, in no event shall (i) the number of Registrable Securities included in the offering be reduced unless all other securities (other than securities to be sold by the Company) are first entirely excluded from the offering, or (ii) the number of Registrable Securities included in the offering be reduced below twenty percent (20%) of the total number of securities included in such offering, unless such offering is the IPO, in which case the selling Holders may be excluded further if the underwriters make the determination described above and no other stockholder's securities are included in such offering. For purposes of the provision in this Subsection 2.3(b) concerning apportionment, for any selling Holder that is a partnership, limited liability company, or corporation, the partners, members, retired partners, retired members, stockholders, and Affiliates of such Holder, or the estates and Immediate Family Members of any such partners, retired partners, members, and retired members and any trusts for the benefit of any of the foregoing Persons, shall be deemed to be a single "selling Holder," and any pro rata reduction with respect to such "selling Holder" shall be based upon the aggregate number of Registrable Securities owned by all Persons included in such "selling Holder," as defined in this sentence.

(c) For purposes of Subsection 2.1, a registration shall not be counted as "effected" if, as a result of an exercise of the underwriter's cutback provisions in Subsection 2.3(a), fewer than fifty percent (50%) of the total number of Registrable Securities that Holders have requested to be included in such registration statement are actually included.

2.4 Obligations of the Company. Whenever required under this Section 2 to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:

(a) prepare and file with the SEC a registration statement with respect to such Registrable Securities and use its commercially reasonable efforts to cause such registration statement to become effective and, upon the request of the Holders of a majority of the Registrable Securities registered thereunder, keep such registration statement effective for a period of up to one hundred twenty (120) days or, if earlier, until the distribution contemplated in the registration statement has been completed; provided, however, that (i) such one hundred twenty (120) day period shall be extended for a period of time equal to the period the Holder refrains, at the request of an underwriter of Common Stock (or other securities) of the Company, from selling any securities included in such registration, and (ii) in the case of any registration of Registrable Securities on Form S-3 that are intended to be offered on a continuous or delayed basis, subject to compliance with applicable SEC rules, such one hundred twenty (120) day period shall be extended for up to ninety (90) days, if necessary, to keep the registration statement effective until all such Registrable Securities are sold;

(b) prepare and file with the SEC such amendments and supplements to such registration statement, and the prospectus used in connection with such registration statement, as may be necessary to comply with the Securities Act in order to enable the disposition of all securities covered by such registration statement;



(c) furnish to the selling Holders such numbers of copies of a prospectus, including a preliminary prospectus, as required by the Securities Act, and such other documents as the Holders may reasonably request in order to facilitate their disposition of their Registrable Securities;

(d) use its commercially reasonable efforts to register and qualify the securities covered by such registration statement under such other securities or blue-sky laws of such jurisdictions as shall be reasonably requested by the selling Holders; provided that the Company shall not be required to qualify to do business or to file a general consent to service of process in any such states or jurisdictions unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act;

(e) in the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the underwriter(s) of such offering;

(f) use its commercially reasonable efforts to cause all such Registrable Securities covered by such registration statement to be listed on a national securities exchange or trading system and each securities exchange and trading system (if any) on which similar securities issued by the Company are then listed;

(g) provide a transfer agent and registrar for all Registrable Securities registered pursuant to this Agreement and provide a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration;

(h) promptly make available for inspection by the selling Holders, any managing underwriter participating in any disposition pursuant to such registration statement, and any attorney or accountant or other agent retained by any such underwriter or selected by the selling Holders, all financial and other records, pertinent corporate documents, and properties of the Company, and cause the Company's officers, directors, employees, and independent accountants to supply all information reasonably requested by any such seller, underwriter, attorney, accountant, or agent, in each case, as necessary or advisable to verify the accuracy of the information in such registration statement and to conduct appropriate due diligence in connection therewith;

(i) notify each selling Holder, promptly after the Company receives notice thereof, of the time when such registration statement has been declared effective or a supplement to any prospectus forming a part of such registration statement has been filed; and

(j) after such registration statement becomes effective, notify each selling Holder of any request by the SEC that the Company amend or supplement such registration statement or prospectus.

In addition, the Company shall ensure that, at all times after any registration statement covering a public offering of securities of the Company under the Securities Act shall have become effective, its insider trading policy shall provide that the Company's directors may implement a trading program under Rule 10b5-1 of the Exchange Act.

2.5 Furnish Information. It shall be a condition precedent to the obligations of the Company to take any action pursuant to this Section 2 with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself, the Registrable Securities held by it, and the intended method of disposition of such securities as is reasonably required to effect the registration of such Holder's Registrable Securities.

2.6 Expenses of Registration. All expenses (other than Selling Expenses) incurred in connection with registrations, filings, or qualifications pursuant to Section 2, including all registration, filing, and qualification fees; printers' and accounting fees; fees and disbursements of counsel for the Company; and the reasonable fees and disbursements of one counsel for the selling Holders ("**Selling Holder Counsel**"), shall be borne and paid by the Company; provided, however, that the Company shall not be required to pay for any expenses of any registration proceeding begun pursuant to Subsection 2.1 if the registration request is subsequently withdrawn at the request of the Holders of a majority of the Registrable Securities to be registered (in which case all selling Holders shall bear such expenses pro rata based upon the number of Registrable Securities that were to be included in the withdrawn registration), unless the Holders of a majority of the Registrable Securities agree to forfeit their right to one registration pursuant to Subsections 2.1(a) or 2.1(b), as the case may be; provided further that if, at the time of such withdrawal, the Holders shall have learned of a material adverse change in the condition, business, or prospects of the Company from that known to the Holders at the time of their request and have withdrawn the request with reasonable promptness after learning of such information then the Holders shall not be required to pay any of such expenses and shall not forfeit their right to one registration pursuant to Subsections 2.1(a) or 2.1(b). All Selling Expenses relating to Registrable Securities registered pursuant to this Section 2 shall be borne and paid by the Holders pro rata on the basis of the number of Registrable Securities registered on their behalf.

2.7 Delay of Registration. No Holder shall have any right to obtain or seek an injunction restraining or otherwise delaying any registration pursuant to this Agreement as the result of any controversy that might arise with respect to the interpretation or implementation of this Section 2.

2.8 Indemnification. If any Registrable Securities are included in a registration statement under this Section 2:

(a) To the extent permitted by law, the Company will indemnify and hold harmless each selling Holder, and the partners, members, officers, directors, and stockholders of each such Holder; legal counsel and accountants for each such Holder; any underwriter (as defined in the Securities Act) for each such Holder; and each Person, if any, who controls such Holder or underwriter within the meaning of the Securities Act or the Exchange Act, against any Damages, and the Company will pay to each such Holder, underwriter, controlling Person, or other aforementioned Person any legal or other expenses reasonably

incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Subsection 2.8(a) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Company, which consent shall not be unreasonably withheld, nor shall the Company be liable for any Damages to the extent that they arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of any such Holder, underwriter, controlling Person, or other aforementioned Person expressly for use in connection with such registration.

(b) To the extent permitted by law, each selling Holder, severally and not jointly, will indemnify and hold harmless the Company, and each of its directors, each of its officers who has signed the registration statement, each Person (if any), who controls the Company within the meaning of the Securities Act, legal counsel and accountants for the Company, any underwriter (as defined in the Securities Act), any other Holder selling securities in such registration statement, and any controlling Person of any such underwriter or other Holder, against any Damages, in each case only to the extent that such Damages arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of such selling Holder expressly for use in connection with such registration; and each such selling Holder will pay to the Company and each other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Subsection 2.8(b) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Holder, which consent shall not be unreasonably withheld; and provided further that in no event shall the aggregate amounts payable by any Holder by way of indemnity or contribution under Subsections 2.8(b) and 2.8(d) exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of fraud or willful misconduct by such Holder.

(c) Promptly after receipt by an indemnified party under this Subsection 2.8 of notice of the commencement of any action (including any governmental action) for which a party may be entitled to indemnification hereunder, such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this Subsection 2.8, give the indemnifying party notice of the commencement thereof. The indemnifying party shall have the right to participate in such action and, to the extent the indemnifying party so desires, participate jointly with any other indemnifying party to which notice has been given, and to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an indemnified party (together with all other indemnified parties that may be represented without conflict by one counsel) shall have the right to retain one separate counsel, with the fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such action. The failure to give notice to the indemnifying party within a reasonable time of the commencement of any such action shall relieve such indemnifying party of any liability to the indemnified party under this

Subsection 2.8, to the extent that such failure materially prejudices the indemnifying party's ability to defend such action. The failure to give notice to the indemnifying party will not relieve it of any liability that it may have to any indemnified party otherwise than under this Subsection 2.8.

(d) To provide for just and equitable contribution to joint liability under the Securities Act in any case in which either: (i) any party otherwise entitled to indemnification hereunder makes a claim for indemnification pursuant to this Subsection 2.8 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case, notwithstanding the fact that this Subsection 2.8 provides for indemnification in such case, or (ii) contribution under the Securities Act may be required on the part of any party hereto for which indemnification is provided under this Subsection 2.8, then, and in each such case, such parties will contribute to the aggregate losses, claims, damages, liabilities, or expenses to which they may be subject (after contribution from others) in such proportion as is appropriate to reflect the relative fault of each of the indemnifying party and the indemnified party in connection with the statements, omissions, or other actions that resulted in such loss, claim, damage, liability, or expense, as well as to reflect any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or allegedly untrue statement of a material fact, or the omission or alleged omission of a material fact, relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission; provided, however, that, in any such case (x) no Holder will be required to contribute any amount in excess of the public offering price of all such Registrable Securities offered and sold by such Holder pursuant to such registration statement, and (y) no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation; and provided further that in no event shall a Holder's liability pursuant to this Subsection 2.8(d), when combined with the amounts paid or payable by such Holder pursuant to Subsection 2.8(b), exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of willful misconduct or fraud by such Holder.

(e) Notwithstanding the foregoing, to the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with the underwritten public offering are in conflict with the foregoing provisions, the provisions in the underwriting agreement shall control.

(f) Unless otherwise superseded by an underwriting agreement entered into in connection with the underwritten public offering, the obligations of the Company and Holders under this Subsection 2.8 shall survive the completion of any offering of Registrable Securities in a registration under this Section 2, and otherwise shall survive the termination of this Agreement.

2.9 Reports Under Exchange Act. With a view to making available to the Holders the benefits of SEC Rule 144 and any other rule or regulation of the SEC that may at any time permit a Holder to sell securities of the Company to the public without registration or pursuant to a registration on Form S-3, the Company shall:

(a) make and keep available adequate current public information, as those terms are understood and defined in SEC Rule 144, at all times after the effective date of the registration statement filed by the Company for the IPO;

(b) use commercially reasonable efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after the Company has become subject to such reporting requirements); and

(c) furnish to any Holder, so long as the Holder owns any Registrable Securities, forthwith upon request (i) to the extent accurate, a written statement by the Company that it has complied with the reporting requirements of SEC Rule 144 (at any time after ninety (90) days after the effective date of the registration statement filed by the Company for the IPO), the Securities Act, and the Exchange Act (at any time after the Company has become subject to such reporting requirements), or that it qualifies as a registrant whose securities may be resold pursuant to Form S-3 (at any time after the Company so qualifies); (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company; and (iii) such other information as may be reasonably requested in availing any Holder of any rule or regulation of the SEC that permits the selling of any such securities without registration (at any time after the Company has become subject to the reporting requirements under the Exchange Act) or pursuant to Form S-3 (at any time after the Company so qualifies to use such form).

2.10 Limitations on Subsequent Registration Rights. From and after the date of this Agreement, the Company shall not, without the prior written consent of Holders holding at least (i) a majority of the shares of Common Stock issued or issuable upon conversion of the Series A Preferred Stock, voting together as a single class and (ii) a majority of the shares of Common Stock issued or issuable upon conversion of the Series B Preferred Stock, voting together as a single class (the foregoing clauses (i) and (ii) together, the “**Requisite Holders**”), enter into any agreement with any holder or prospective holder of any securities of the Company that would provide to such holder the right to include securities in any registration on other than either a pro rata basis with respect to the Registrable Securities or on a subordinate basis after all Holders have had the opportunity to include in the registration and offering all shares of Registrable Securities that they wish to so include.

2.11 “Market Stand-off” Agreement. Each Holder hereby agrees that it will not, without the prior written consent of the managing underwriter, during the period commencing on the date of the final prospectus relating to the registration by the Company for its own behalf of shares of its Common Stock or any other equity securities under the Securities Act on a registration statement on Form S-1 or Form S-3, and ending on the date specified by the Company and the managing underwriter (such period not to exceed one hundred eighty (180)

days in the case of the IPO, or such other period as may be requested by the Company or an underwriter to accommodate regulatory restrictions on (1) the publication or other distribution of research reports, and (2) analyst recommendations and opinions, including, but not limited to, the restrictions contained in FINRA Rule 2711(f)(4) or NYSE Rule 472(f)(4), or any successor provisions or amendments thereto), (i) lend; offer; pledge; sell; contract to sell; sell any option or contract to purchase; purchase any option or contract to sell; grant any option, right, or warrant to purchase; or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Stock held immediately before the effective date of the registration statement for such offering or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or other securities, in cash, or otherwise. The foregoing provisions of this Subsection 2.11 shall apply only to the IPO, shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement, or the transfer of any shares to any trust for the direct or indirect benefit of the Holder or the immediate family of the Holder, provided that the trustee of the trust agrees to be bound in writing by the restrictions set forth herein, and provided further that any such transfer shall not involve a disposition for value, and shall be applicable to the Holders only if all officers and directors and holders of more than one percent (1%) of the Company's outstanding Common Stock (after giving effect to conversion into Common Stock of all outstanding Preferred Stock) enter into similar agreements. The underwriters in connection with such registration are intended third-party beneficiaries of this Subsection 2.11 and shall have the right, power and authority to enforce the provisions hereof as though they were a party hereto. Each Holder further agrees to execute such agreements as may be reasonably requested by the underwriters in connection with such registration that are consistent with this Subsection 2.11 or that are necessary to give further effect thereto. Any discretionary waiver or termination of the restrictions of any or all of such agreements by the Company or the underwriters shall apply pro rata to all Holders subject to such agreements, based on the number of shares subject to such agreements.

#### 2.12 Restrictions on Transfer.

(a) The Preferred Stock and the Registrable Securities shall not be sold, pledged, or otherwise transferred, and the Company shall not recognize and shall issue stop-transfer instructions to its transfer agent with respect to any such sale, pledge, or transfer, except upon the conditions specified in this Agreement, which conditions are intended to ensure compliance with the provisions of the Securities Act. A transferring Holder will cause any proposed purchaser, pledgee, or transferee of the Preferred Stock and the Registrable Securities held by such Holder to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Agreement.

(b) Each certificate, instrument, or book entry representing (i) the Preferred Stock, (ii) the Registrable Securities, and (iii) any other securities issued in respect of the securities referenced in clauses (i) and (ii), upon any stock split, stock dividend, recapitalization, merger, consolidation, or similar event, shall (unless otherwise permitted by the provisions of Subsection 2.12(c)) be notated with a legend substantially in the following form:

THE SECURITIES REPRESENTED HEREBY HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. SUCH SHARES MAY NOT BE SOLD, PLEDGED, OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR A VALID EXEMPTION FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SAID ACT.

THE SECURITIES REPRESENTED HEREBY MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF AN AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.

The Holders consent to the Company making a notation in its records and giving instructions to any transfer agent of the Restricted Securities in order to implement the restrictions on transfer set forth in this Subsection 2.12.

(c) The holder of such Restricted Securities, by acceptance of ownership thereof, agrees to comply in all respects with the provisions of this Section 2. Before any proposed sale, pledge, or transfer of any Restricted Securities, unless there is in effect a registration statement under the Securities Act covering the proposed transaction, the Holder thereof shall give notice to the Company of such Holder's intention to effect such sale, pledge, or transfer. Each such notice shall describe the manner and circumstances of the proposed sale, pledge, or transfer in sufficient detail and, if reasonably requested by the Company, shall be accompanied at such Holder's expense by either (i) a written opinion of legal counsel who shall, and whose legal opinion shall, be reasonably satisfactory to the Company, addressed to the Company, to the effect that the proposed transaction may be effected without registration under the Securities Act; (ii) a "no action" letter from the SEC to the effect that the proposed sale, pledge, or transfer of such Restricted Securities without registration will not result in a recommendation by the staff of the SEC that action be taken with respect thereto; or (iii) any other evidence reasonably satisfactory to counsel to the Company to the effect that the proposed sale, pledge, or transfer of the Restricted Securities may be effected without registration under the Securities Act, whereupon the Holder of such Restricted Securities shall be entitled to sell, pledge, or transfer such Restricted Securities in accordance with the terms of the notice given by the Holder to the Company. The Company will not require such a legal opinion or "no action" letter (x) in any transaction in compliance with SEC Rule 144; or (y) in any transaction in which such Holder distributes or transfers Restricted Securities to an Affiliate of such Holder; provided that each transferee agrees in writing to be subject to the terms of this Subsection 2.12. Each certificate, instrument, or book entry representing the Restricted Securities transferred as above provided shall be notated with, except if such transfer is made pursuant to SEC Rule 144, the appropriate restrictive legend set forth in Subsection 2.12(b), except that such certificate instrument, or book entry shall not be notated with such restrictive legend if, in the opinion of counsel for such Holder and the Company, such legend is not required in order to establish compliance with any provisions of the Securities Act.

2.13 Termination of Registration Rights. The right of any Holder to request registration or inclusion of Registrable Securities in any registration pursuant to Subsections 2.1 or 2.2 shall terminate upon the earliest to occur of:

(a) the closing of a Deemed Liquidation Event, as such term is defined in the Company's Certificate of Incorporation;

(b) such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such Holder's shares without limitation during a three-month period without registration; and

(c) the fifth anniversary of the IPO.

### 3. Information and Observer Rights.

3.1 Delivery of Financial Statements. The Company shall deliver to each Major Investor, provided that the Board of Directors has not reasonably determined that such Major Investor is a Competitor of the Company:

(a) as soon as practicable, but in any event within one hundred twenty (120) days after the end of each fiscal year of the Company (i) a balance sheet as of the end of such year, (ii) statements of income and of cash flows for such year, and (iii) a statement of stockholders' equity as of the end of such year; provided that, in the event that the Company undertakes an audit of such financial statements, all financial statements delivered to each Major Investor pursuant to this Section 3.1(a) for the fiscal year of such audit and thereafter shall be audited and certified by independent public accountants of nationally recognized standing selected by the Company;

(b) as soon as practicable, but in any event within forty-five (45) days after the end of each of the first three (3) quarters of each fiscal year of the Company, unaudited statements of income and cash flows for such fiscal quarter, and an unaudited balance sheet and a statement of stockholders' equity as of the end of such fiscal quarter, all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments; and (ii) not contain all notes thereto that may be required in accordance with GAAP);

(c) as soon as practicable, but in any event within forty-five (45) days after the end of each of the first three (3) quarters of each fiscal year of the Company, a statement showing the number of shares of each class and series of capital stock and securities convertible into or exercisable for shares of capital stock outstanding at the end of the period, the Common Stock issuable upon conversion or exercise of any outstanding securities convertible or exercisable for Common Stock and the exchange ratio or exercise price applicable thereto, and the number of shares of issued stock options and stock options not yet issued but reserved for issuance, if any, all in sufficient detail as to permit the Major Investors to calculate their respective percentage equity ownership in the Company, and certified by the chief financial officer or chief executive officer of the Company as being true, complete, and correct;



(d) as soon as practicable, but in any event thirty (30) days before the end of each fiscal year, a budget and business plan for the next fiscal year (collectively the “**Budget**”), approved by the Board of Directors and prepared on a monthly basis, including balance sheets, income statements, and statements of cash flow for such months and, promptly after prepared, any other budgets or revised budgets prepared by the Company; and

(e) such other information relating to the financial condition, business, prospects, or corporate affairs of the Company as any Major Investor may from time to time reasonably request; provided, however, that the Company shall not be obligated under this Subsection 3.1 to provide information (i) that the Company reasonably determines in good faith to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in a form acceptable to the Company); or (ii) the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

If, for any period, the Company has any subsidiary whose accounts are consolidated with those of the Company, then in respect of such period the financial statements delivered pursuant to the foregoing sections shall be the consolidated and consolidating financial statements of the Company and all such consolidated subsidiaries.

Notwithstanding anything else in this Subsection 3.1 to the contrary, the Company may cease providing the information set forth in this Subsection 3.1 during the period starting with the date sixty (60) days before the Company’s good-faith estimate of the date of filing of a registration statement if it reasonably concludes it must do so to comply with the SEC rules applicable to such registration statement and related offering; provided that the Company’s covenants under this Subsection 3.1 shall be reinstated at such time as the Company is no longer actively employing its commercially reasonable efforts to cause such registration statement to become effective.

3.2 Inspection. The Company shall permit each Major Investor (provided that the Board of Directors has not reasonably determined that such Major Investor is a Competitor of the Company), at such Major Investor’s expense, to visit and inspect the Company’s properties; examine its books of account and records; and discuss the Company’s affairs, finances, and accounts with its officers, during normal business hours of the Company as may be reasonably requested by the Major Investor; provided, however, that the Company shall not be obligated pursuant to this Subsection 3.2 to provide access to any information that it reasonably and in good faith considers to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in form acceptable to the Company) or the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

3.3 Observer Rights. The Company shall invite (i) a representative of Novartis, for as long as Novartis is a Major Investor, and (ii) Joan Mannick, for as long as Joan Mannick is an officer of the Company, to attend all meetings of its Board of Directors in a nonvoting observer capacity and, in this respect, shall give such representatives copies of all notices, minutes, consents, and other materials that it provides to its directors at the same time and in the same manner as provided to such directors; provided, however, that such

representatives shall agree to hold in confidence and trust and to act in a fiduciary manner with respect to all information so provided; and provided further, that the Company reserves the right to withhold any information and to exclude such representatives from any meeting or portion thereof if access to such information or attendance at such meeting would (after consultation with qualified outside counsel) reasonably be expected to adversely affect the attorney-client privilege between the Company and its counsel.

3.4 Termination of Information and Observer Rights. The covenants set forth in Subsection 3.1, Subsection 3.2 and Subsection 3.3 shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO, (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act, or (iii) upon a Deemed Liquidation Event, as such term is defined in the Company's Certificate of Incorporation, whichever event occurs first.

3.5 Confidentiality. Each Investor agrees that such Investor will keep confidential and will not disclose, divulge, or use for any purpose (other than to monitor its investment in the Company) any confidential information obtained from the Company pursuant to the terms of this Agreement (including notice of the Company's intention to file a registration statement), unless such confidential information (a) is known or becomes known to the public in general (other than as a result of a breach of this Subsection 3.4 by such Investor), (b) is or has been independently developed or conceived by the Investor without use of the Company's confidential information, or (c) is or has been made known or disclosed to the Investor by a third party without a breach of any obligation of confidentiality such third party may have to the Company; provided, however, that an Investor may disclose confidential information (i) to its attorneys, accountants, consultants, and other professionals to the extent necessary to obtain their services in connection with monitoring its investment in the Company; (ii) to any prospective purchaser of any Registrable Securities from such Investor, if such prospective purchaser agrees to be bound by the provisions of this Subsection 3.4, provided that the Board of Directors has not reasonably determined that such prospective purchaser is a Competitor of the Company; (iii) to any existing or prospective Affiliate, partner, member, stockholder, or wholly owned subsidiary of such Investor in the ordinary course of business, provided that such Investor informs such Person that such information is confidential and directs such Person to maintain the confidentiality of such information; or (iv) as may otherwise be required by law, provided that the Investor promptly notifies the Company of such disclosure and takes reasonable steps to minimize the extent of any such required disclosure.

#### 4. Rights to Future Stock Issuances.

4.1 Right of First Offer. Subject to the terms and conditions of this Subsection 4.1 and applicable securities laws, if the Company proposes to offer or sell any New Securities, the Company shall first offer such New Securities to each Investor. An Investor shall be entitled to apportion the right of first offer hereby granted to it, in such proportions as it deems appropriate, among (i) itself, (ii) its Affiliates and (iii) its beneficial interest holders, such as limited partners, members or any other Person having "beneficial ownership," as such term is defined in Rule 13d-3 promulgated under the Exchange Act, of such Investor ("**Investor Beneficial Owners**"); provided that each such Affiliate or Investor Beneficial Owner (x) is not a

Competitor or FOIA Party, unless such party's purchase of New Securities is otherwise consented to by the Board of Directors, (y) agrees to enter into this Agreement and each of the Voting Agreement and Right of First Refusal and Co-Sale Agreement of even date herewith among the Company, the Investors and the other parties named therein, as an "Investor" under each such agreement (provided that any Competitor or FOIA Party shall not be entitled to any rights as an Investor under Subsections 3.1, 3.2 and 4.1 hereof), and (z) agrees to purchase at least such number of New Securities as are allocable hereunder to the Investor holding the fewest number of shares of Preferred Stock and any other Derivative Securities.

(a) The Company shall give notice (the "Offer Notice") to each Investor, stating (i) its bona fide intention to offer such New Securities, (ii) the number of such New Securities to be offered, and (iii) the price and terms, if any, upon which it proposes to offer such New Securities.

(b) By notification to the Company within twenty (20) days after the Offer Notice is given, each Investor may elect to purchase or otherwise acquire, at the price and on the terms specified in the Offer Notice, up to that portion of such New Securities which equals the proportion that the Common Stock then held by such Investor (including all shares of Common Stock then issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of the Preferred Stock and any other Derivative Securities then held by such Investor) bears to the total Common Stock of the Company then outstanding (assuming full conversion and/or exercise, as applicable, of all Preferred Stock and other Derivative Securities). At the expiration of such twenty (20) day period, the Company shall promptly notify each Investor that elects to purchase or acquire all the shares available to it (each, a "Fully Exercising Investor") of any other Investor's failure to do likewise. During the ten (10) day period commencing after the Company has given such notice, each Fully Exercising Investor may, by giving notice to the Company, elect to purchase or acquire, in addition to the number of shares specified above, up to that portion of the New Securities for which Investors were entitled to subscribe but that were not subscribed for by the Investors which is equal to the proportion that the Common Stock issued and held, or issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of Preferred Stock and any other Derivative Securities then held, by such Fully Exercising Investor bears to the Common Stock issued and held, or issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of the Preferred Stock and any other Derivative Securities then held, by all Fully Exercising Investors who wish to purchase such unsubscribed shares. The closing of any sale pursuant to this Subsection 4.1(b) shall occur within the later of ninety (90) days of the date that the Offer Notice is given and the date of initial sale of New Securities pursuant to Subsection 4.1(c).

(c) If all New Securities referred to in the Offer Notice are not elected to be purchased or acquired as provided in Subsection 4.1(b), the Company may, during the ninety (90) day period following the expiration of the periods provided in Subsection 4.1(b), offer and sell the remaining unsubscribed portion of such New Securities to any Person or Persons at a price not less than, and upon terms no more favorable to the offeree than, those specified in the Offer Notice. If the Company does not enter into an agreement for the sale of the New Securities within such period, or if such agreement is not consummated within thirty (30) days of the execution thereof, the right provided hereunder shall be deemed to be revived and such New Securities shall not be offered unless first reoffered to the Investors in accordance with this Subsection 4.1.

(d) The right of first offer in this Subsection 4.1 shall not be applicable to (i) Exempted Securities (as defined in the Company's Certificate of Incorporation); (ii) shares of Common Stock issued in the IPO; and (iii) the issuance of shares of Series B Preferred Stock pursuant to the Purchase Agreement.

4.2 Termination. The covenants set forth in Subsection 4.1 shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO, or (ii) upon a Deemed Liquidation Event, as such term is defined in the Company's Certificate of Incorporation.

#### 5. Additional Covenants.

5.1 Insurance. The Company shall use its commercially reasonable efforts to obtain, within ninety (90) days of the date hereof, from financially sound and reputable insurers Directors and Officers liability insurance and term "key-person" insurance on Chen Schor and Joan Mannick, each in an amount and on terms and conditions satisfactory to the Board of Directors, and will use commercially reasonable efforts to cause such insurance policies to be maintained until such time as the Board of Directors determines that such insurance should be discontinued. The key-person policy shall name the Company as loss payee, and neither policy shall be cancelable by the Company without prior approval by the Board of Directors.

5.2 Employee Agreements. The Company will cause (i) each person now or hereafter employed by it or by any subsidiary (or engaged by the Company or any subsidiary as a consultant/independent contractor) with access to confidential information and/or trade secrets to enter into a nondisclosure and proprietary rights assignment agreement; and (ii) each Key Employee now or hereafter employed by it or by any subsidiary to enter into a one (1) year noncompetition and nonsolicitation agreement, substantially in the form approved by the Board of Directors. In addition, the Company shall not amend, modify, terminate, waive, or otherwise alter, in whole or in part, any of the above-referenced agreements or any restricted stock agreement between the Company and any employee, without the consent of the Board of Directors.

5.3 Employee Stock. Unless otherwise approved by the Board of Directors, all future employees and consultants of the Company who purchase, receive options to purchase, or receive awards of shares of the Company's capital stock after the date hereof shall be required to execute restricted stock or option agreements, as applicable, providing for (i) vesting of shares over a four (4) year period, with the first twenty-five percent (25%) of such shares vesting following twelve (12) months of continued employment or service, and the remaining shares vesting in equal monthly installments over the following thirty-six (36) months, and (ii) a market stand-off provision substantially similar to that in Subsection 2.11. In addition, unless otherwise approved by the Board of Directors, the Company shall retain a "right of first refusal" on employee transfers until the Company's IPO and shall have the right to repurchase unvested shares at cost upon termination of employment of a holder of restricted stock.

5.4 Matters Requiring Investor Director Approval. The Company hereby covenants and agrees with each of the Investors that it shall not, without approval of the Board of Directors:

(a) make, or permit any subsidiary to make, any loan or advance to, or own any stock or other securities of, any subsidiary or other corporation, partnership, or other entity unless it is wholly owned by the Company;

(b) make, or permit any subsidiary to make, any loan or advance to any Person, including, without limitation, any employee or director of the Company or any subsidiary, except advances and similar expenditures in the ordinary course of business or under the terms of an employee stock or option plan approved by the Board of Directors;

(c) guarantee, directly or indirectly, or permit any subsidiary to guarantee, directly or indirectly, any indebtedness except for trade accounts of the Company or any subsidiary arising in the ordinary course of business;

(d) make any investment inconsistent with any investment policy approved by the Board of Directors;

(e) incur any indebtedness that is not already included in a budget approved by the Board of Directors, other than trade credit incurred in the ordinary course of business;

(f) hire, terminate, or change the compensation of the executive officers, including approving any option grants or stock awards to executive officers; or

(g) change the principal business of the Company, enter new lines of business, or exit the current line of business.

5.5 Board Matters. Unless otherwise determined by the vote of a majority of the directors then in office, the Board of Directors shall meet at least quarterly in accordance with an agreed-upon schedule. The Company shall reimburse the nonemployee directors for all reasonable out-of-pocket travel expenses incurred (consistent with the Company's travel policy) in connection with attending meetings of the Board of Directors.

5.6 Successor Indemnification. If the Company or any of its successors or assignees consolidates with or merges into any other Person and is not the continuing or surviving corporation or entity of such consolidation or merger, then to the extent necessary, proper provision shall be made so that the successors and assignees of the Company assume the obligations of the Company with respect to indemnification of members of the Board of Directors as in effect immediately before such transaction, whether such obligations are contained in the Company's Bylaws, its Certificate of Incorporation, or elsewhere, as the case may be.

5.7 Indemnification Matters. The Company hereby acknowledges that one (1) or more of the directors nominated to serve on the Board of Directors by the Investors (each an “**Investor Director**”) may have certain rights to indemnification, advancement of expenses and/or insurance provided by one or more of the Investors and certain of their affiliates (collectively, the “**Investor Indemnitors**”). The Company hereby agrees (a) that it is the indemnitor of first resort (*i.e.*, its obligations to any such Investor Director are primary and any obligation of the Investor Indemnitors to advance expenses or to provide indemnification for the same expenses or liabilities incurred by such Investor Director are secondary), (b) that it shall be required to advance the full amount of expenses incurred by such Investor Director and shall be liable for the full amount of all expenses, judgments, penalties, fines and amounts paid in settlement by or on behalf of any such Investor Director to the extent legally permitted and as required by the Company’s Certificate of Incorporation or Bylaws of the Company (or any agreement between the Company and such Investor Director), without regard to any rights such Investor Director may have against the Investor Indemnitors, and, (c) that it irrevocably waives, relinquishes and releases the Investor Indemnitors from any and all claims against the Investor Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the Investor Indemnitors on behalf of any such Investor Director with respect to any claim for which such Investor Director has sought indemnification from the Company shall affect the foregoing and the Investor Indemnitors shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of such Investor Director against the Company.

5.8 Right to Conduct Activities. The Company hereby agrees and acknowledges that each of PureTech Health LLC (together with its Affiliates), OrbiMed (together with its Affiliates) and Novartis (together with its Affiliates) is a healthcare business, and as such invests in numerous portfolio companies, some of which may be deemed competitive with the Company’s business (as currently conducted or as currently proposed to be conducted). The Company hereby agrees that, to the extent permitted under applicable law, none of PureTech Health LLC, OrbiMed or Novartis shall be liable to the Company for any claim arising out of, or based upon, (i) the investment by PureTech Health LLC, OrbiMed and/or Novartis (or any of their respective Affiliates) in any entity competitive with the Company, or (ii) actions taken by any partner, officer or other representative of PureTech Health LLC, OrbiMed and/or Novartis (or any of their respective Affiliates) to assist any such competitive company, whether or not such action was taken as a member of the board of directors of such competitive company or otherwise, and whether or not such action has a detrimental effect on the Company; provided, however, that the foregoing shall not relieve (x) any of the Investors from liability associated with the unauthorized disclosure of the Company’s confidential information obtained pursuant to this Agreement, or (y) any director or officer of the Company from any liability associated with his or her fiduciary duties to the Company.

5.9 FCPA. The Company represents that it shall not (and shall not permit any of its subsidiaries or affiliates or any of its or their respective directors, officers, managers, employees, independent contractors, representatives or agents to) promise, authorize or make any payment to, or otherwise contribute any item of value to, directly or indirectly, to any third party, including any Non-U.S. Official (as such term is defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended (the “**FCPA**”)), in each case, in violation of the FCPA, the U.K. Bribery Act, or any other applicable anti-bribery or anti-corruption law. The

Company further represents that it shall (and shall cause each of its subsidiaries and affiliates to) cease all of its or their respective activities, as well as remediate any actions taken by the Company, its subsidiaries or affiliates, or any of their respective directors, officers, managers, employees, independent contractors, representatives or agents in violation of the FCPA, the U.K. Bribery Act, or any other applicable anti-bribery or anti-corruption law. The Company further represents that it shall (and shall cause each of its subsidiaries and affiliates to) maintain systems of internal controls (including, but not limited to, accounting systems, purchasing systems and billing systems) to ensure compliance with the FCPA, the U.K. Bribery Act, or any other applicable anti-bribery or anti-corruption law. Upon request, the Company agrees to provide responsive information and/or certifications concerning its compliance with applicable anti-corruption laws. The Company shall promptly notify each Investor if the Company becomes aware of any Enforcement Action (as defined in the Purchase Agreement). The Company shall, and shall cause any direct or indirect subsidiary or entity controlled by it, whether now in existence or formed in the future, to comply with the FCPA. The Company shall use its best efforts to cause any direct or indirect subsidiary, whether now in existence or formed in the future, to comply in all material respects with all applicable laws.

5.10 Termination of Covenants. The covenants set forth in this Section 5, except for Subsections 5.6 and 5.7, shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO, (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act, or (iii) upon a Deemed Liquidation Event, as such term is defined in the Company's Certificate of Incorporation, whichever event occurs first.

#### 6. Miscellaneous.

6.1 Successors and Assigns. The rights under this Agreement may be assigned (but only with all related obligations) by a Holder to a transferee of Registrable Securities that (i) is an Affiliate of a Holder; (ii) is a Holder's Immediate Family Member or trust for the benefit of an individual Holder or one or more of such Holder's Immediate Family Members; or (iii) after such transfer, holds at least 100,000 shares of Registrable Securities (subject to appropriate adjustment for stock splits, stock dividends, combinations, and other recapitalizations); provided, however, that (x) the Company is, within a reasonable time after such transfer, furnished with written notice of the name and address of such transferee and the Registrable Securities with respect to which such rights are being transferred; and (y) such transferee agrees in a written instrument delivered to the Company to be bound by and subject to the terms and conditions of this Agreement, including the provisions of Subsection 2.11. For the purposes of determining the number of shares of Registrable Securities held by a transferee, the holdings of a transferee (1) that is an Affiliate or stockholder of a Holder; (2) who is a Holder's Immediate Family Member; or (3) that is a trust for the benefit of an individual Holder or such Holder's Immediate Family Member shall be aggregated together and with those of the transferring Holder; provided further that all transferees who would not qualify individually for assignment of rights shall have a single attorney-in-fact for the purpose of exercising any rights, receiving notices, or taking any action under this Agreement. The terms and conditions of this Agreement inure to the benefit of and are binding upon the respective successors and permitted assignees of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assignees any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided herein.

6.2 Governing Law. This Agreement shall be governed by the internal law of the State of Delaware.

6.3 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, *e.g.*, www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

6.4 Titles and Subtitles. The titles and subtitles used in this Agreement are for convenience only and are not to be considered in construing or interpreting this Agreement.

6.5 Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt or (i) personal delivery to the party to be notified; (ii) when sent, if sent by electronic mail or facsimile during the recipient's normal business hours, and if not sent during normal business hours, then on the recipient's next business day; (iii) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (iv) one (1) business day after the business day of deposit with a nationally recognized overnight courier, freight prepaid, specifying next-day delivery, with written verification of receipt. All communications shall be sent to the respective parties at their addresses as set forth on Schedule A hereto, or to the principal office of the Company and to the attention of the Chief Executive Officer, in the case of the Company, or to such email address, facsimile number, or address as subsequently modified by written notice given in accordance with this Subsection 6.5. If notice is given to Stockholders, a copy shall also be given to Sidley Austin LP, 787 7th Avenue, New York, NY 10019, Attn: Geoffrey W. Levin.

6.6 Amendments and Waivers. Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance, and either retroactively or prospectively) only with the written consent of the Company and the Requisite Holders; provided that the Company may in its sole discretion waive compliance with Subsection 2.12(c) (and the Company's failure to object promptly in writing after notification of a proposed assignment allegedly in violation of Subsection 2.12(c) shall be deemed to be a waiver); and provided further that any provision hereof may be waived by any waiving party on such party's own behalf, without the consent of any other party. Notwithstanding the foregoing, (i) this Agreement may not be amended or terminated and the observance of any term hereof may not be waived with respect to any Investor without the written consent of such Investor, unless such amendment, termination, or waiver applies to all Investors in the same fashion (provided that the rights granted to Major Investors in Section 4 may not be waived with respect to a particular transaction unless all Major Investors are



provided with the opportunity to purchase Shares on similar terms and in proportionally similar amounts as the other Major Investors who are participating in such offering), (ii) Subsection 1.17 (solely as it relates to Novartis and its Affiliates) and Subsection 3.3 may not be amended or waived without the prior written consent of Novartis, and (iii) an amendment to the definition of Major Investor in Section 1.17 that would cause a Major Investor to no longer qualify as a Major Investor shall require the consent of such Major Investor. The Company shall give prompt notice of any amendment or termination hereof or waiver hereunder to any party hereto that did not consent in writing to such amendment, termination, or waiver. Any amendment, termination, or waiver effected in accordance with this Subsection 6.6 shall be binding on all parties hereto, regardless of whether any such party has consented thereto. No waivers of or exceptions to any term, condition, or provision of this Agreement, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, condition, or provision.

6.7 Severability. In case any one or more of the provisions contained in this Agreement is for any reason held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement, and such invalid, illegal, or unenforceable provision shall be reformed and construed so that it will be valid, legal, and enforceable to the maximum extent permitted by law.

6.8 Aggregation of Stock. All shares of Registrable Securities held or acquired by Affiliates shall be aggregated together for the purpose of determining the availability of any rights under this Agreement and such Affiliated persons may apportion such rights as among themselves in any manner they deem appropriate.

6.9 Additional Investors. Notwithstanding anything to the contrary contained herein, if the Company issues additional shares of the Company's Series B Preferred Stock after the date hereof, any purchaser of such shares of Series B Preferred Stock may become a party to this Agreement by executing and delivering an additional counterpart signature page to this Agreement, and thereafter shall be deemed an "Investor" for all purposes hereunder. No action or consent by the Investors shall be required for such joinder to this Agreement by such additional Investor, so long as such additional Investor has agreed in writing to be bound by all of the obligations as an "Investor" hereunder.

6.10 Entire Agreement. This Agreement (including any Schedules and Exhibits hereto) constitutes the full and entire understanding and agreement among the parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof existing between the parties is expressly canceled. Upon the effectiveness of this Agreement, the Prior Agreement shall be deemed amended and restated and superseded and replaced in its entirety by this Agreement, and shall be of no further force or effect.

6.11 Dispute Resolution. The parties (a) hereby irrevocably and unconditionally submit to the jurisdiction of the state courts of Delaware and to the jurisdiction of the United States District Court for the District of Delaware for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (b) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in the state courts of Delaware or the United States District Court for the District of Delaware, and (c)

hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court.

WAIVER OF JURY TRIAL: EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, THE OTHER TRANSACTION DOCUMENTS, THE SECURITIES OR THE SUBJECT MATTER HEREOF OR THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS TRANSACTION, INCLUDING, WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER WARRANTS AND REPRESENTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.

6.12 Delays or Omissions. No delay or omission to exercise any right, power, or remedy accruing to any party under this Agreement, upon any breach or default of any other party under this Agreement, shall impair any such right, power, or remedy of such nonbreaching or nondefaulting party, nor shall it be construed to be a waiver of or acquiescence to any such breach or default, or to any similar breach or default thereafter occurring, nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. All remedies, whether under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

**RESTORBIO, INC.**

By: /s/ Chen Schor

Name: Chen Schor

Title: Chief Executive Officer

*[Signature Page to Amended and Restated Investors' Rights Agreement]*

INVESTORS:

**PURETECH HEALTH LLC**

By: /s/ Stephen Muniz

Name: Stephen Muniz

Title: Chief Operating Officer

**NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.**

By: \_\_\_\_\_

Name:

Title:

*[Signature Page to Amended and Restated Investors' Rights Agreement]*

**ORBIMED PRIVATE INVESTMENTS VI, LP**  
**BY: ORBiMED CAPITAL GP VI LLC,**  
**ITS: GENERAL PARTNER**  
**BY: ORBiMED ADVISORS LLC**  
**ITS: MANAGING MEMBER**

By: /s/ Jonathan Silverstein  
Name: Jonathan Silverstein  
Title: Member

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*[Signature Page to Amended and Restated Investors' Rights Agreement]*

**Fidelity Contrafund: Fidelity Advisor  
New Insights Fund**

By: /s/ Colm Hogan

Name: Colm Hogan

Title: Authorized Signatory

*[Signature Page to Amended and Restated Investors' Rights Agreement]*

**Rock Springs Capital Master Fund LP**  
**By: Rock Springs General Partner LLC**

By: /s/ Kris N. Jenner  
Name: Kris N. Jenner  
Title: Managing Member

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*[Signature Page to Amended and Restated Investors' Rights Agreement]*

**Quan Venture Fund I, L.P.**

By: **Quan Venture Partners I, L.L.C.**

Its: General Partner

By: /s/ Marietta Wu

Name: Marietta Wu

Title: Managing Director

*[Signature Page to Amended and Restated Investors' Rights Agreement]*



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**LEERINK HOLDINGS LLC**

By: /s/ Timothy A.G. Gerhold  
Name: Timothy A.G. Gerhold  
Title: General Counsel

**LEERINK SWANN CO-INVESTMENT FUND, LLC**

By: /s/ Jeffrey A. Leerink  
Name: Jeffrey A. Leerink  
Title: Manager

*[Signature Page to Amended and Restated Investors' Rights Agreement]*

**NESTBIO WO VI HOLDING LP**

**BY: ADENA PARTNERS GP I, LLC  
ITS GENERAL PARTNER**

By: /s/ Cheryl Hao Cui

Name: Cheryl Hao Cui

Title: Member

*[Signature Page to Amended and Restated Investors' Rights Agreement]*

## SCHEDULE A

### Investors

PureTech Health LLC  
501 Boylston Street, Suite 6102  
Boston, Massachusetts 02116

Novartis Institutes for BioMedical Research, Inc.  
250 Massachusetts Avenue  
Cambridge, MA 02139  
Attn: General Counsel

OrbiMed Private Investments VI, LP  
601 Lexington Avenue  
New York, NY 10022

Fidelity Contrafund: Fidelity Advisor New Insights Fund  
Mag & Co.  
c/o Brown Brothers Harriman & Co.  
Attn: Corporate Actions /Vault  
140 Broadway  
New York, NY 10005  
BBH.Fidelity.CA.Notifications@BBH.com

Quan Venture Fund I, L.P.  
Ugland House, PO Box 309  
Grand Cayman, Cayman Islands KY1-1104

Leerink Holdings LLC  
c/o Leerink Partners LLC  
One Federal Street, 37<sup>th</sup> Floor  
Boston, MA 02110  
Attention: General Counsel

Leerink Swann Co-Investment Fund, LLC  
c/o Leerink Partners LLC  
One Federal Street, 37<sup>th</sup> Floor  
Boston, MA 02110  
Attention: General Counsel

Rock Springs Capital Master Fund LP  
650 South Exeter Street #1070  
Baltimore, Maryland 21202

Nestbio WO VI Holding LP  
43 Charles St., Unit 2  
Boston, MA 02114  
Attention: Cheryl Cui

## RESTORBIO, INC.

2017 STOCK INCENTIVE PLAN1. Purpose

The purpose of this 2017 Stock Incentive Plan (the “Plan”) of resTORbio, Inc., a Delaware corporation (the “Company”), is to advance the interests of the Company’s stockholders by enhancing the Company’s ability to attract, retain and motivate persons who are expected to make important contributions to the Company and by providing such persons with equity ownership opportunities and performance-based incentives that are intended to better align the interests of such persons with those of the Company’s stockholders. Except where the context otherwise requires, the term “Company” shall include any of the Company’s present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the “Code”) and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a controlling interest, as determined by the Board of Directors of the Company (the “Board”).

2. Eligibility

All of the Company’s employees, officers, directors, consultants and advisors are eligible to be granted options, restricted stock, restricted stock units and other stock-based awards (each, an “Award”) under the Plan. Each person who receives an Award under the Plan is deemed a “Participant”.

3. Administration and Delegation

(a) Administration by Board of Directors. The Plan will be administered by the Board. The Board shall have authority to grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may construe and interpret the terms of the Plan and any Award agreements entered into under the Plan. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem expedient to carry the Plan into effect and it shall be the sole and final judge of such expediency. All decisions by the Board shall be made in the Board’s sole discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Award. No director or person acting pursuant to the authority delegated by the Board shall be liable for any action or determination relating to or under the Plan made in good faith.

(b) Appointment of Committees. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a “Committee”). All references in the Plan to the “Board” shall mean the Board or a Committee of the Board or the officers referred to in Section 3(c) to the extent that the Board’s powers or authority under the Plan have been delegated to such Committee or officers.

(c) Delegation to Officers. To the extent permitted by applicable law, the Board may delegate to one or more officers of the Company the power to grant Awards (subject to any limitations under the Plan) to employees or officers of the Company or any of its present or future subsidiary corporations and to exercise such other powers under the Plan as the Board may determine, provided that the Board shall fix the terms of the Awards to be granted by such officers (including the exercise price of such Awards, which may include a formula by which the exercise price will be determined) and the maximum number of shares subject to Awards that the officers may grant; provided further, however, that no officer shall be authorized to grant Awards to any “executive officer” of the Company (as defined by Rule 3b-7 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) or to any “officer” of the Company (as defined by Rule 16a-1 under the Exchange Act).

#### 4. Stock Available for Awards.

(a) Number of Shares. Subject to adjustment under Section 8, Awards may be made under the Plan for up to 581,875 shares of common stock, \$0.0001 par value per share, of the Company (the “Common Stock”). If any Award expires or is terminated, surrendered or canceled without having been fully exercised, is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right), or results in any Common Stock not being issued, the unused Common Stock covered by such Award shall again be available for the grant of Awards under the Plan. Further, shares of Common Stock tendered to the Company by a Participant to exercise an Award shall be added to the number of shares of Common Stock available for the grant of Awards under the Plan. However, in the case of Incentive Stock Options (as hereinafter defined), the foregoing provisions shall be subject to any limitations under the Code. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares.

(b) Substitute Awards. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or stock of an entity, the Board may grant Awards in substitution for any options or other stock or stock-based awards granted by such entity or an affiliate thereof. Substitute Awards may be granted on such terms as the Board deems appropriate in the circumstances, notwithstanding any limitations on Awards contained in the Plan. Substitute Awards shall not count against the overall share limit set forth in Section 4(a), except as may be required by reason of Section 422 and related provisions of the Code.

#### 5. Stock Options

(a) General. The Board may grant options to purchase Common Stock (each, an “Option”) and determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to applicable federal or state securities laws, as it considers necessary or advisable. An Option that is not intended to be an Incentive Stock Option shall be designated a “Nonstatutory Stock Option”.

(b) Incentive Stock Options. An Option that the Board intends to be an “incentive stock option” as defined in Section 422 of the Code (an “Incentive Stock Option”) shall only be granted to employees of the Company, any of the Company’s present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Code, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code, and shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code. The Company shall have no liability to a Participant, or any other party, if an Option (or any part thereof) that is intended to be an Incentive Stock Option is not an Incentive Stock Option or for any action taken by the Board, including without limitation the conversion of an Incentive Stock Option to a Nonstatutory Stock Option.

(c) Exercise Price. The Board shall establish the exercise price of each Option and specify the exercise price in the applicable option agreement. The exercise price shall be not less than 100% of the Fair Market Value (as defined below) on the date the Option is granted.

(d) Duration of Options. Each Option shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable option agreement.

(e) Exercise of Options. Options may be exercised by delivery to the Company of a written notice of exercise signed by the proper person or by any other form of notice (including electronic notice) approved by the Board together with payment in full as specified in Section 5(f) for the number of shares for which the Option is exercised. Shares of Common Stock subject to the Option will be delivered by the Company as soon as practicable following exercise.

(f) Payment Upon Exercise. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for as follows:

(1) in cash or by check, payable to the order of the Company;

(2) when the Common Stock is registered under the Exchange Act, except as may otherwise be provided in the applicable option agreement, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;

(3) when the Common Stock is registered under the Exchange Act and to the extent provided for in the applicable option agreement or approved by the Board, in its sole discretion, by delivery (either by actual delivery or attestation) of shares of Common Stock owned by the Participant valued at their fair market value as determined by (or in a manner approved by) the Board (“Fair Market Value”), provided (i) such method of payment is then permitted under applicable law, (ii) such Common Stock, if acquired directly from the Company, was owned by the Participant for such minimum period of time, if any, as may be established by the Board in its discretion and (iii) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;

(4) to the extent permitted by applicable law and provided for in the applicable option agreement or approved by the Board, in its sole discretion, by (i) delivery of a promissory note of the Participant to the Company on terms determined by the Board, or (ii) payment of such other lawful consideration as the Board may determine; or

(5) by any combination of the above permitted forms of payment.

## 6. Restricted Stock; Restricted Stock Units

(a) General. The Board may grant Awards entitling recipients to acquire shares of Common Stock ("Restricted Stock"), subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) from the recipient in the event that conditions specified by the Board in the applicable Award are not satisfied prior to the end of the applicable restriction period or periods established by the Board for such Award. Instead of granting Awards for Restricted Stock, the Board may grant Awards entitling the recipient to receive shares of Common Stock or cash to be delivered at the time such Award vests ("Restricted Stock Units") (Restricted Stock and Restricted Stock Units are each referred to herein as a "Restricted Stock Award").

(b) Terms and Conditions for All Restricted Stock Awards. The Board shall determine the terms and conditions of a Restricted Stock Award, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

### (c) Additional Provisions Relating to Restricted Stock.

(1) Dividends. Participants holding shares of Restricted Stock will be entitled to all ordinary cash dividends paid with respect to such shares, unless otherwise provided by the Board. Unless otherwise provided, by the Board, if any dividends or distributions are paid in shares, or consist of a dividend or distribution to holders of Common Stock other than an ordinary cash dividend, the shares, cash or other property will be subject to the same restrictions on transferability and forfeitability as the shares of Restricted Stock with respect to which they were paid. Each dividend payment will be made no later than the end of the calendar year in which the dividends are paid to shareholders of that class of stock or, if later, the 15th day of the third month following the date the dividends are paid to shareholders of that class of stock.

(2) Stock Certificates. The Company may require that any stock certificates issued in respect of shares of Restricted Stock shall be deposited in escrow by the Participant, together with a stock power endorsed in blank, with the Company (or its designee). At the expiration of the applicable restriction periods, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death (the "Designated Beneficiary"). In the absence of an effective designation by a Participant, "Designated Beneficiary" shall mean the Participant's estate.



## 7. Other Stock-Based Awards

Other Awards of shares of Common Stock, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, shares of Common Stock or other property, may be granted hereunder to Participants (“Other Stock-Based Awards”), including without limitation stock appreciation rights (“SARs”) and Awards entitling recipients to receive shares of Common Stock to be delivered in the future. Such Other Stock-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock-Based Awards may be paid in shares of Common Stock or cash, as the Board shall determine. Subject to the provisions of the Plan, the Board shall determine the terms and conditions of each Other Stock-Based Award, including any purchase price applicable thereto.

## 8. Adjustments for Changes in Common Stock and Certain Other Events

(a) Changes in Capitalization. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of Common Stock other than an ordinary cash dividend, (i) the number and class of securities available under this Plan, (ii) the number and class of securities and exercise price per share of each outstanding Option, (iii) the number of shares subject to and the repurchase price per share subject to each outstanding Restricted Stock Award, and (iv) the terms of each other outstanding Award shall be equitably adjusted by the Company (or substituted Awards may be made, if applicable) in the manner determined by the Board. Without limiting the generality of the foregoing, in the event the Company effects a split of the Common Stock by means of a stock dividend and the exercise price of and the number of shares subject to an outstanding Option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then an optionee who exercises an Option between the record date and the distribution date for such stock dividend shall be entitled to receive, on the distribution date, the stock dividend with respect to the shares of Common Stock acquired upon such Option exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

### (b) Reorganization Events.

(1) Definition. A “Reorganization Event” shall mean: (a) any merger or consolidation of the Company with or into another entity as a result of which all of the Common Stock of the Company is converted into or exchanged for the right to receive cash, securities or other property or is cancelled, (b) any exchange of all of the Common Stock of the Company for cash, securities or other property pursuant to a share exchange transaction or (c) any liquidation or dissolution of the Company.

(2) Consequences of a Reorganization Event on Awards Other than Restricted Stock Awards. In connection with a Reorganization Event, the Board may take any one or more of the following actions as to all or any (or any portion of) outstanding Awards other than Restricted Stock Awards on such terms as the Board determines: (i) provide that Awards shall be assumed, or substantially equivalent Awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to a Participant, provide that the Participant’s unexercised Awards will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the Participant within a specified period following the date of such notice, (iii) provide that outstanding Awards shall become exercisable,

realizable, or deliverable, or restrictions applicable to an Award shall lapse, in whole or in part prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the "Acquisition Price"), make or provide for a cash payment to a Participant equal to the excess, if any, of (A) the Acquisition Price times the number of shares of Common Stock subject to the Participant's Awards (to the extent the exercise price does not exceed the Acquisition Price) over (B) the aggregate exercise price of all such outstanding Awards and any applicable tax withholdings, in exchange for the termination of such Awards, (v) provide that, in connection with a liquidation or dissolution of the Company, Awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise price thereof and any applicable tax withholdings) and (vi) any combination of the foregoing. In taking any of the actions permitted under this Section 8(b), the Board shall not be obligated by the Plan to treat all Awards, all Awards held by a Participant, or all Awards of the same type, identically.

For purposes of clause (i) above, an Option shall be considered assumed if, following consummation of the Reorganization Event, the Option confers the right to purchase, for each share of Common Stock subject to the Option immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); provided, however, that if the consideration received as a result of the Reorganization Event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise of Options to consist solely of common stock of the acquiring or succeeding corporation (or an affiliate thereof) equivalent in value (as determined by the Board) to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.

(3) Consequences of a Reorganization Event on Restricted Stock Awards. Upon the occurrence of a Reorganization Event other than a liquidation or dissolution of the Company, the repurchase and other rights of the Company under each outstanding Restricted Stock Award shall inure to the benefit of the Company's successor and shall, unless the Board determines otherwise, apply to the cash, securities or other property which the Common Stock was converted into or exchanged for pursuant to such Reorganization Event in the same manner and to the same extent as they applied to the Common Stock subject to such Restricted Stock Award. Upon the occurrence of a Reorganization Event involving the liquidation or dissolution of the Company, except to the extent specifically provided to the contrary in the instrument evidencing any Restricted Stock Award or any other agreement between a Participant and the Company, all restrictions and conditions on all Restricted Stock Awards then outstanding shall automatically be deemed terminated or satisfied.

## 9. General Provisions Applicable to Awards

(a) Transferability of Awards. Except as the Board may otherwise determine or provide in an Award, Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution or, other than in the case of an Incentive Stock Option, pursuant to a qualified domestic relations order, and, during the life of the Participant, shall be exercisable only by the Participant. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees.

(b) Documentation. Each Award shall be evidenced in such form (written, electronic or otherwise) as the Board shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) Board Discretion. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.

(d) Termination of Status. The Board shall determine the effect on an Award of the disability, death, termination or other cessation of employment, authorized leave of absence or other change in the employment or other status of a Participant and the extent to which, and the period during which, the Participant, or the Participant's legal representative, conservator, guardian or Designated Beneficiary, may exercise rights under the Award.

(e) Withholding. The Participant must satisfy all applicable federal, state, and local or other income and employment tax withholding obligations before the Company will deliver stock certificates or otherwise recognize ownership of Common Stock under an Award. The Company may decide to satisfy the withholding obligations through additional withholding on salary or wages. If the Company elects not to or cannot withhold from other compensation, the Participant must pay the Company the full amount, if any, required for withholding or have a broker tender to the Company cash equal to the withholding obligations. Payment of withholding obligations is due before the Company will issue any shares on exercise or release from forfeiture of an Award or, if the Company so requires, at the same time as payment of the exercise price unless the Company determines otherwise. If provided for in an Award or approved by the Board in its sole discretion, a Participant may satisfy such tax obligations in whole or in part by delivery of shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their Fair Market Value; provided, however, except as otherwise provided by the Board, that the total tax withholding where stock is being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal and state tax purposes, including payroll taxes, that are applicable to such supplemental taxable income). Shares surrendered to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements.

(f) Amendment of Award.

(1) The Board may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or realization, and converting an Incentive Stock Option to a Nonstatutory Stock Option. The Participant's consent to such action shall be required unless (i) the Board determines that the action, taking into account any related action, would not materially and adversely affect the Participant's rights under the Plan or (ii) the change is permitted under Section 8 hereof.

(2) The Board may, without stockholder approval, amend any outstanding Award granted under the Plan to provide an exercise price per share that is lower than the then-current exercise price per share of such outstanding Award. The Board may also, without stockholder approval, cancel any outstanding award (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan covering the same or a different number of shares of Common Stock and having an exercise price per share lower than the then-current exercise price per share of the cancelled award.

(g) Conditions on Delivery of Stock. The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(h) Acceleration. The Board may at any time provide that any Award shall become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part, as the case may be.

10. Miscellaneous

(a) No Right to Employment or Other Status. No person shall have any claim or right to be granted an Award, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.

(b) No Rights as Stockholder. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be distributed with respect to an Award until becoming the record holder of such shares.

(c) Effective Date and Term of Plan. The Plan shall become effective on the date on which it is adopted by the Board. No Awards shall be granted under the Plan after the expiration of 10 years from the earlier of (i) the date on which the Plan was adopted by the Board or (ii) the date the Plan was approved by the Company's stockholders, but Awards previously granted may extend beyond that date.

(d) Amendment of Plan. The Board may amend, suspend or terminate the Plan or any portion thereof at any time; provided that if at any time the approval of the Company's stockholders is required as to any modification or amendment under Section 422 of the Code or any successor provision with respect to Incentive Stock Options, the Board may not effect such modification or amendment without such approval. Unless otherwise specified in the amendment, any amendment to the Plan adopted in accordance with this Section 10(d) shall apply to, and be binding on the holders of, all Awards outstanding under the Plan at the time the amendment is adopted, provided the Board determines that such amendment does not materially and adversely affect the rights of Participants under the Plan.

(e) Authorization of Sub-Plans. The Board may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable blue sky, securities or tax laws of various jurisdictions. The Board shall establish such sub-plans by adopting supplements to this Plan containing (i) such limitations on the Board's discretion under the Plan as the Board deems necessary or desirable or (ii) such additional terms and conditions not otherwise inconsistent with the Plan as the Board shall deem necessary or desirable. All supplements adopted by the Board shall be deemed to be part of the Plan, but each supplement shall apply only to Participants within the affected jurisdiction and the Company shall not be required to provide copies of any supplement to Participants in any jurisdiction which is not the subject of such supplement.

(f) Compliance with Code Section 409A. No Award shall provide for deferral of compensation that does not comply with Section 409A of the Code, unless the Board, at the time of grant, specifically provides that the Award is not intended to comply with Section 409A of the Code. The Company shall have no liability to a Participant, or any other party, if an Award that is intended to be exempt from, or compliant with, Section 409A is not so exempt or compliant or for any action taken by the Board.

(g) Governing Law. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the State of Delaware, excluding choice-of-law principles of the law of such state that would require the application of the laws of a jurisdiction other than such state.

RESTORBIO, INC.

Restricted Stock Agreement  
Granted Under 2017 Stock Incentive Plan

AGREEMENT made this [\_\_\_\_\_] day of [\_\_\_\_\_\_\_], 20[\_\_\_\_], between resTORbio, Inc., a Delaware corporation (the "Company"), and [\_\_\_\_\_] (the "Participant").

For valuable consideration, receipt of which is acknowledged, the parties hereto agree as follows:

1. Purchase of Shares.

The Company shall issue and sell to the Participant, and the Participant shall purchase from the Company, subject to the terms and conditions set forth in this Agreement and in the Company's 2017 Stock Incentive Plan (the "Plan"), [\_\_\_\_\_] shares (the "Shares") of common stock, \$0.0001 par value, of the Company ("Common Stock"), at a purchase price of \$[ ] per share. The aggregate purchase price for the Shares shall be paid by the Participant by check payable to the order of the Company or such other method as may be acceptable to the Company. Upon receipt by the Company of payment for the Shares, the Company shall issue to the Participant one or more certificates in the name of the Participant for that number of Shares purchased by the Participant. The Participant agrees that the Shares shall be subject to the purchase options set forth in Sections 2 and 5 of this Agreement and the restrictions on transfer set forth in Section 4 of this Agreement.

2. Purchase Option.

(a) In the event that the Participant ceases to be employed by the Company for any reason or no reason, with or without cause, prior to [\_\_\_\_], the Company shall have the right and option (the "Purchase Option") to purchase from the Participant, for a sum of \$[ ] per share (the "Option Price"), some or all of the Unvested Shares (as defined below).

"Unvested Shares" means the total number of Shares multiplied by the Applicable Percentage at the time the Purchase Option becomes exercisable by the Company. The "Applicable Percentage" shall be (i) 100% during the 12-month period ending [\_\_\_\_], 20[ ], (ii) [75%] less [12.5%] for each [six] months of employment completed by the Participant with the Company from and after [\_\_\_\_], 20[ ], and (iii) zero on or after [\_\_\_\_], 20[\_\_\_\_].

(b) If the Participant is employed by a parent or subsidiary of the Company, any references in this Agreement to employment with the Company or termination of employment by or with the Company shall instead be deemed to refer to such parent or subsidiary.

### 3. Exercise of Purchase Option and Closing.

(a) The Company may exercise the Purchase Option by delivering or mailing to the Participant (or his estate), within 90 days after the termination of the employment of the Participant with the Company, a written notice of exercise of the Purchase Option. Such notice shall specify the number of Shares to be purchased. If and to the extent the Purchase Option is not so exercised by the giving of such a notice within such 90-day period, the Purchase Option shall automatically expire and terminate effective upon the expiration of such 90-day period.

(b) Within 10 days after delivery to the Participant of the Company's notice of the exercise of the Purchase Option pursuant to subsection (a) above, the Participant (or his estate) shall, pursuant to the provisions of the Joint Escrow Instructions referred to in Section 7 below, tender to the Company at its principal offices the certificate or certificates representing the Shares which the Company has elected to purchase in accordance with the terms of this Agreement, duly endorsed in blank or with duly endorsed stock powers attached thereto, all in form suitable for the transfer of such Shares to the Company. Promptly following its receipt of such certificate or certificates, the Company shall pay to the Participant the aggregate Option Price for such Shares (provided that any delay in making such payment shall not invalidate the Company's exercise of the Purchase Option with respect to such Shares).

(c) After the time at which any Shares are required to be delivered to the Company for transfer to the Company pursuant to subsection (b) above, the Company shall not pay any dividend to the Participant on account of such Shares or permit the Participant to exercise any of the privileges or rights of a stockholder with respect to such Shares, but shall, in so far as permitted by law, treat the Company as the owner of such Shares.

(d) The Option Price may be payable, at the option of the Company, in cancellation of all or a portion of any outstanding indebtedness of the Participant to the Company or in cash (by check) or both.

(e) The Company shall not purchase any fraction of a Share upon exercise of the Purchase Option, and any fraction of a Share resulting from a computation made pursuant to Section 2 of this Agreement shall be rounded to the nearest whole Share (with any one-half Share being rounded upward).

(f) The Company may assign its Purchase Option to one or more persons or entities.

### 4. Restrictions on Transfer.

(a) The Participant shall not sell, assign, transfer, pledge, hypothecate or otherwise dispose of, by operation of law or otherwise (collectively "transfer") any Shares, or any interest therein, that are subject to the Purchase Option, except that the Participant may transfer such Shares (i) to or for the benefit of any spouse, children, parents, uncles, aunts, siblings, grandchildren and any other relatives approved by the Board of Directors (collectively, "Approved Relatives") or to a trust established solely for the benefit of the Participant and/or

Approved Relatives, provided that such Shares shall remain subject to this Agreement (including without limitation the restrictions on transfer set forth in this Section 4, the Purchase Option and the right of first refusal set forth in Section 5) and such permitted transferee shall, as a condition to such transfer, deliver to the Company a written instrument confirming that such transferee shall be bound by all of the terms and conditions of this Agreement or (ii) as part of the sale of all or substantially all of the shares of capital stock of the Company (including pursuant to a merger or consolidation), provided that, in accordance with the Plan, the securities or other property received by the Participant in connection with such transaction shall remain subject to this Agreement.

(b) The Participant shall not transfer any Shares, or any interest therein, that are no longer subject to the Purchase Option, except in accordance with Section 5 below.

#### 5. Right of First Refusal.

(a) If the Participant proposes to transfer any Shares that are no longer subject to the Purchase Option (either because they are no longer Unvested Shares or because the Purchase Option expired unexercised), then the Participant shall first give written notice of the proposed transfer (the "Transfer Notice") to the Company. The Transfer Notice shall name the proposed transferee and state the number of such Shares the Participant proposes to transfer (the "Offered Shares"), the price per share and all other material terms and conditions of the transfer.

(b) For 30 days following its receipt of such Transfer Notice, the Company shall have the option to purchase all or part of the Offered Shares at the price and upon the terms set forth in the Transfer Notice. In the event the Company elects to purchase all or part of the Offered Shares, it shall give written notice of such election to the Participant within such 30-day period. Within 10 days after his or her receipt of such notice, the Participant shall tender to the Company at its principal offices the certificate or certificates representing the Offered Shares to be purchased by the Company, duly endorsed in blank by the Participant or with duly endorsed stock powers attached thereto, all in a form suitable for transfer of the Offered Shares to the Company. Promptly following receipt of such certificate or certificates, the Company shall deliver or mail to the Participant a check in payment of the purchase price for such Offered Shares; provided that if the terms of payment set forth in the Transfer Notice were other than cash against delivery, the Company may pay for the Offered Shares on the same terms and conditions as were set forth in the Transfer Notice; and provided further that any delay in making such payment shall not invalidate the Company's exercise of its option to purchase the Offered Shares.

(c) If the Company does not elect to acquire all of the Offered Shares, the Participant may, within the 30-day period following the expiration of the option granted to the Company under subsection (b) above, transfer the Offered Shares which the Company has not elected to acquire to the proposed transferee, provided that such transfer shall not be on terms and conditions more favorable to the transferee than those contained in the Transfer Notice. Notwithstanding any of the above, all Offered Shares transferred pursuant to this Section 5 shall remain subject to this Agreement (including without limitation the restrictions on transfer set forth in Section 4 and the right of first refusal set forth in this Section 5) and such transferee shall, as a condition to such transfer, deliver to the Company a written instrument confirming that such transferee shall be bound by all of the terms and conditions of this Agreement.



(d) After the time at which the Offered Shares are required to be delivered to the Company for transfer to the Company pursuant to subsection (b) above, the Company shall not pay any dividend to the Participant on account of such Offered Shares or permit the Participant to exercise any of the privileges or rights of a stockholder with respect to such Offered Shares, but shall, insofar as permitted by law, treat the Company as the owner of such Offered Shares.

(e) The following transactions shall be exempt from the provisions of this Section 5:

(1) a transfer of Shares to or for the benefit of any Approved Relatives, or to a trust established solely for the benefit of the Participant and/or Approved Relatives;

(2) any transfer pursuant to an effective registration statement filed by the Company under the Securities Act of 1933, as amended (the "Securities Act"); and

(3) the sale of all or substantially all of the outstanding shares of capital stock of the Company (including pursuant to a merger or consolidation);

provided, however, that in the case of a transfer pursuant to clause (1) above, such Shares shall remain subject to this Agreement (including without limitation the restrictions on transfer set forth in Section 4 and the right of first refusal set forth in this Section 5) and such transferee shall, as a condition to such transfer, deliver to the Company a written instrument confirming that such transferee shall be bound by all of the terms and conditions of this Agreement.

(f) The Company may assign its rights to purchase Offered Shares in any particular transaction under this Section 5 to one or more persons or entities.

(g) The provisions of this Section 5 shall terminate upon the earlier of the following events:

(1) the closing of the sale of shares of Common Stock in an underwritten public offering pursuant to an effective registration statement filed by the Company under the Securities Act; or

(2) the sale of all or substantially all of the outstanding shares of capital stock, assets or business of the Company, by merger, consolidation, sale of assets or otherwise (other than a merger or consolidation in which all or substantially all of the individuals and entities who were beneficial owners of the Company's voting securities immediately prior to such transaction beneficially own, directly or indirectly, more than 50% (determined on an as-converted basis) of the outstanding securities entitled to vote generally in the election of directors of the resulting, surviving or acquiring corporation in such transaction).

(h) The Company shall not be required (1) to transfer on its books any of the Shares which shall have been sold or transferred in violation of any of the provisions set forth in this Agreement, or (2) to treat as owner of such Shares or to pay dividends to any transferee to whom any such Shares shall have been so sold or transferred.

#### 6. Agreement in Connection with Initial Public Offering.

The Participant agrees, in connection with the initial underwritten public offering of the Common Stock pursuant to a registration statement under the Securities Act, (i) not to (a) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable for shares of Common Stock or (b) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of shares of Common Stock, whether any transaction described in clause (a) or (b) is to be settled by delivery of shares of Common Stock or other securities, in cash or otherwise, during the period beginning on the date of the filing of such registration statement with the Securities and Exchange Commission and ending 180 days from the date of the final prospectus relating to the offering (plus up to an additional 34 days to the extent requested by the managing underwriters for such offering in order to address Rule 2711(f) of the National Association of Securities Dealers, Inc. or any similar successor provision), and (ii) to execute any agreement reflecting clause (i) above as may be requested by the Company or the managing underwriters at the time of such offering. The Company may impose stop-transfer instructions with respect to the shares of Common Stock or other securities subject to the foregoing restriction until the end of the “lock-up” period.

#### 7. Escrow.

The Participant shall, upon the execution of this Agreement, execute Joint Escrow Instructions in the form attached to this Agreement as Exhibit A. The Joint Escrow Instructions shall be delivered to the President of the Company, as escrow agent thereunder. The Participant shall deliver to such escrow agent a stock assignment duly endorsed in blank, in the form attached to this Agreement as Exhibit B, and hereby instructs the Company to deliver to such escrow agent, on behalf of the Participant, the certificate(s) evidencing the Shares issued hereunder. Such materials shall be held by such escrow agent pursuant to the terms of such Joint Escrow Instructions.

#### 8. Restrictive Legends.

All certificates representing Shares shall have affixed thereto legends in substantially the following form, in addition to any other legends that may be required under federal or state securities laws:

“The shares of stock represented by this certificate are subject to restrictions on transfer and an option to purchase set forth in a certain Restricted Stock Agreement between the corporation and the registered owner of these shares (or his predecessor in interest), and such Agreement is available for inspection without charge at the office of the Secretary of the corporation.”

“The shares represented by this certificate have not been registered under the Securities Act of 1933, as amended, and may not be sold, transferred or otherwise disposed of in the absence of an effective registration statement under such Act or an opinion of counsel satisfactory to the corporation to the effect that such registration is not required.”

9. Provisions of the Plan.

(a) This Agreement is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this Agreement.

(b) As provided in the Plan, upon the occurrence of a Reorganization Event (as defined in the Plan), the repurchase and other rights of the Company hereunder shall inure to the benefit of the Company's successor and shall apply to the cash, securities or other property which the Shares were converted into or exchanged for pursuant to such Reorganization Event in the same manner and to the same extent as they applied to the Shares under this Agreement. If, in connection with a Reorganization Event, a portion of the cash, securities and/or other property received upon the conversion or exchange of the Shares is to be placed into escrow to secure indemnification or similar obligations, the mix between the vested and unvested portion of such cash, securities and/or other property that is placed into escrow shall be the same as the mix between the vested and unvested portion of such cash, securities and/or other property that is not subject to escrow.

10. Investment Representations.

The Participant represents, warrants and covenants as follows:

(a) The Participant is purchasing the Shares for his own account for investment only, and not with a view to, or for sale in connection with, any distribution of the Shares in violation of the Securities Act, or any rule or regulation under the Securities Act.

(b) The Participant has had such opportunity as he has deemed adequate to obtain from representatives of the Company such information as is necessary to permit him to evaluate the merits and risks of his investment in the Company.

(c) The Participant has sufficient experience in business, financial and investment matters to be able to evaluate the risks involved in the purchase of the Shares and to make an informed investment decision with respect to such purchase.

(d) The Participant can afford a complete loss of the value of the Shares and is able to bear the economic risk of holding such Shares for an indefinite period.

(e) The Participant understands that (i) the Shares have not been registered under the Securities Act and are “restricted securities” within the meaning of Rule 144 under the Securities Act; (ii) the Shares cannot be sold, transferred or otherwise disposed of unless they are subsequently registered under the Securities Act or an exemption from registration is then available; (iii) in any event, the exemption from registration under Rule 144 will not be available for at least one year and even then will not be available unless a public market then exists for the Common Stock, adequate information concerning the Company is then available to the public, and other terms and conditions of Rule 144 are complied with; and (iv) there is now no registration statement on file with the Securities and Exchange Commission with respect to any stock of the Company and the Company has no obligation or current intention to register the Shares under the Securities Act.

11. Withholding Taxes; Section 83(b) Election.

(a) The Participant acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Participant any federal, state or local taxes of any kind required by law to be withheld with respect to the purchase of the Shares by the Participant or the lapse of the Purchase Option.

(b) The Participant has reviewed with the Participant’s own tax advisors the federal, state, local and foreign tax consequences of this investment and the transactions contemplated by this Agreement. The Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents. The Participant understands that the Participant (and not the Company) shall be responsible for the Participant’s own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement. The Participant understands that it may be beneficial in many circumstances to elect to be taxed at the time the Shares are purchased rather than when and as the Company’s Purchase Option expires by filing an election under Section 83(b) of the Internal Revenue Code of 1986 with the I.R.S. within 30 days from the date of purchase.

THE PARTICIPANT ACKNOWLEDGES THAT IT IS SOLELY THE PARTICIPANT’S RESPONSIBILITY AND NOT THE COMPANY’S TO FILE TIMELY THE ELECTION UNDER SECTION 83(b), EVEN IF THE PARTICIPANT REQUESTS THE COMPANY OR ITS REPRESENTATIVES TO MAKE THIS FILING ON THE PARTICIPANT’S BEHALF.

12. Miscellaneous.

(a) No Rights to Employment. The Participant acknowledges and agrees that the vesting of the Shares pursuant to Section 2 hereof is earned only by continuing service as an employee at the will of the Company (not through the act of being hired or purchasing shares hereunder). The Participant further acknowledges and agrees that the transactions contemplated hereunder and the vesting schedule set forth herein do not constitute an express or implied promise of continued engagement as an employee or consultant for the vesting period, for any period, or at all.

(b) Severability. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, and each other provision of this Agreement shall be severable and enforceable to the extent permitted by law.

(c) Waiver. Any provision for the benefit of the Company contained in this Agreement may be waived, either generally or in any particular instance, by the Board of Directors of the Company.

(d) Binding Effect. This Agreement shall be binding upon and inure to the benefit of the Company and the Participant and their respective heirs, executors, administrators, legal representatives, successors and assigns, subject to the restrictions on transfer set forth in Sections 4 and 5 of this Agreement.

(e) Notice. All notices required or permitted hereunder shall be in writing and deemed effectively given upon personal delivery or five days after deposit in the United States Post Office, by registered or certified mail, postage prepaid, addressed to the other party hereto at the address shown beneath his or its respective signature to this Agreement, or at such other address or addresses as either party shall designate to the other in accordance with this Section 12(e).

(f) Pronouns. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular form of nouns and pronouns shall include the plural, and vice versa.

(g) Entire Agreement. This Agreement and the Plan constitute the entire agreement between the parties, and supersedes all prior agreements and understandings, relating to the subject matter of this Agreement.

(h) Amendment. This Agreement may be amended or modified only by a written instrument executed by both the Company and the Participant.

(i) Governing Law. This Agreement shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware without regard to any applicable conflicts of laws.

(j) Participant's Acknowledgments. The Participant acknowledges that he or she: (i) has read this Agreement; (ii) has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of the Participant's own choice or has voluntarily declined to seek such counsel; (iii) understands the terms and consequences of this Agreement; (iv) is fully aware of the legal and binding effect of this Agreement; and (v) understands that the law firm of WilmerHale, is acting as counsel to the Company in connection with the transactions contemplated by the Agreement, and is not acting as counsel for the Participant.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

RESTORBIO, INC.

By: \_\_\_\_\_

Name:

Title:

PARTICIPANT:

\_\_\_\_\_  
[Name of Participant]

Address: \_\_\_\_\_

\_\_\_\_\_

RESTORBIO, INC.

Joint Escrow Instructions

\_\_\_\_\_, [ ]

resTORbio, Inc.  
President  
501 Boylston Street, Suite 6102  
Boston, MA 02116

Dear Sir or Madam:

As Escrow Agent for resTORbio, Inc., a Delaware corporation, and its successors in interest (the "Company") under the Restricted Stock Agreement (the "Agreement") of even date herewith, to which a copy of these Joint Escrow Instructions is attached, and the undersigned person ("Holder"), you are hereby authorized and directed to hold the documents delivered to you pursuant to the terms of the Agreement in accordance with the following instructions:

1. Appointment. Holder irrevocably authorizes the Company to deposit with you any certificates evidencing Shares (as defined in the Agreement) to be held by you hereunder and any additions and substitutions to said Shares. For purposes of these Joint Escrow Instructions, "Shares" shall be deemed to include any additional or substitute property. Holder does hereby irrevocably constitute and appoint you as his attorney-in-fact and agent for the term of this escrow to execute with respect to such Shares all documents necessary or appropriate to make such Shares negotiable and to complete any transaction herein contemplated. Subject to the provisions of this Section 1 and the terms of the Agreement, Holder shall exercise all rights and privileges of a stockholder of the Company while the Shares are held by you.

2. Closing of Purchase.

(a) Upon any purchase by the Company of the Shares pursuant to the Agreement, the Company shall give to Holder and you a written notice specifying the number of Shares to be purchased, the purchase price for the Shares, as determined pursuant to the Agreement, and the time for a closing hereunder (the "Closing") at the principal office of the Company. Holder and the Company hereby irrevocably authorize and direct you to close the transaction contemplated by such notice in accordance with the terms of said notice.

(b) At the Closing, you are directed (i) to date the stock assignment form or forms necessary for the transfer of the Shares, (ii) to fill in on such form or forms the number of Shares being transferred, and (iii) to deliver the same, together with the certificate or certificates evidencing the Shares to be transferred, to the Company against the simultaneous delivery to you of the purchase price for the Shares being purchased pursuant to the Agreement.

3. Withdrawal. The Holder shall have the right to withdraw from this escrow any Shares as to which the Purchase Option (as defined in the Agreement) has terminated or expired.

4. Duties of Escrow Agent.

(a) Your duties hereunder may be altered, amended, modified or revoked only by a writing signed by all of the parties hereto.

(b) You shall be obligated only for the performance of such duties as are specifically set forth herein and may rely and shall be protected in relying or refraining from acting on any instrument reasonably believed by you to be genuine and to have been signed or presented by the proper party or parties. You shall not be personally liable for any act you may do or omit to do hereunder as Escrow Agent or as attorney-in-fact of Holder while acting in good faith and in the exercise of your own good judgment, and any act done or omitted by you pursuant to the advice of your own attorneys shall be conclusive evidence of such good faith.

(c) You are hereby expressly authorized to disregard any and all warnings given by any of the parties hereto or by any other person or entity, excepting only orders or process of courts of law, and are hereby expressly authorized to comply with and obey orders, judgments or decrees of any court. If you are uncertain of any actions to be taken or instructions to be followed, you may refuse to act in the absence of an order, judgment or decrees of a court. In case you obey or comply with any such order, judgment or decree of any court, you shall not be liable to any of the parties hereto or to any other person or entity, by reason of such compliance, notwithstanding any such order, judgment or decree being subsequently reversed, modified, annulled, set aside, vacated or found to have been entered without jurisdiction.

(d) You shall not be liable in any respect on account of the identity, authority or rights of the parties executing or delivering or purporting to execute or deliver the Agreement or any documents or papers deposited or called for hereunder.

(e) You shall be entitled to employ such legal counsel and other experts as you may deem necessary properly to advise you in connection with your obligations hereunder and may rely upon the advice of such counsel.

(f) Your rights and responsibilities as Escrow Agent hereunder shall terminate if (i) you cease to be Secretary of the Company or (ii) you resign by written notice to each party. In the event of a termination under clause (i), your successor as Secretary shall become Escrow Agent hereunder; in the event of a termination under clause (ii), the Company shall appoint a successor Escrow Agent hereunder.

(g) If you reasonably require other or further instruments in connection with these Joint Escrow Instructions or obligations in respect hereto, the necessary parties hereto shall join in furnishing such instruments.



(h) It is understood and agreed that if you believe a dispute has arisen with respect to the delivery and/or ownership or right of possession of the securities held by you hereunder, you are authorized and directed to retain in your possession without liability to anyone all or any part of said securities until such dispute shall have been settled either by mutual written agreement of the parties concerned or by a final order, decree or judgment of a court of competent jurisdiction after the time for appeal has expired and no appeal has been perfected, but you shall be under no duty whatsoever to institute or defend any such proceedings.

(i) These Joint Escrow Instructions set forth your sole duties with respect to any and all matters pertinent hereto and no implied duties or obligations shall be read into these Joint Escrow Instructions against you.

(j) The Company shall indemnify you and hold you harmless against any and all damages, losses, liabilities, costs, and expenses, including attorneys' fees and disbursements, (including without limitation the fees of counsel retained pursuant to Section 4(e) above, for anything done or omitted to be done by you as Escrow Agent in connection with this Agreement or the performance of your duties hereunder, except such as shall result from your gross negligence or willful misconduct.

5. Notice. Any notice required or permitted hereunder shall be given in writing and shall be deemed effectively given upon personal delivery or upon deposit in the United States Post Office, by registered or certified mail with postage and fees prepaid, addressed to each of the other parties thereunto entitled at the following addresses, or at such other addresses as a party may designate by ten days' advance written notice to each of the other parties hereto.

COMPANY:	Notices to the Company shall be sent to the address set forth in the salutation hereto, Attn: President
HOLDER:	Notices to Holder shall be sent to the address set forth below Holder's signature below.
ESCROW AGENT:	Notices to the Escrow Agent shall be sent to the address set forth in the salutation hereto.

6. Miscellaneous.

(a) By signing these Joint Escrow Instructions, you become a party hereto only for the purpose of said Joint Escrow Instructions, and you do not become a party to the Agreement.

(b) This instrument shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

Very truly yours,

RESTORBIO, INC.

By: \_\_\_\_\_

Name:

Title:

HOLDER:

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
Print Name

Address: \_\_\_\_\_

Date Signed: \_\_\_\_\_

ESCROW AGENT:  
\_\_\_\_\_

Exhibit B

(STOCK ASSIGNMENT SEPARATE FROM CERTIFICATE)

FOR VALUE RECEIVED, I hereby sell, assign and transfer unto \_\_\_\_\_ (\_\_\_\_\_) shares of Common Stock, \$0.0001 par value per share, of resTORbio, Inc. (the "Corporation") standing in my name on the books of the Corporation represented by Certificate(s) Number \_\_\_\_\_ herewith, and do hereby irrevocably constitute and appoint \_\_\_\_\_ attorney to transfer the said stock on the books of the Corporation with full power of substitution in the premises.

HOLDER:

\_\_\_\_\_  
Name:

Dated: \_\_\_\_\_

IN PRESENCE OF \_\_\_\_\_

NOTICE: The signature(s) to this assignment must correspond with the name as written upon the face of the certificate, in every particular, without alteration, enlargement, or any change whatever and must be guaranteed by a commercial bank, trust company or member firm of the Boston, New York or Midwest Stock Exchange.

Nonstatutory Stock Option Agreement  
Granted Under 2017 Stock Incentive Plan

1. Grant of Option.

This agreement evidences the grant by resTORbio, Inc., a Delaware corporation (the "Company"), on \_\_\_\_\_, 20[\_\_\_\_] (the "Grant Date") to [\_\_\_\_], an [employee], [consultant], [director] of the Company (the "Participant"), of an option to purchase, in whole or in part, on the terms provided herein and in the Company's 2017 Stock Incentive Plan (the "Plan"), a total of [\_\_\_\_] shares (the "Shares") of common stock, \$0.0001 par value per share, of the Company ("Common Stock") at \$[\_\_\_\_\_] per Share. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on [\_\_\_\_\_] (the "Final Exercise Date").

It is intended that the option evidenced by this agreement shall not be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code"). Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

2. Vesting Schedule.

This option will become exercisable ("vest") as to [25]% of the original number of Shares on the [first] anniversary of the Vesting Commencement Date and as to an additional [12.5]% of the original number of Shares at the end of each successive [six-month] period following the first anniversary of the Vesting Commencement Date until the [fourth] anniversary of the Vesting Commencement Date. The Vesting Commencement Date shall be [\_\_\_\_\_].

The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this option under Section 3 hereof or the Plan.

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this option shall be accompanied by a completed Notice of Stock Option Exercise in the form attached hereto as Exhibit A, signed by the Participant, and received by the Company at its principal office, accompanied by this Agreement, and payment in full in the manner provided in the Plan. The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the Grant Date, an [employee or officer of], or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive option grants under the Plan (an "Eligible Participant").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (d) and (e) below, the right to exercise this option shall terminate three months after such cessation (but in no event after the Final Exercise Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the non-competition or confidentiality provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(d) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Final Exercise Date while he or she is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (e) below, this option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee), provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death or disability, and further provided that this option shall not be exercisable after the Final Exercise Date.

(e) Termination for Cause. If, prior to the Final Exercise Date, the Participant's employment or other relationship with the Company is terminated by the Company for Cause (as defined below), the right to exercise this option shall terminate immediately upon the effective date of such termination of employment or other relationship. If the Participant is party to an employment, consulting or severance agreement with the Company that contains a definition of "cause" for termination of employment or other relationship, "Cause" shall have the meaning ascribed to such term in such agreement. Otherwise, "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant's employment or other relationship shall be considered to have been terminated for "Cause" if the Company determines, within 30 days after the Participant's resignation, that termination for Cause was warranted.

#### 4. Company Right of First Refusal.

(a) Notice of Proposed Transfer. If the Participant proposes to sell, assign, transfer, pledge, hypothecate or otherwise dispose of, by operation of law or otherwise (collectively, "transfer") any Shares acquired upon exercise of this option, then the Participant shall first give written notice of the proposed transfer (the "Transfer Notice") to the Company. The Transfer Notice shall name the proposed transferee and state the number of such Shares the Participant proposes to transfer (the "Offered Shares"), the price per share and all other material terms and conditions of the transfer.

(b) Company Right to Purchase. For 30 days following its receipt of such Transfer Notice, the Company shall have the option to purchase all or part of the Offered Shares at the price and upon the terms set forth in the Transfer Notice. In the event the Company elects to purchase all or part of the Offered Shares, it shall give written notice of such election to the Participant within such 30-day period. Within 10 days after his or her receipt of such notice, the Participant shall tender to the Company at its principal offices the certificate or certificates representing the Offered Shares to be purchased by the Company, duly endorsed in blank by the Participant or with duly endorsed stock powers attached thereto, all in a form suitable for transfer of the Offered Shares to the Company. Promptly following receipt of such certificate or certificates, the Company shall deliver or mail to the Participant a check in payment of the purchase price for such Offered Shares; provided that if the terms of payment set forth in the Transfer Notice were other than cash against delivery, the Company may pay for the Offered Shares on the same terms and conditions as were set forth in the Transfer Notice; and provided further that any delay in making such payment shall not invalidate the Company's exercise of its option to purchase the Offered Shares.

(c) Shares Not Purchased By Company. If the Company does not elect to acquire all of the Offered Shares, the Participant may, within the 30-day period following the expiration of the option granted to the Company under subsection (b) above, transfer the Offered Shares which the Company has not elected to acquire to the proposed transferee, provided that such transfer shall not be on terms and conditions more favorable to the transferee than those contained in the Transfer Notice. Notwithstanding any of the above, all Offered Shares transferred pursuant to this Section 4 shall remain subject to the right of first refusal set forth in this Section 4 and such transferee shall, as a condition to such transfer, deliver to the Company a written instrument confirming that such transferee shall be bound by all of the terms and conditions of this Section 4.

(d) Consequences of Non-Delivery. After the time at which the Offered Shares are required to be delivered to the Company for transfer to the Company pursuant to subsection (b) above, the Company shall not pay any dividend to the Participant on account of such Offered Shares or permit the Participant to exercise any of the privileges or rights of a stockholder with respect to such Offered Shares, but shall, insofar as permitted by law, treat the Company as the owner of such Offered Shares.

(e) Exempt Transactions. The following transactions shall be exempt from the provisions of this Section 4:

- (1) any transfer of Shares to or for the benefit of any spouse, child or grandchild of the Participant, or to a trust for their benefit;
- (2) any transfer pursuant to an effective registration statement filed by the Company under the Securities Act of 1933, as amended (the "Securities Act"); and
- (3) the sale of all or substantially all of the outstanding shares of capital stock of the Company (including pursuant to a merger or consolidation);

provided, however, that in the case of a transfer pursuant to clause (1) above, such Shares shall remain subject to the right of first refusal set forth in this Section 4.

(f) Assignment of Company Right. The Company may assign its rights to purchase Offered Shares in any particular transaction under this Section 4 to one or more persons or entities.

(g) Termination. The provisions of this Section 4 shall terminate upon the earlier of the following events:

(1) the closing of the sale of shares of Common Stock in an underwritten public offering pursuant to an effective registration statement filed by the Company under the Securities Act; or

(2) the sale of all or substantially all of the outstanding shares of capital stock, assets or business of the Company, by merger, consolidation, sale of assets or otherwise (other than a merger or consolidation in which all or substantially all of the individuals and entities who were beneficial owners of the Company's voting securities immediately prior to such transaction beneficially own, directly or indirectly, more than 50% (determined on an as-converted basis) of the outstanding securities entitled to vote generally in the election of directors of the resulting, surviving or acquiring corporation in such transaction).

(h) No Obligation to Recognize Invalid Transfer. The Company shall not be required (1) to transfer on its books any of the Shares which shall have been sold or transferred in violation of any of the provisions set forth in this Section 4, or (2) to treat as owner of such Shares or to pay dividends to any transferee to whom any such Shares shall have been so sold or transferred.

(i) Legends. The certificate representing Shares shall bear a legend substantially in the following form (in addition to, or in combination with, any legend required by applicable federal and state securities laws and agreements relating to the transfer of the Company securities):

"The shares represented by this certificate are subject to a right of first refusal in favor of the Company, as provided in a certain stock option agreement with the Company."

#### 5. Agreement in Connection with Initial Public Offering.

The Participant agrees, in connection with the initial underwritten public offering of the Common Stock pursuant to a registration statement under the Securities Act, (i) not to (a) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any other securities of the Company or (b) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of shares of Common Stock or other securities of the Company, whether any transaction described in clause (a) or (b) is to be settled by delivery of securities, in cash or otherwise, during the period beginning on the date of

the filing of such registration statement with the Securities and Exchange Commission and ending 180 days after the date of the final prospectus relating to the offering (plus up to an additional 34 days to the extent requested by the managing underwriters for such offering in order to address Rule 2711(f) of the National Association of Securities Dealers, Inc. or any similar successor provision), and (ii) to execute any agreement reflecting clause (i) above as may be requested by the Company or the managing underwriters at the time of such offering. The Company may impose stop-transfer instructions with respect to the shares of Common Stock or other securities subject to the foregoing restriction until the end of the "lock-up" period.

6. Withholding.

No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option.

7. Transfer Restrictions.

(a) This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this option shall be exercisable only by the Participant.

(b) The Participant agrees that he or she will not transfer any Shares issued pursuant to the exercise of this option unless the transferee, as a condition to such transfer, delivers to the Company a written instrument confirming that such transferee shall be bound by all of the terms and conditions of Section 4 and Section 5; provided that such a written confirmation shall not be required with respect to (1) Section 4 after such provision has terminated in accordance with Section 4(g) or (2) Section 5 after the completion of the lock-up period in connection with the Company's initial underwritten public offering.

8. Provisions of the Plan.

This option is subject to the provisions of the Plan (including the provisions relating to amendments to the Plan), a copy of which is furnished to the Participant with this option.



IN WITNESS WHEREOF, the Company has caused this option to be executed under its corporate seal by its duly authorized officer. This option shall take effect as a sealed instrument.

RESTORBIO, INC.

By: \_\_\_\_\_  
Name:  
Title:

PARTICIPANT'S ACCEPTANCE

The undersigned hereby accepts the foregoing option and agrees to the terms and conditions thereof. The undersigned hereby acknowledges receipt of a copy of the Company's 2017 Stock Incentive Plan.

PARTICIPANT:

\_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

EXHIBIT A

NOTICE OF STOCK OPTION EXERCISE

[DATE]<sup>1</sup>

resTORbio, Inc.  
501 Boylston Street, Suite 6102  
Boston, MA 02116

Attention: Treasurer

Dear Sir or Madam:

I am the holder of a Nonstatutory Stock Option granted to me under the resTORbio, Inc. (the “**Company**”) 2017 Stock Incentive Plan on [ ]<sup>2</sup> for the purchase of [ ]<sup>3</sup> shares of Common Stock of the Company at a purchase price of \$[ ]<sup>4</sup> per share.

I hereby exercise my option to purchase [ ]<sup>5</sup> shares of Common Stock (the “**Shares**”), for which I have enclosed [ ]<sup>6</sup> in the amount of [ ]<sup>7</sup>. Please register my stock certificate as follows:

Name(s): \_\_\_\_\_<sup>8</sup>

\_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

I represent, warrant and covenant as follows:

- \_\_\_\_\_
- 1 Enter date of exercise.
  - 2 Enter the date of grant.
  - 3 Enter the total number of shares of Common Stock for which the option was granted.
  - 4 Enter the option exercise price per share of Common Stock.
  - 5 Enter the number of shares of Common Stock to be purchased upon exercise of all or part of the option.
  - 6 Enter “cash”, “personal check” or if permitted by the option or Plan, “stock certificates No. XXXX and XXXX”.
  - 7 Enter the dollar amount (price per share of Common Stock times the number of shares of Common Stock to be purchased), or the number of shares tendered. Fair market value of shares tendered, together with cash or check, must cover the purchase price of the shares issued upon exercise.
  - 8 Enter name(s) to appear on stock certificate in one of the following formats: (a) your name only (i.e., John Doe); (b) your name and other name (i.e., John Doe and Jane Doe, Joint Tenants with Right to Survivorship); or for Nonstatutory Stock Options only, (c) a child’s name, with you as custodian (i.e. Jane Doe, Custodian for Tommy Doe). Note: There may be income and/or gift tax consequences for registering shares in a child’s name.

1. I am purchasing the Shares for my own account for investment only, and not with a view to, or for sale in connection with, any distribution of the Shares in violation of the Securities Act of 1933 (the “**Securities Act**”), or any rule or regulation under the Securities Act.
2. I have had such opportunity as I have deemed adequate to obtain from representatives of the Company such information as is necessary to permit me to evaluate the merits and risks of my investment in the Company.
3. I have sufficient experience in business, financial and investment matters to be able to evaluate the risks involved in the purchase of the Shares and to make an informed investment decision with respect to such purchase.
4. I can afford a complete loss of the value of the Shares and am able to bear the economic risk of holding such Shares for an indefinite period.
5. I understand that (i) the Shares have not been registered under the Securities Act and are “restricted securities” within the meaning of Rule 144 under the Securities Act, (ii) the Shares cannot be sold, transferred or otherwise disposed of unless they are subsequently registered under the Securities Act or an exemption from registration is then available; (iii) in any event, the exemption from registration under Rule 144 will not be available for at least one year and even then will not be available unless a public market then exists for the Common Stock, adequate information concerning the Company is then available to the public, and other terms and conditions of Rule 144 are complied with; and (iv) there is now no registration statement on file with the Securities and Exchange Commission with respect to any stock of the Company and the Company has no obligation or current intention to register the Shares under the Securities Act.

Very truly yours,

---

[Name]

RESTORBIO, INC.

Incentive Stock Option Agreement  
Granted Under 2017 Stock Incentive Plan

1. Grant of Option.

This agreement evidences the grant by resTORbio, Inc., a Delaware corporation (the "Company"), on \_\_\_\_\_, 20[\_\_\_\_] (the "Grant Date") to [\_\_\_\_], an employee of the Company (the "Participant"), of an option to purchase, in whole or in part, on the terms provided herein and in the Company's 2017 Stock Incentive Plan (the "Plan"), a total of [\_\_\_\_] shares (the "Shares") of common stock, \$0.0001 par value per share, of the Company ("Common Stock") at \$[\_\_\_\_] per Share. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on [\_\_\_\_] (the "Final Exercise Date").

It is intended that the option evidenced by this agreement shall be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code"). Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

2. Vesting Schedule.

This option will become exercisable ("vest") as to [25]% of the original number of Shares on the [first] anniversary of the Vesting Commencement Date and as to an additional [12.5]% of the original number of Shares at the end of each successive [six-month] period following the first anniversary of the Vesting Commencement Date until the [fourth] anniversary of the Vesting Commencement Date. The Vesting Commencement Date shall be [\_\_\_\_].

The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this option under Section 3 hereof or the Plan.

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this option shall be accompanied by a completed Notice of Stock Option Exercise in the form attached hereto as Exhibit A, signed by the Participant, and received by the Company at its principal office, accompanied by this Agreement, and payment in full in the manner provided in the Plan. The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the Grant Date, an employee or officer of, or consultant or advisor to, the Company or any parent or subsidiary of the Company as defined in Section 424(e) or (f) of the Code (an "Eligible Participant").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (d) and (e) below, the right to exercise this option shall terminate three months after such cessation (but in no event after the Final Exercise Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the non-competition or confidentiality provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(d) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Final Exercise Date while he or she is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (e) below, this option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee), provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death or disability, and further provided that this option shall not be exercisable after the Final Exercise Date.

(e) Termination for Cause. If, prior to the Final Exercise Date, the Participant's employment is terminated by the Company for Cause (as defined below), the right to exercise this option shall terminate immediately upon the effective date of such termination of employment. If the Participant is party to an employment or severance agreement with the Company that contains a definition of "cause" for termination of employment, "Cause" shall have the meaning ascribed to such term in such agreement. Otherwise, "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant's employment shall be considered to have been terminated for Cause if the Company determines, within 30 days after the Participant's resignation, that termination for Cause was warranted.

#### 4. Company Right of First Refusal.

(a) Notice of Proposed Transfer. If the Participant proposes to sell, assign, transfer, pledge, hypothecate or otherwise dispose of, by operation of law or otherwise (collectively, "transfer") any Shares acquired upon exercise of this option, then the Participant shall first give written notice of the proposed transfer (the "Transfer Notice") to the Company. The Transfer Notice shall name the proposed transferee and state the number of such Shares the Participant proposes to transfer (the "Offered Shares"), the price per share and all other material terms and conditions of the transfer.

(b) Company Right to Purchase. For 30 days following its receipt of such Transfer Notice, the Company shall have the option to purchase all or part of the Offered Shares at the price and upon the terms set forth in the Transfer Notice. In the event the Company elects to purchase all or part of the Offered Shares, it shall give written notice of such election to the Participant within such 30-day period. Within 10 days after his or her receipt of such notice, the Participant shall tender to the Company at its principal offices the certificate or certificates representing the Offered Shares to be purchased by the Company, duly endorsed in blank by the Participant or with duly endorsed stock powers attached thereto, all in a form suitable for transfer of the Offered Shares to the Company. Promptly following receipt of such certificate or certificates, the Company shall deliver or mail to the Participant a check in payment of the purchase price for such Offered Shares; provided that if the terms of payment set forth in the Transfer Notice were other than cash against delivery, the Company may pay for the Offered Shares on the same terms and conditions as were set forth in the Transfer Notice; and provided further that any delay in making such payment shall not invalidate the Company's exercise of its option to purchase the Offered Shares.

(c) Shares Not Purchased By Company. If the Company does not elect to acquire all of the Offered Shares, the Participant may, within the 30-day period following the expiration of the option granted to the Company under subsection (b) above, transfer the Offered Shares which the Company has not elected to acquire to the proposed transferee, provided that such transfer shall not be on terms and conditions more favorable to the transferee than those contained in the Transfer Notice. Notwithstanding any of the above, all Offered Shares transferred pursuant to this Section 4 shall remain subject to the right of first refusal set forth in this Section 4 and such transferee shall, as a condition to such transfer, deliver to the Company a written instrument confirming that such transferee shall be bound by all of the terms and conditions of this Section 4.

(d) Consequences of Non-Delivery. After the time at which the Offered Shares are required to be delivered to the Company for transfer to the Company pursuant to subsection (b) above, the Company shall not pay any dividend to the Participant on account of such Offered Shares or permit the Participant to exercise any of the privileges or rights of a stockholder with respect to such Offered Shares, but shall, insofar as permitted by law, treat the Company as the owner of such Offered Shares.

(e) Exempt Transactions. The following transactions shall be exempt from the provisions of this Section 4:

- (1) any transfer of Shares to or for the benefit of any spouse, child or grandchild of the Participant, or to a trust for their benefit;
- (2) any transfer pursuant to an effective registration statement filed by the Company under the Securities Act of 1933, as amended (the "Securities Act"); and
- (3) the sale of all or substantially all of the outstanding shares of capital stock of the Company (including pursuant to a merger or consolidation);

provided, however, that in the case of a transfer pursuant to clause (1) above, such Shares shall remain subject to the right of first refusal set forth in this Section 4.

(f) Assignment of Company Right. The Company may assign its rights to purchase Offered Shares in any particular transaction under this Section 4 to one or more persons or entities.

(g) Termination. The provisions of this Section 4 shall terminate upon the earlier of the following events:

(1) the closing of the sale of shares of Common Stock in an underwritten public offering pursuant to an effective registration statement filed by the Company under the Securities Act; or

(2) the sale of all or substantially all of the outstanding shares of capital stock, assets or business of the Company, by merger, consolidation, sale of assets or otherwise (other than a merger or consolidation in which all or substantially all of the individuals and entities who were beneficial owners of the Company's voting securities immediately prior to such transaction beneficially own, directly or indirectly, more than 50% (determined on an as-converted basis) of the outstanding securities entitled to vote generally in the election of directors of the resulting, surviving or acquiring corporation in such transaction).

(h) No Obligation to Recognize Invalid Transfer. The Company shall not be required (1) to transfer on its books any of the Shares which shall have been sold or transferred in violation of any of the provisions set forth in this Section 4, or (2) to treat as owner of such Shares or to pay dividends to any transferee to whom any such Shares shall have been so sold or transferred.

(i) Legends. The certificate representing Shares shall bear a legend substantially in the following form (in addition to, or in combination with, any legend required by applicable federal and state securities laws and agreements relating to the transfer of the Company securities):

"The shares represented by this certificate are subject to a right of first refusal in favor of the Company, as provided in a certain stock option agreement with the Company."

#### 5. Agreement in Connection with Initial Public Offering.

The Participant agrees, in connection with the initial underwritten public offering of the Common Stock pursuant to a registration statement under the Securities Act, (i) not to (a) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any other securities of the Company or (b) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of shares of Common Stock or other securities of the Company, whether any transaction described in clause (a) or (b) is to be settled by delivery of securities, in cash or otherwise, during the period beginning on the date of



the filing of such registration statement with the Securities and Exchange Commission and ending 180 days after the date of the final prospectus relating to the offering (plus up to an additional 34 days to the extent requested by the managing underwriters for such offering in order to address Rule 2711(f) of the National Association of Securities Dealers, Inc. or any similar successor provision), and (ii) to execute any agreement reflecting clause (i) above as may be requested by the Company or the managing underwriters at the time of such offering. The Company may impose stop-transfer instructions with respect to the shares of Common Stock or other securities subject to the foregoing restriction until the end of the "lock-up" period.

6. Tax Matters.

(a) Withholding. No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option.

(b) Disqualifying Disposition. If the Participant disposes of Shares acquired upon exercise of this option within two years from the Grant Date or one year after such Shares were acquired pursuant to exercise of this option, the Participant shall notify the Company in writing of such disposition.

7. Transfer Restrictions.

(a) This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this option shall be exercisable only by the Participant.

(b) The Participant agrees that he or she will not transfer any Shares issued pursuant to the exercise of this option unless the transferee, as a condition to such transfer, delivers to the Company a written instrument confirming that such transferee shall be bound by all of the terms and conditions of Section 4 and Section 5; provided that such a written confirmation shall not be required with respect to (1) Section 4 after such provision has terminated in accordance with Section 4(g) or (2) Section 5 after the completion of the lock-up period in connection with the Company's initial underwritten public offering.

8. Provisions of the Plan.

This option is subject to the provisions of the Plan (including the provisions relating to amendments to the Plan), a copy of which is furnished to the Participant with this option.

IN WITNESS WHEREOF, the Company has caused this option to be executed under its corporate seal by its duly authorized officer. This option shall take effect as a sealed instrument.

RESTORBIO, INC.

By: \_\_\_\_\_  
Name:  
Title:

PARTICIPANT'S ACCEPTANCE

The undersigned hereby accepts the foregoing option and agrees to the terms and conditions thereof. The undersigned hereby acknowledges receipt of a copy of the Company's 2017 Stock Incentive Plan.

PARTICIPANT:

Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

EXHIBIT A

NOTICE OF STOCK OPTION EXERCISE

[DATE]<sup>1</sup>

resTORbio, Inc.  
501 Boylston Street, Suite 6102  
Boston, MA 02116

Attention: Treasurer

Dear Sir or Madam:

I am the holder of an Incentive Stock Option granted to me under the resTORbio, Inc. (the “**Company**”) 2017 Stock Incentive Plan on [\_\_\_\_\_] <sup>2</sup> for the purchase of [\_\_\_\_\_] <sup>3</sup> shares of Common Stock of the Company at a purchase price of \$[\_\_\_\_\_] <sup>4</sup> per share.

I hereby exercise my option to purchase [\_\_\_\_\_] <sup>5</sup> shares of Common Stock (the “**Shares**”), for which I have enclosed [\_\_\_\_\_] <sup>6</sup> in the amount of [\_\_\_\_\_] <sup>7</sup>. Please register my stock certificate as follows:

Name(s): \_\_\_\_\_ <sup>8</sup>

Address: \_\_\_\_\_

I represent, warrant and covenant as follows:

- 1 Enter date of exercise.
- 2 Enter the date of grant.
- 3 Enter the total number of shares of Common Stock for which the option was granted.
- 4 Enter the option exercise price per share of Common Stock.
- 5 Enter the number of shares of Common Stock to be purchased upon exercise of all or part of the option.
- 6 Enter “cash”, “personal check” or if permitted by the option or Plan, “stock certificates No. XXXX and XXXX”.
- 7 Enter the dollar amount (price per share of Common Stock times the number of shares of Common Stock to be purchased), or the number of shares tendered. Fair market value of shares tendered, together with cash or check, must cover the purchase price of the shares issued upon exercise.
- 8 Enter name(s) to appear on stock certificate in one of the following formats: (a) your name only (i.e., John Doe); (b) your name and other name (i.e., John Doe and Jane Doe, Joint Tenants with Right to Survivorship); or for Nonstatutory Stock Options only, (c) a child’s name, with you as custodian (i.e. Jane Doe, Custodian for Tommy Doe). Note: There may be income and/or gift tax consequences for registering shares in a child’s name.

1. I am purchasing the Shares for my own account for investment only, and not with a view to, or for sale in connection with, any distribution of the Shares in violation of the Securities Act of 1933 (the “**Securities Act**”), or any rule or regulation under the Securities Act.
2. I have had such opportunity as I have deemed adequate to obtain from representatives of the Company such information as is necessary to permit me to evaluate the merits and risks of my investment in the Company.
3. I have sufficient experience in business, financial and investment matters to be able to evaluate the risks involved in the purchase of the Shares and to make an informed investment decision with respect to such purchase.
4. I can afford a complete loss of the value of the Shares and am able to bear the economic risk of holding such Shares for an indefinite period.
5. I understand that (i) the Shares have not been registered under the Securities Act and are “restricted securities” within the meaning of Rule 144 under the Securities Act, (ii) the Shares cannot be sold, transferred or otherwise disposed of unless they are subsequently registered under the Securities Act or an exemption from registration is then available; (iii) in any event, the exemption from registration under Rule 144 will not be available for at least one year and even then will not be available unless a public market then exists for the Common Stock, adequate information concerning the Company is then available to the public, and other terms and conditions of Rule 144 are complied with; and (iv) there is now no registration statement on file with the Securities and Exchange Commission with respect to any stock of the Company and the Company has no obligation or current intention to register the Shares under the Securities Act.

Very truly yours,

---

[Name]

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EXECUTION COPY

## LICENSE AGREEMENT

This License Agreement ("Agreement"), made as of March 23, 2017 ("Effective Date"), is by and between Novartis International Pharmaceutical Ltd., a for-profit corporation with its principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland ("Novartis") and resTORbio, Inc., a Delaware corporation located at 501 Boylston Street, Suite 6102, Boston, Massachusetts 02116 ("resTORbio"). Novartis and resTORbio are each referred to individually as a "Party" and together as the "Parties."

### *Background*

Novartis Controls (as defined below) the Novartis Patents and Know-How (each as defined below) relating to the Compounds (as defined below). resTORbio wishes to obtain, and Novartis wishes to grant, rights under the Novartis Technology (as defined below) to develop, make, use and sell products incorporating BEZ235 or BEZ235 together with RAD001 in the Field (as defined below), as set forth herein.

*For good and valuable consideration, the Parties agree as follows:*

## 1. DEFINITIONS AND INTERPRETATION

1.1 **Definitions.** Unless the context otherwise requires, the terms in this Agreement with initial letters capitalized, will have the meanings set forth below, or the meaning as designated in the indicated places throughout this Agreement.

"Accounting Standards" means, with respect to resTORbio, US GAAP (United States Generally Accepted Accounting Principles) and means, with respect to Novartis, IFRS (International Financial Reporting Standards), in each case as generally and consistently applied throughout the Party's organization. Each Party will promptly notify the other Party in the event that it changes the Accounting Standards pursuant to which its records relating to this Agreement are maintained; *provided, however*, that each Party may only use internationally recognized accounting principles (*e.g.*, IFRS, US GAAP, *etc.*).

"Affiliate" means, with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "control" will mean, direct or indirect, ownership of 50% or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or 50% or more of the equity interest in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby the entity or Person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity, or the ability to cause the direction of the management or policies of a corporation or other entity, or otherwise has "control" over the relevant entity as set forth in applicable Accounting Standards, as amended from time to time. In the case of entities organized under the laws of certain countries, the maximum percentage ownership permitted by law for a foreign investor may be less than 50%, and in such case such lower percentage will be substituted in the preceding sentence, *provided* that such foreign investor has the power to direct the management and policies of such entity.

"Alliance Manager" will have the meaning set forth in Section 3.1.

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“BEZ235” means the compound described as BEZ235 in *Exhibit A* to this Agreement, including all pharmaceutically acceptable salts and metabolites thereof, whether produced by chemical synthesis or otherwise, which is owned or Controlled by Novartis or its Affiliates.

“BEZ235 Patents” means the Patent Rights listed in *Exhibit B-2*.

“BEZ235/RAD001 Combination Patents” means the Patent Rights listed in *Exhibit B-3*.

“Calendar Quarter” means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 and December 31.

“Calendar Year” means a period of twelve consecutive calendar months ending on December 31.

“Claims” means all Third Party demands, claims, actions, proceedings and liability (whether criminal or civil, in contract, tort or otherwise) for losses, damages, reasonable legal costs and other reasonable expenses of any nature whatsoever.

“Code” means Title 11 of the U.S. Code.

“Combination Therapy” means any product (in any composition or formulation) containing one or more active biologic or pharmaceutical ingredients in addition to Compounds, or any Combination Therapy approved by a Regulatory Authority in any country where one or more active biologic or pharmaceutical ingredients in addition to Compounds is administered separately from Compounds. For the avoidance of doubt, the combination of BEZ235 and RAD001 alone (*i.e.*, without an additional active ingredient) does not constitute a Combination Therapy.

“Commercialize” means to market, promote, distribute, import, export, offer to sell and/or sell Product, and “Commercialization” means commercialization activities relating to Product, including activities relating to marketing, promoting, distributing, importing, exporting, offering for sale and/or selling Product.

“Commercially Reasonable Efforts” means, with respect to a Party, the efforts and resources typically used by reasonable biotechnology or pharmaceutical companies to perform the obligation at issue, which efforts will not be less than those efforts made by such Party with respect to other products at a similar stage of development or in a similar stage of product life, with similar developmental risk profiles, of similar market and commercial potential, taking into account the proprietary position of the products relative to the products of Third Parties, the regulatory structure involved, Regulatory Authority approved labeling, product profile, the profitability of the applicable products, issues of safety and efficacy, the likely timing of the product’s entry into the market, the likelihood of receiving Regulatory Approval, and other relevant scientific, technical and commercial factors, including potential competitive products.

“Compounds” means, without distinction, either or both of BEZ235 and RAD001.

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“Control” or “Controlled” means, with respect to any Know-How, Patent Rights, other intellectual property rights, or any proprietary or trade secret information, the legal authority or right (whether by ownership, license or otherwise, other than by a license granted under this Agreement) of a Party or its Affiliates, to grant a license or a sublicense of or under such Know-How, Patent Rights, or intellectual property rights to another Person, or to otherwise disclose such proprietary or trade secret information to another Person, without breaching the terms of any agreement with a Third Party or misappropriating the proprietary or trade secret information of a Third Party.

“Develop” or “Development” means drug development activities, including, without limitation, test method development and stability testing, assay development and audit development, toxicology, formulation, quality assurance/quality control development, statistical analysis, clinical studies, packaging development, regulatory affairs, and the preparation, filing and prosecution of INDs, NDAs and MAAs.

“Effective Date” has the meaning in the preamble (*i.e.*, in the first paragraph of this Agreement).

“EMA” means the European Medicines Agency or any successor entity thereto.

“Encumbrance” means any claim, charge, equitable interest, hypothecation, lien, mortgage, pledge, option, license, assignment, power of sale, retention of title, right of pre-emption, right of first refusal or security interest of any kind.

“European Regulatory Approval” means, with respect to a Product, **(a)** MAA approval from the EMA and pricing and reimbursement approval in three of the Major European Countries, or **(b)** marketing, pricing, and reimbursement approvals in three of the Major European Countries.

“FDA” means the United States Food and Drug Administration or any successor entity thereto.

“Field” means **(a)** with respect to BEZ235, the treatment, prevention and diagnosis of diseases and other conditions in all Indications in humans and animals; and **(b)** with respect to RAD001, limited to uses together with BEZ235 as part of a Fixed Dose Combination that includes at least 0.1mg of BEZ235 per dose, for any Indication in humans related to **(i)** the improvement in immune function or immunosenescence in the elderly; **(ii)** the reduction of infection frequency, severity, duration, health care resource utilization, hospitalization, morbidity or mortality, or the treatment of infections; **(iii)** the reduction of pulmonary disease exacerbation frequency, severity, or related hospitalization; **(iv)** the enhancement of therapeutic or prophylactic benefits of vaccines; or **(v)** any aging-related disease or condition; *provided, however*, that notwithstanding the foregoing, the Field does not include application or use of RAD001 in connection with organ transplantation, oncology, immuno- oncology or in the Cardiac Stent Field. For this purpose, the term “Cardiac Stent Field” means the prevention and/or treatment of coronary and peripheral vascular diseases with stents, stent delivery systems or other site-specific local, vascular delivery systems, but does not extend to any systemic application. It is understood and agreed that the Field also does not include any rights for resTORbio to develop, make, use and sell RAD001 **(A)** in any combination other than a Fixed Dose Combination; **(B)** by itself (except in connection with the Development of a Fixed Dose Combination as set forth in Section 5.1 of this Agreement); or **(C)** in any use outside of the Indications described in clauses (i) through (v) of the preceding sentence.



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“First Commercial Sale” means, with respect to a Product in a particular country, the first arm’s length sale to a Third Party for value for use or consumption of any such Product following receipt of Regulatory Approval of such Product in such country.

“Fixed Dose Combination” means, with respect to BEZ235 and RAD001, the combination of BEZ API and RAD API in a single dosage form which is manufactured and distributed in such single dosage form.

“Generic Equivalent” means, with respect to a particular Product in a country, any product that **(a)** has Regulatory Approval for use in such country pursuant to a regulatory process governing approval of generic, interchangeable, or biosimilar pharmaceutical or biological product based on the then-current standards for regulatory approval in such country, where such regulatory approval relied on or incorporated clinical data generated by either Party to this Agreement or their Affiliates or licensees, or was obtained using an abbreviated, expedited, or other similar process; **(b)** during the Royalty Term, is not owned or licensed by resTORbio under this Agreement; and **(c)** is sold in the same country as the relevant Product by a Third Party that is not a sublicensee or Affiliate of resTORbio, and that did not purchase such product in a chain of distribution that included resTORbio, or its Affiliates or its or their sublicensees.

“IND” means an Investigational New Drug application in the US filed with the FDA or the corresponding application for the investigation of Products in any other country or group of countries, as defined in the applicable laws and regulations and filed with the Regulatory Authority of a given country or group of countries.

“Indication” means a specific disease, impairment, medical condition, or symptom thereof that is the intended subject of a Product. For the purposes of the Milestones set forth in Section 8.3, a “Second Indication” shall mean an intended subject of a Product that is a different disease, impairment, medical condition, or symptom thereof than the subject of the first Indication for a Product.

“Information” means all Know-How and other proprietary information and data of a financial, commercial or technical nature which the disclosing Party, its Affiliates, or its or their licensors has supplied or otherwise made available to the other Party or its Affiliates, whether made available orally, in writing or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data, designs or formulae in relation to this Agreement.

“Initiation” means, with respect to a Product and a clinical trial, the first dosing in such clinical trial of the first human with the relevant Product.

“Insolvency Event” means **(a)** resTORbio ceases to function as a going concern by suspending or discontinuing its business; **(b)** resTORbio becomes insolvent (*i.e.*, is unable to pay its debts as they become due); **(c)** resTORbio is the subject of voluntary or involuntary bankruptcy proceedings instituted on behalf of or against resTORbio (except for involuntary bankruptcy proceedings that are dismissed within 90 days); **(d)** an administrative receiver, receiver and manager, interim receiver, custodian, sequestrator, or similar officer is appointed for resTORbio; **(e)** a resolution to wind up resTORbio is passed at a meeting of the directors or shareholders of resTORbio; or **(f)** a resolution shall have been passed by resTORbio or resTORbio’s directors to make an application for an administration order or to appoint an administrator for all of resTORbio’s assets; or **(g)** resTORbio makes any general assignment for the benefit of all of its creditors.

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“Invoice” means an invoice in a form reasonably acceptable to resTORbio and to Novartis.

“Know-How” means all technical information, know-how and data, including inventions (whether patentable or not), discoveries, trade secrets, specifications, instructions, processes, formulae, materials, expertise and other technology applicable to Compounds, formulations, compositions, Products or to their manufacture, development, registration, use or commercialization or methods of assaying or testing them or processes for their manufacture, formulations containing them, compositions incorporating or comprising them and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data, instructions, processes, formulae, expertise and information, regulatory filings and copies thereof, relevant to the development, manufacture, use or commercialization of and/or which may be useful in studying, testing, development, production or formulation of Products, or intermediates for the synthesis thereof.

“MAA” means an application for the authorization to market the Product in any country or group of countries outside the United States, as defined in the applicable laws and regulations and filed with the Regulatory Authority of a given country or group of countries.

“Major European Countries” means France, Germany, Italy, Spain and the United Kingdom.

“Major Market” means any of the United States, Japan, and each of the Major European Countries.

“Milestones” means the milestones relating to the Product as set forth in Sections 8.3 and 8.4.

“Milestone Payments” means the payments to be made by resTORbio to Novartis upon the achievement of the corresponding Milestones as set forth in Sections 8.3 and 8.4.

“NDA” shall mean a New Drug Application, as described in the FDA regulations, 21 CFR Section 314.50, including all amendments and supplements to the application.

“Net Sales” means the net sales recorded by resTORbio or any of its Affiliates or sublicensees for any Product sold to Third Parties other than sublicensees, as determined by computing the gross sales of such Product and deducting the following amounts, in all cases to the extent permitted by the resTORbio Accounting Standards, as consistently applied:

- (i) normal trade and cash discounts;
- (ii) amounts repaid or credited by reasons of defects, rejections, recalls or returns;
- (iii) rebates and chargebacks to customers and third parties (including, without limitation, Medicare, Medicaid, Managed Healthcare and similar types of rebates);
- (iv) amounts provided or credited to customers through coupons and other discount programs;

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- (v) delayed ship order credits, discounts or payments related to the impact of price increases between purchase and shipping dates or retroactive price reductions; and
- (vi) fee for service payments to customers for any non-separable services (including compensation for maintaining agreed inventory levels and providing information).

With respect to the calculation of Net Sales:

- (i) Net Sales only include the value charged or invoiced on the first arm's length sale to a Third Party, and sales between or among resTORbio and its Affiliates and sublicensees will be disregarded for purposes of calculating Net Sales;
- (ii) If a Product is delivered to the Third Party before being invoiced (or is not invoiced), Net Sales will be calculated at the time all the revenue recognition criteria under Accounting Standards are met;
- (iii) In the event that the Product is sold as a part of a Combination Therapy, the Net Sales will be calculated by multiplying the Net Sales of the Combination Therapy by the fraction,  $A/(A+B)$  where  $A$  is the weighted (by sales volume) average sale price in the relevant country of the Product containing the Compounds as the sole active ingredient in finished form, and  $B$  is the weighted average sale price (by sales volume) in that country of the product(s) containing the other component(s) as the sole active ingredient(s) in finished form in an Indication similar to the intended use of the Product. Regarding prices comprised in the weighted average price when sold separately referred to above, if these are available for different dosages from the dosages of Compounds and other active ingredient components that are included in the Combination Therapy, then resTORbio will be entitled to make a proportional adjustment to such prices in calculating the royalty-bearing Net Sales of the Combination Therapy. If the weighted average sale price cannot be determined for the Product or other product(s) containing the Compounds or component(s), the calculation of Net Sales for any such Combination Therapy will be agreed by the Parties based on the relative value contributed by each component (each Party's agreement not to be unreasonably withheld or delayed).

“Novartis Know-How” means any Know-How Controlled by Novartis or any of its Affiliates as of the Effective Date that is material for the research, Development, manufacture, preparation, use of the Compounds or the Commercialization of the Compounds and Products, in each case in the Field. Notwithstanding the foregoing, Novartis Know-How will not include information relating to (a) Novartis' proprietary products containing RAD001; (b) matters outside the Field; and (c) the manufacturing of RAD001, particularly related to the active pharmaceutical ingredient and/or any formulation technologies.

“Novartis Patents” means any Patent Rights Controlled by Novartis or any of its Affiliates as of the Effective Date that are set forth on *Exhibit B*. For convenience, the Novartis Patents are divided into three categories: (a) RAD001 Patents (listed in *Exhibit B-1*); (b) BEZ235 Patents (listed in *Exhibit B-2*); and (c) BEZ235/RAD001 Combination Patents (listed in *Exhibit B-3*).

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“Novartis Technology” means the Novartis Know-How and Novartis Patents.

“Patent Rights” means all patents and patent applications, in any country, including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, reissues, additions, renewals, extensions, registrations, supplemental protection certificates, utility models, design patents and the like of any of the foregoing.

“Person” means any individual, partnership, limited liability company, firm, corporation, association, trust, unincorporated organization or other entity.

“Phase I Clinical Trial” means a clinical study of a Product in human subjects designed to obtain data on the safety and tolerability of such Product, including pharmacological or pharmacokinetic information, as more fully defined in 21 C.F.R. §312.21(a) (or the non- United States equivalent thereof).

“Phase II Clinical Trial” means a clinical study of a Product in patients designed to establish the dosing range for such Product and the safety and efficacy of such Product, as further defined in 21 C.F.R. §312.21(b) (or the non-United States equivalent thereof).

“Phase III Clinical Trial” means a controlled clinical study of a Product in patients designed to establish efficacy and safety of such Product for the purpose of preparing and submitting a filing for BLA approval in the US, or European Regulatory Approval, as further defined in 21 C.F.R. §312.21(c) (or the non-United States equivalent thereof).

“Prior Confidentiality Agreement” means the Confidentiality Agreement between the Parties dated August 9, 2016.

“Product” means a therapeutic product incorporating or comprising either **(a)** BEZ235; or

**(b)** BEZ235 and RAD001 together in a Fixed Dose Combination, in both cases in finished dosage form, **(i)** the Development, manufacture, preparation, use or Commercialization of which would, but for the license granted hereunder, infringe a Valid Claim of the Novartis Patents; and/or **(ii)** that is Developed using, incorporates, or embodies Novartis Know-How.

“RAD001” means the compound described as RAD001 in *Exhibit A* to this Agreement and pharmaceutically acceptable salts, whether produced by chemical synthesis or otherwise, which is owned or Controlled by Novartis or its Affiliates.

“RAD001 Patents” means the Patent Rights listed in *Exhibit B-1*.

“Regulatory Approval” means, with respect to a product in any country or jurisdiction, any approval, registration, license or authorization from a Regulatory Authority in a country or other jurisdiction that is reasonably necessary to market and sell a Product in such country or jurisdiction (including, *e.g.*, any applicable pricing and reimbursement approvals).

“Regulatory Authority” means any governmental authority or agency responsible for authorizing or approving the marketing and/or sale of products in a jurisdiction (*e.g.*, the FDA, EMA, the Japanese Ministry of Health, Labour and Welfare, and corresponding national or regional regulatory agencies or organizations).

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“Regulatory Exclusivity” means with respect to a Product in a country, the period of time during which **(a)** a Party or its Affiliate or sublicensee has been granted the exclusive legal right by a Regulatory Authority (or is otherwise entitled to the exclusive legal right by operation of applicable law) in such country to market and sell the Product; or **(b)** the data and information submitted by a Party or its Affiliate or sublicensee to the relevant Regulatory Authority in such country for purposes of obtaining Regulatory Approval may not be disclosed, referenced or relied upon in any way by a Third Party or such Regulatory Authority (including by relying upon the Regulatory Authority’s previous findings regarding the safety or effectiveness of the Product) to support the Regulatory Approval or marketing of any product by a Third Party in such country.

“Regulatory Filings” means, with respect to the Compounds or a Product, any submission to a Regulatory Authority of any appropriate regulatory application, and will include, without limitation, any submission to a regulatory advisory board, marketing authorization application, and any supplement or amendment thereto. For the avoidance of doubt, Regulatory Filings will include any IND, NDA, MAA or the corresponding application in any other country or group of countries.

“Royalty Term” means the period commencing on the First Commercial Sale of a Product in a specified country until the latest of **(a)** the expiration of the last to expire Valid Claim of the Novartis Patents that, but for the licenses granted in this Agreement, would be infringed by the Development, manufacture, use, importation or other Commercialization of such Product in such country; **(b)** the expiration of any Regulatory Exclusivity for such Product in such country; or **(c)** the ten year anniversary of the First Commercial Sale of the Product in the relevant country.

“Sales & Royalty Report” means a written report or reports showing each of: **(a)** the gross and Net Sales of each Product, on a country-by-country basis, during the reporting period by resTORbio and its Affiliates and sublicensees (in all cases itemizing the various deductions taken from gross to compute Net Sales as set forth in the definition of Net Sales, above); **(b)** the royalties payable, in USD, which will have accrued hereunder with respect to such Net Sales; and **(c)** if sales include any Combination Therapy, the methodology and data used to determine Net Sales as set forth in the Net Sales definition.

“Senior Officers” means, for Novartis, the Chief Executive Officer of the Novartis Institutes for BioMedical Research, or his/her designee, and for resTORbio, its Chief Executive Officer or his designee.

“Serious Adverse Event” means any untoward medical occurrence in a human clinical trial subject or in a patient who is administered a Product, whether or not having a causal relationship with such Product, that **(a)** results in death or poses a threat to life; **(b)** requires or prolongs hospitalization; **(c)** results in persistent or significant disability or incapacity; **(d)** is medically significant; or **(e)** results in a congenital abnormality or birth defect. In the case of other significant events, medical and scientific judgment should be exercised in deciding whether expedited reporting is appropriate. Such events may be important medical events that may not be immediately life-threatening or result in death or hospitalization but which may jeopardize the patient or may require intervention to prevent one of the other outcomes described above in this definition. Such events should usually be considered Serious Adverse Events.

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“Term” with reference to this Agreement shall mean the period of time beginning on the Effective Date and ending upon the expiration of the Royalty Term for the last Product with a Royalty Term.

“Territory” means worldwide.

“Third Party” means any Person other than a Party or an Affiliate of a Party.

“United States” or “US” means the United States of America, its territories and possessions. “USD” or “US\$” means the lawful currency of the United States.

“Valid Claim” means (a) claim of an issued and unexpired patent included within the Novartis Patents that (i) covers the practice of the relevant Compound or Product in the relevant jurisdiction; (ii) has not been irrevocably or unappealably disclaimed or abandoned, or been held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction; and (iii) has not been admitted to be invalid or unenforceable through reissue, disclaimer, or otherwise; or (b) a claim included in a patent application included within the Novartis Patents that (i) would cover the practices of the relevant Product in the relevant jurisdiction if such claim was to issue; and (ii) has not been cancelled, withdrawn or abandoned, nor been pending for more than five (5) years from the earliest filing date to which such patent application or claim is entitled.

1.2 **Interpretation.** In this agreement unless otherwise specified:

- (a) “includes” and “including” will mean respectively includes and including without limitation;
- (b) a Party includes its permitted assignees and/or the respective successors in title to substantially the whole of its undertaking;
- (c) a statute or statutory instrument or any of their provisions is to be construed as a reference to that statute or statutory instrument or such provision as the same may have been or may from time to time hereafter be amended or re-enacted;
- (d) words denoting the singular will include the plural and vice versa and words denoting any gender will include all genders;
- (e) the Exhibits and other attachments form part of the operative provision of this Agreement and references to this Agreement shall, unless the context otherwise requires, include references to the Exhibits and attachments;
- (f) the headings in this Agreement are for information only and will not be considered in the interpretation of this Agreement;
- (g) general words will not be given a restrictive interpretation by reason of their being preceded or followed by words indicating a particular class of acts, matters or things; and
- (h) the terms and conditions of this Agreement are the result of negotiations between the Parties and that this Agreement will not be construed in favor of or against any Party by reason of the extent to which any Party participated in the preparation of this Agreement.

**2. LICENSE; SUBLICENSES; GRANT BACKS.**

2.1 **License Grant.** Subject to the terms and conditions of this Agreement, Novartis hereby grants to resTORbio **(a)** an exclusive (even as to Novartis and its Affiliates), sub-licensable (pursuant to Section 2.2) license or sublicense, as applicable, under Novartis' interest in the Novartis Technology to research, Develop, make, have made, use, import, offer for sale, sell, have sold and otherwise Commercialize BEZ235 and BEZ235-containing Products; and **(b)** an exclusive (even as to Novartis and its Affiliates), sub-licensable (pursuant to Section 2.2) license or sublicense, as applicable, under Novartis' interest in the Novartis Technology to research, Develop, make, have made, use, import, offer for sale, sell, have sold and otherwise Commercialize a Fixed Dose Combination Product containing both

RAD001 and BEZ235, in both cases (*i.e.*, clauses (a) and (b)) limited to the Field in the Territory; *provided, however*, that this license will not include any right of access to Novartis Know How related to RAD001 other than as provided in Section 4. The foregoing license is exclusive to resTORbio in the Field; *provided, however*, that Novartis and its Affiliates will retain the right to conduct research (but not Development or Commercialization activities) using the Novartis Technology in the Field (including both with respect to BEZ235 individually and BEZ235 and RAD001 in combination); and *provided* [\*\*\*].

2.2 **Sublicense Rights.** resTORbio may sublicense (through multiple tiers) the rights granted to it by Novartis under this Agreement at any time at its sole discretion, but subject to the applicable terms of this Agreement. Prior to the 40 Patient Trial Date with Fixed Dose Combination, resTORbio must obtain Novartis' written consent prior to sublicensing its rights under this Agreement, to the extent that such rights include rights to research, Develop, or Commercialize a Fixed Dose Combination. resTORbio may exercise its rights and perform its rights and obligations under this Agreement itself or through any of its Affiliates. In addition, resTORbio may subcontract to Third Parties the performance of tasks and obligations with respect to the Development and Commercialization of the Products as resTORbio deems appropriate, subject to the applicable terms and conditions of this Agreement. resTORbio shall provide Novartis with a copy of any sublicense agreement it enters with respect to the Novartis Technology within ten (10) days after the execution thereof, *provided* that such copy may be subject to redaction as resTORbio reasonably believes appropriate to protect confidential business information, including financial provisions and other sensitive information as applicable, but resTORbio shall not redact provisions that are useful to Novartis to confirm payments by resTORbio to Novartis under Section 8.2. Each such sublicense agreement shall be considered confidential Information of resTORbio and subject to Article 10 of this Agreement. Each sublicense of the Novartis Technology shall be consistent with the terms and conditions of this Agreement. Upon the termination of this Agreement by Novartis pursuant to Section 11.2 or Section 11.3 or by resTORbio pursuant to Section 11.2(a) or 11.4, any sublicense granted by resTORbio under the Novartis Technology will terminate upon the effective date of termination of this Agreement. resTORbio will remain liable for the acts and omissions of its sublicensees and Affiliates as if such sublicensees and Affiliates were resTORbio hereunder.

- 2.3 **Grant Back of RAD001 Improvements Outside the Field.** To the extent resTORbio creates, conceives of, or reduces to practice any improvements to RAD001 Novartis Know How outside the Field (including but not limited to dosing, formulation, and combinations of RAD001 other than with BEZ235) during the Term (“RAD001 Improvements”), then resTORbio hereby grants to Novartis and its Affiliates a non-exclusive, fully-paid, perpetual (*i.e.*, for the life of the relevant Patent Rights and Know How, subject to reversion as set forth in Section 12.2), sub-licensable license in the Territory to resTORbio’s interest in such RAD001 Improvements; *provided, however*, that for the avoidance of doubt, such license is limited to practice outside of the Field. Novartis may sublicense (through multiple tiers) the rights granted to it by resTORbio under this Agreement at any time at its sole discretion, but subject to the applicable terms of this Agreement. Each sublicense of the RAD001 Improvements shall be consistent with the terms and conditions of this Agreement. Upon the termination of this Agreement by resTORbio pursuant to Section 11.2, any license granted to Novartis to the RAD001 Improvements will terminate upon the effective date of termination of this Agreement. Novartis will remain liable for the acts and omissions of its sublicensees as if such sublicensees were Novartis hereunder
- 2.4 **Covenant Not to Enforce.** To the extent Novartis creates, conceives of or reduces to practice during the Term any improvements to the Novartis Technology relating to BEZ235 or its use (“BEZ235 Technology Improvements”), Novartis agrees that it will not take action against resTORbio to enforce its intellectual property rights in BEZ235 Technology Improvements in connection with resTORbio Development and Commercialization of Products and Compounds in the Field.

### 3. GOVERNANCE

- 3.1 **Alliance Managers.** Within 30 days after the Effective Date, each Party will appoint (and notify the other Party of the identity of) a senior representative having a general understanding of pharmaceutical development and commercialization issues to act as its alliance manager under this Agreement (“Alliance Manager”). The Alliance Managers will **(a)** serve as the contact point between the Parties for the purpose of providing Novartis with information on the progress of resTORbio’s Development and Commercialization of the Products; **(b)** be primarily responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties, including in particular the transfer of information and Know-How from Novartis to resTORbio; **(c)** provide a single point of communication for seeking consensus both internally within the respective Party’s organization and facilitating review of external corporate communications; and **(d)** raise cross-Party and/or cross-functional disputes in a timely manner. Each Party may replace its Alliance Manager on written notice to the other Party.
- 3.2 **Development Information.** Within ninety (90) days after the Effective Date, resTORbio will provide Novartis with a high level summary development plan setting forth the anticipated Development activities to be conducted by resTORbio and its Affiliates and sublicensees related to the Compounds and Products during the following 18 month period (the “Development Plan”). No later than ninety (90) days after each anniversary of the Effective Date, until the approval of the first NDA or MAA for a Product, resTORbio will provide Novartis an updated Development Plan providing, in reasonable detail, the



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Development activities conducted by resTORbio and its Affiliates and sublicensees related to Compounds and Products during the immediately preceding year and its anticipated plans for Development of the Compounds and Products for next 18 month period. In addition to this annual report, resTORbio will provide to Novartis a high level summary of all Development activities that resTORbio, its agents, or their sublicensees have conducted in the prior six month period until the approval of the first NDA or MAA for a Product. resTORbio may revise the Development Plan or any update thereto in its sole discretion, subject to satisfaction of its obligations under Section 5.2.

- 3.3 **Meetings.** During the period from the Effective Date until the first NDA or MAA filing for a Product, the Alliance Managers will meet (either in person or by teleconference) at least twice per year, to review and discuss progress made under, and any changes to, the Development, Plan, including the Development work performed, clinical trials, Milestones, any key issues and the overall status of Development.
- 3.4 **Reports.** The Information provided by resTORbio to Novartis under Sections 3.2 and 3.3 will be provided for the purpose of demonstrating the Commercially Reasonable Efforts of resTORbio in connection with the Development and Commercialization of Compounds and Products.

#### 4. DISCLOSURE OF LICENSOR KNOW-HOW & COOPERATION

- 4.1 **Technology Transfer.** Within 45 days after the Effective Date, Novartis will transfer BEZ235-related Know How (limited to BEZ235 API and BEZ235 Drug Product) to resTORbio that is available to Novartis and that would reasonably consist of Novartis Know How set forth in *Exhibit C* (the "Technology Transfer Activities") at no additional cost; *provided, however*, that Novartis shall not be required to provide more than [\*\*\*] man hours of service in connection with the Technology Transfer Activities. For clarity, with respect to the BEZ Placebo (as defined in Section 6.1), Novartis will only provide certificates of analysis and will not conduct a further technology transfer.

Except as provided below, to the extent that additional services are reasonably requested by resTORbio in writing (*i.e.*, in excess of the [\*\*\*] hours are needed to complete the Technology Transfer Activities), and such additional services are approved by Novartis (not to be unreasonably withheld) in writing, such activities will **(a)** be charged at the rate of \$[\*\*\*] per man-hour (plus any applicable expenses); and **(b)** shall not exceed a term longer than six months after the Effective Date.

- 4.2 **Clinical and Pre-clinical Documents.** The Parties acknowledge that as of the Effective Date, *Exhibit C* includes only CMC-related Technology Transfer Activities. Following the Effective Date, the Parties will negotiate in good faith to agree upon a revised *Exhibit C*, which will add a list of pre-clinical and clinical documents in Novartis' possession that are material to the BEZ-335 Know How and reasonably necessary for the Development of BEZ235.
- 4.3 **Analytical Methods.** During a term not to exceed twelve months after the Effective Date, to the extent that resTORbio requests in writing that Novartis transfer RAD001 analytical methods for drug substance release and RAD001 analysis/stability to resTORbio or its designee, such activities will be provided at no additional cost to resTORbio and for no more than a total of [\*\*\*] hours of work, and will be delivered approximately three months following such request, and are subject to the execution by

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resTORbio of a separate, commercially standard confidentiality agreement to be provided by Novartis. Any additional work related to the transfer of analytical methods upon resTORbio's reasonable request will be charged by Novartis to resTORbio at the rate of \$[\*\*\*] per man hour (plus any applicable expenses).

- 4.4 For clarity, notwithstanding anything in this Agreement to the contrary, **(i)** Know How relating to RAD001 that is subject to transfer will be limited to specific analytical methods for drug substance release and analysis/stability, and **(ii)** Novartis Know-How required for the manufacturing of RAD001 placebo, RAD001 active pharmaceutical ingredient, and/or any RAD001 formulation Know-How will not be included in the Technology Transfer Activities or otherwise transferred to resTORbio.
- 4.5 For further clarity, the [\*\*\*] hour time periods described in Section 4.1, Section 4.3, and Section 5.3(e) are independent of one another, but may not be exchanged (*i.e.*, they total [\*\*\*] hours, but unused time under one Section may not be applied to another Section), and each of these time periods will only be triggered upon resTORbio's written request.

## 5. DEVELOPMENT AND REGULATORY

- 5.1 **Development.** Subject to Section 5.2, resTORbio will have sole control over all Development activities and full decision-making authority with respect to the Development of the Products and will be responsible for conducting, at its sole expense, such research and preclinical, clinical and other Development of Compounds and/or Products as it determines appropriate in its sole discretion; *provided, however*, **(a)** that resTORbio shall have the right to use RAD001 by itself to the extent required for Development (but not Commercialization) of Products, with the objective of obtaining Regulatory Approval for a Fixed Dose Combination, so long as **(i)** the relevant Regulatory Authority requires such activity; **(ii)** resTORbio provides advance notice to Novartis on the proposed clinical trial plans for use of RAD001 as monotherapy; and **(iii)** resTORbio considers in good faith comments made by Novartis on such planned activities so long as such comments are provided within 30 days of resTORbio providing such clinical trial plans to the Novartis Alliance Manager; and **(b)** the use in a Fixed Dose Combination resulting in daily dose of RAD001 in excess of [\*\*\*]mg must be subject to the prior written approval of Novartis.
- 5.2 **Development Diligence.** resTORbio will itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Develop at least one Product in the Field. Subject to compliance with the provisions of Section 5.1, the Development of the Product will be in resTORbio's sole discretion.
- 5.3 **Regulatory.**
- (a)** Novartis will promptly assign to resTORbio the following Regulatory Filings: [\*\*\*],[\*\*\*], and [\*\*\*], and thereafter resTORbio shall be responsible for all future correspondence relating to these INDs and any and all subsequent Regulatory Filings relating to BEZ235, it being understood that any such activities will be conducted in accordance with Applicable Law. Within 90 days after the Effective Date, to the extent permitted by applicable law, Novartis will assign to resTORbio or provide a copy of any Regulatory Filings solely related to BEZ235.

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- (b) Novartis hereby grants to resTORbio, together with resTORbio's Affiliates and sublicensees, a right of reference to the Novartis-sponsored [\*\*\*] to permit resTORbio to Develop or obtain Regulatory Approval of the BEZ235/RAD001 Fixed Dose Combination Product in the Field in the Territory, and Novartis agrees to submit such documentation within 21 days after the Effective Date as may be reasonably required to cause such right of reference to become effective; *provided, however* that no data contained in the RAD001 dossier will be shared with or provided to resTORbio, and the investigator brochure for RAD001 that resTORbio intends to use for Development of Compounds and Products will be independently developed by resTORbio, although it may rely on information from the Novartis investigator brochure to the extent required by applicable law. resTORbio may also cross-reference to [\*\*\*](RAD001) in regards to Module 3 (quality), Non-clinical info (Module 4) and corresponding summaries in Module 2. For CTAs in Europe, resTORbio will provide information on RAD001 as a publicly available simplified investigational medical product (sIMPD), which is a Summary of Product Characteristics (SmPC) of RAD001 medicinal product authorized in corresponding European Member State. Novartis shall be free to withdraw any and all Regulatory Filings for BEZ235 (and combinations with BEZ235) or RAD001 unless resTORbio agrees to compensate Novartis for all costs (including internal costs) relating to the maintenance of the respective Regulatory Filings. For clarity, in case a Regulatory Authority requires or actively withdraws a Regulatory Filing Novartis will inform resTORbio hereof without undue delay but shall not be forced to appeal such decision. Novartis agrees to provide reasonable collaborative assistance to resTORbio, at the rates set forth in Article 4, in connection with the regulatory process involving the Fixed Dose Combination as may be required to address aspects of referenced materials to which resTORbio will not have access.
- (c) resTORbio will (i) determine the regulatory plans and strategies for the Compounds and/or Products, (ii) (either itself or through its Affiliates or sublicensees) make all Regulatory Filings with respect to the Products, and (iii) be responsible for obtaining and maintaining Regulatory Approvals throughout the world in the name of resTORbio or its Affiliates or sublicensees; *provided, however*, that any activity involving the use of a Fixed Dose Combination product resulting in daily dose of RAD001 in excess of [\*\*\*]mg will be subject to the prior written approval of Novartis.
- (d) resTORbio will have the right to disclose the existence of, and the results from, any clinical trials conducted under this Agreement in accordance with its standard policies.
- (e) Novartis will provide up to [\*\*\*] man hours, over a period of [\*\*\*] months commencing on the Effective Date, with respect to all regulatory matters.

5.4 **Adverse Event Reporting and Safety Data Exchange.** The Parties shall cooperate with regard to the reporting and handling of safety information involving or relating to RAD001 to the extent required by applicable laws. Following the Effective Date, and in time to ensure that all regulatory requirements are met, and to the extent required by applicable law or any Regulatory Authority, the Parties shall enter into one or more Safety Data Exchange Agreements, which will define the pharmacovigilance responsibilities of the Parties and safety data exchange procedures to enable each Party to comply with all of its legal and regulatory obligations related to BEZ235 and RAD001.

- 5.5 **Product Recalls.** If any Regulatory Authority issues or requests a recall or takes similar action with respect to a Product, or in the event either Party reasonably believes that an event, incident or circumstance has occurred that may result in the need for such a recall, such Party shall promptly notify the other Party thereof by telephone, facsimile or email. Following such notification, resTORbio shall decide and have control of whether to conduct a recall or market withdrawal (except if a recall or market withdrawal is mandated by a Regulatory Authority, in which case it shall be required) or take such other corrective action in any country and the manner in which any such recall, market withdrawal or corrective action shall be conducted, *provided* that resTORbio shall keep Novartis regularly informed regarding any such recall, market withdrawal or corrective action.
- 5.6 **Compliance.** resTORbio will, and will cause its Affiliates and sublicensees to, **(a)** comply with all applicable current international regulatory standards, including cGMP, cGLP, cGCP and other rules, regulations and requirements, and **(b)** not employ or use any person that has been debarred under Section 306(a) or 306(b) of the U.S. Federal Food, Drug and Cosmetic Act.

## 6. MANUFACTURING AND SUPPLY.

- 6.1 **Inventory of BEZ235 and Placebos.** Within 30 days after the written request of resTORbio, Novartis will make available for pick up by resTORbio and/or resTORbio's designee or identified carrier companies and Third Party contract manufacturing organizations ("CMO" or "CMOs"), from Novartis' facilities where the materials are currently stored, Novartis' inventory of BEZ235 active pharmaceutical ingredient ("BEZ API") and [\*\*\*] mg capsules of BEZ235 drug product ("BEZ Drug Product") in its current form ("as is"), and as well as approximately [\*\*\*] capsules of [\*\*\*] mg BEZ235 placebo for BEZ Drug Product ("BEZ Placebo") (of which approximately [\*\*\*] capsules will be provided in matching placebo bottles), as is and without warranty as to their usefulness (see *Exhibit D*). Within 90 days after the Effective Date, the Parties will execute a commercially reasonable quality agreement, an initial draft of which will be provided by resTORbio, relating to the supply of BEZ API, BEZ Drug Product, and BEZ Placebo. The BEZ API, BEZ Drug Product, and BEZ Placebo will be picked up in not more than one or two installments. resTORbio and Novartis will cooperate to permit resTORbio to provide necessary information as may be required to pick-up, in a timely manner, the BEZ API, BEZ Drug Product, and BEZ Placebo. In connection with the transfer of this material, Novartis will share will resTORbio any information that is readily available to Novartis (and not otherwise available to resTORbio), in particular Compound-specific information, as is necessary to permit resTORbio to pick up the material as described in this Section 6.1. If resTORbio does not provide such information within 20 days after resTORbio's written request or does not pick up the materials in 30 days after resTORbio's written request it will forfeit its right to pick up these materials, but such forfeit will not occur if Novartis does not provide necessary documentation and information required for resTORbio or its designee to pick up the BEZ API, BEZ Drug Product, and BEZ Placebo for shipment. resTORbio will be responsible for all documentation, licenses, customs clearance, costs, *etc.* that are needed for and related to the pick up, transport, and subsequent delivery of the materials to the first destination as defined by resTORbio. The BEZ API, BEZ Drug Product, and BEZ Placebo shall be provided Ex Works (Novartis' facility) (Incoterms 2010) [\*\*\*]. All BEZ API and BEZ Drug Product supplied by Novartis will only be used according to its specifications, especially release specifications and applicable laws, and will not be used for Commercial purposes.

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6.2 [Reserved].

6.3 **RAD001 Dispersible Batch.** At resTORbio’s request and written purchase order to be placed before April 10, 2017, Novartis will make a once-off supply of commercially packaged RAD001 dispersible tablets (the “**RAD001 Dispersible Once-Off Supply**”), with such supply consisting of approximately [\*\*\*] tablets ([\*\*\*] mg) and [\*\*\*] tablets ([\*\*\*] mg). The RAD001 Dispersible Once-Off Supply shall be manufactured by Novartis in accordance with cGMP. The Parties agree that all other warranties are excluded including any implied warranties as to merchantability or fitness for purpose. The RAD001 Dispersible Once-Off Supply will be delivered FCA or EXW at Novartis’ option, from a Novartis facility which address shall be notified by Novartis to resTORbio in writing (Incoterms 2010). Delivery of the RAD001 Dispersible Once-Off Supply is anticipated to occur five months after receipt of the purchase order from resTORbio. The RAD001 Dispersible Once-Off Supply may be made by Novartis, an Affiliate or third party at Novartis’ discretion. resTORbio will use the RAD001 Dispersible Once-Off Supply for Development purposes only and shall not ship or use it, even partially outside of the United States. resTORbio will be responsible for all documentation and licenses required for resTORbio to accept delivery of the RAD001 Dispersible Once-Off Supply. resTORbio will

pay USD\$[\*\*\*] for these materials within 60 days after receipt of an invoice for the same, which will be issued by Novartis on or after the Effective Date. The RAD001 Dispersible Once-Off Supply shall consist of the following SKUs:

<u>Material No.</u>	<u>Product description</u>	<u>Tablets per blister</u>	<u>Blister cards per finished pack</u>	<u>Tablets per finished pack</u>	<u>Tablets required by resTORbio</u>	<u>Price per pack</u>
[***]	[***] [***] [***] [***]	[***]	[***]	[***]	[***]	USD \$[***]
[***]	[***] [***] [***] [***]	[***]	[***]	[***]	[***]	USD \$[***]

## 7. COMMERCIALIZATION

- 7.1 **Commercialization.** resTORbio will be solely responsible for all aspects of Commercialization of the Products, including planning and implementation, distribution, booking of sales, pricing, and reimbursement. resTORbio will itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Commercialize at least one Product in at least one Major Market. Notwithstanding the foregoing, resTORbio's application of Commercially Reasonable Efforts will not require resTORbio to Commercialize a Product in any particular country or territory other than a Major Market if resTORbio reasonably determines that it is not commercially reasonable to do so for such Product. Subject to compliance with the foregoing, the Commercialization of the Product will be in resTORbio's sole discretion.

## 8. FINANCIAL PROVISIONS

- 8.1 **Upfront Equity in resTORbio.** In consideration of the licenses and rights granted to resTORbio hereunder, on the Effective Date and at the same time as the closing of a \$15 million investment in Series A preferred shares of resTORbio by other investors, resTORbio will issue to Novartis Series A Preferred Shares, representing USD \$5 million worth of Series A Preferred Shares of resTORbio on the terms and conditions set forth in the various agreements and instruments set forth in *Exhibit E*.
- 8.2 **Sublicense Revenue.** To the extent that resTORbio receives consideration from a sublicensee for the granting of a sublicense of the licenses and rights granted to resTORbio by Novartis in this Agreement, and such consideration is not for the purpose of funding the reasonable costs directly related to research and development by resTORbio of the Compounds (such an agreement is referred to as a "Sublicense Agreement"), then resTORbio shall pay to Novartis **(x)** forty percent (40%) of the value of the consideration received by resTORbio pursuant to any Sublicense Agreement executed prior to the date that resTORbio or its sublicensee has completed the last visit in of the 40th subject of any Clinical Trial (the "40 Patient Trial Date"), and **(y)** twenty percent (20%) of the value of such consideration received by resTORbio or its sublicensee pursuant to any Sublicense Agreement executed after the 40 Patient Trial Date but executed prior to the date that resTORbio or its sublicensee has completed (last patient visit) a clinical trial or clinical trials of a Product, which studies include in the aggregate at least 400 patients (the "400 Patient Trial Date"). resTORbio shall not be required to share with Novartis any additional sublicensing consideration pursuant to this Section 8.2 received pursuant to Agreements executed after the 400 Patient Trial Date. resTORbio shall give Novartis notice of the execution of such Sublicense Agreement within 15 days after its execution and such payment shall be made within 30 days after receipt of such consideration by resTORbio. For the avoidance of doubt, in each case, Milestone Payments under Section 8.3, Sales Milestones under Section 8.4, and Royalties under Section 8.5 will continue to be due with respect to any such sublicense; *provided, however*, that resTORbio shall be entitled to offset the amount of any Milestone Payments against corresponding Milestone Payments payable to Novartis under Section 8.3(a) of this Agreement (but not Sales Milestones under Section 8.4 or Royalties under Section 8.5) pursuant to Sublicense Agreements executed prior to the 400 Patient Trial Date against amounts payable to Novartis by resTORbio under this Section 8.2 (but in no event will such set off result in a refund).

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### 8.3 Milestone Payments.

- (a) In further consideration of the licenses and rights granted to resTORbio hereunder, upon achievement of each of the following Milestones set forth below for a Product by resTORbio, its Affiliates, or its sublicensees (as applicable), the corresponding Milestone Payments will be payable to Novartis:

<u>Milestone</u>	<u>Milestone Payment (USD)</u>
<i>Clinical Milestones</i>	
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]
<i>Regulatory Milestones</i>	
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]

- (b) Each Milestone Payment will be deemed earned as of the first achievement of the corresponding Milestone, and will be paid within 30 days after the relevant Milestone is achieved. resTORbio will provide Novartis with written notice of the achievement of each Milestone within fifteen (15) days after such Milestone is determined to have been achieved.
- (c) Each Milestone in the table above will be paid only once. The total potential Milestone Payments that may be paid under this Section 8.3 is \$46,100,000. For the avoidance of doubt, no additional Milestone Payments will be due for Milestones completed for the Development and Commercialization of Products that were previously achieved by a different Product for the same Indication, or for any Product intended to treat any additional Indications (by the same Product) (after the first two).
- (d) In the event that a clinical Milestone is skipped for any reason and a subsequent milestone is achieved with respect to any Product (e.g., if a Phase II Clinical Trial was not required for a Product and a Phase III Clinical Trial was initiated), then resTORbio shall pay the amount of the skipped clinical Milestone upon achievement of the subsequent Milestone.

### 8.4 Sales Milestones.

- (a) resTORbio will make each of the following one time payments when worldwide Annual Net Sales of all Products in a given Calendar Year by it, its Affiliates, or their sublicensees first meet the corresponding thresholds:

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<u>Aggregate Net Sales of Products in any Calendar Year during the Royalty Term</u>	<u>Sales Milestone Payment (USD)</u>
[***]	\$ [***]
[***]	\$ [***]
[***]	\$ [***]
[***]	\$ [***]
[***]	\$ [***]

- (b) For example, if Annual Net Sales of Products in the first Calendar Year of Net Sales equals \$600 million, then both the first and second Sales Milestone Payments will be made in that year.
- (c) Each Milestone Payment in the table above will be paid only once. The total potential Milestone Payments that may be paid under this Section 8.4 is \$125,000,000.
- (d) Each Milestone Payment will be deemed earned as of the first achievement of the corresponding sales milestone, and will be paid within 30 days after the relevant sales milestone is achieved. resTORbio will provide Novartis with written notice of the achievement of each Milestone within fifteen (15) days after such sales milestone is determined to have been achieved.

## 8.5 Royalty Payments.

(a) In consideration of the licenses and rights granted to resTORbio hereunder, during the Royalty Term, resTORbio will make royalty payments to Novartis on Net Sales of Products by resTORbio, its Affiliates and sublicensees, at the rates set forth below:

<u>Aggregate Net Sales of Product in any Calendar Year during the Royalty Term</u>	<u>Royalty Rate</u>
[***]	[***]%
[***]	[***]%
[***]	[***]%
[***]	[***]%
[***]	[***]%
[***]	[***]%

- (b) For example, if Net Sales in a Calendar Year are \$[\*\*\*], the royalty on such Net Sales will be equal to [\*\*\*] of USD \$[\*\*\*], [\*\*\*]% of USD \$[\*\*\*], [\*\*\*]% of USD \$[\*\*\*], [\*\*\*]% of USD \$[\*\*\*], and [\*\*\*]% of USD \$[\*\*\*], or USD \$[\*\*\*].
- (c) Royalties will be payable on a Product-by-Product and country-by-country basis during the Royalty Term for such Product in such country. Following the expiration of the applicable Royalty Term for a Product in a country, resTORbio licenses under this Agreement with respect to such Product in such country will continue in effect, but will become fully paid-up, royalty-free, transferable, perpetual and irrevocable. For the avoidance of doubt, royalties will be payable only once with respect to the same unit of Product.
- (d) Within thirty (30) days after each Calendar Quarter during the term of this Agreement following the First Commercial Sale of a Product, resTORbio will provide to Novartis a Sales & Royalty Report. Novartis will submit an Invoice to resTORbio with respect to the royalty amount shown therein. resTORbio will pay such royalty amount within thirty (30) days after receipt of the Invoice.



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- (e) Notwithstanding anything to the contrary herein, in the event that, with respect to a Product in a specified country, if (i) the Royalty Term for such Product in such country continues solely due to clause (b) or clause (c) of the definition of Royalty Term (i.e., there is no Valid Claim of a Patent Right included in the Novartis Technology Covering the Product), or (ii) a Generic Equivalent exists with respect to such Product in the Field in such country in a Calendar Year, [\*\*\*].

#### 8.6 Third Party Obligations; Set Off.

- (a) [Reserved].
- (b) If resTORbio reasonably determines that, in order to avoid infringement of any Patent Right not licensed hereunder that covers the composition of matter or method of use of a Compound, it is required to obtain a license under such Patent Right from a Third Party in order to Commercialize a Product in the Field in a country and is required under a license agreement entered into after the Effective Date to pay a licensing fee and/or royalty to such Third Party under such license (including in connection with the settlement of a patent infringement claim), [\*\*\*].
- (b) [\*\*\*]. Any amount that resTORbio is entitled to deduct that is reduced by this limitation will be carried forward and resTORbio may deduct such amount from royalty payments due to Novartis until the full amount that resTORbio was entitled to deduct is deducted.

#### 8.7 Payments.

- (a) All payments from resTORbio to Novartis will be made by wire transfer in US Dollars to the credit of such bank account as may be designated by Novartis in this Agreement or in writing to resTORbio. Any payment which falls due on a date which is not a business day in the location from which the payment will be made may be made on the next succeeding business day in such location.
- (b) All payments under this Agreement will be payable in USD. When conversion of payments from any foreign currency is required to be undertaken by resTORbio, the USD equivalent will be calculated using resTORbio's then-current standard exchange rate methodology as applied in its external reporting. If there is no standard exchange rate methodology applied by resTORbio in its external reporting in accordance with Accounting Standards, then any amount in a currency other than USD shall be converted to USD using the exchange rate most recently quoted in the *Wall Street Journal* in New York as of the last business day of the applicable Calendar Quarter.
- (c) Novartis will pay any and all taxes levied on account of any payments made to it under this Agreement. If any taxes are required to be withheld by resTORbio, resTORbio will: (i) deduct such taxes from the payment made to Novartis; (ii) timely pay the taxes to the proper taxing authority; (iii) send proof of payment to Novartis; and (iv) reasonably assist Novartis in its efforts to obtain a credit for such tax payment. Each Party will reasonably assist the other Party in lawfully claiming exemptions from and/or minimizing such deductions or withholdings under double taxation laws or similar circumstances.

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- (d) Without limiting any other rights or remedies available to Novartis hereunder, if resTORbio does not pay any amount due on or before the due date, any such payment shall bear interest at a rate of four percentage points (4%) above the six (6) months LIBOR for US dollars on the date the payment was due or the highest rate permitted by law (whichever is lower), computed from the date such payment was due until the date resTORbio makes the payment.

#### 8.8 Records and Audit Rights.

- (a) resTORbio will keep, and will cause its Affiliates and sublicensees to keep, complete, true and accurate books and records in accordance with its Accounting Standards in relation to Net Sales and royalties payable to Novartis hereunder. resTORbio will keep, and will cause its Affiliates and sublicensees to keep, such books and records for at least three (3) years following the Calendar Quarter to which they pertain.
- (b) Novartis may, upon written notice to resTORbio, appoint an internationally- recognized independent accounting firm (which is reasonably acceptable to resTORbio) (the "Auditor") to inspect the relevant reports, statements, records or books of accounts (as applicable) of resTORbio or its Affiliates or sublicensees to verify the accuracy of any Sales & Royalty Report. Before beginning its audit, the Auditor will execute an undertaking reasonably acceptable to resTORbio by which the Auditor will keep confidential all Information reviewed during such audit. The Auditor will have the right to disclose to Novartis its conclusions regarding any payment owed under this Agreement.
- (c) resTORbio and its Affiliates and sublicensees will make their records available for inspection by such Auditor during regular business hours at such place or places where such records are customarily kept, upon receipt of reasonable advance notice from Novartis. The records will be reviewed solely to verify the accuracy of the Sales & Royalty Reports. Such inspection right will not be exercised more than once in any Calendar Year and not more frequently than once with respect to records covering any specific period of time. In addition, Novartis will only be entitled to audit the relevant books and records of resTORbio relating to a Sales & Royalty Report for a period of three (3) Calendar Years after receipt of the applicable Sales & Royalty Report. Novartis will hold in confidence all Information received and all Information learned in the course of any audit or inspection, except to the extent necessary to enforce its rights under this Agreement or if disclosure is required by law, regulation or judicial order.
- (d) The Auditor will provide its audit report and basis for any determination to resTORbio at the time such report is provided to Novartis, before it is considered final. resTORbio will have the right to request a further determination by such Auditor as to matters which resTORbio disputes

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within thirty (30) days following receipt of such report. resTORbio will provide Novartis and the Auditor with a reasonably detailed statement of the grounds upon which it disputes any findings in the audit report and the Auditor will undertake to complete such further determination within thirty (30) days after the dispute notice is provided, which determination will be limited to the disputed matters. Any matter that remains unresolved will be resolved in accordance with the dispute resolution procedures contained in Section 16.5.

- (e) In the event that the final result of the inspection reveals an undisputed underpayment or overpayment by resTORbio, the underpaid or overpaid amount will be settled promptly.
- (f) Novartis will pay for such audits, as well as its own expenses associated with enforcing its rights with respect to any payments hereunder, except that in the event there is any upward adjustment in aggregate amounts payable for any Calendar Quarter shown by such audit of more than four percent (4%) of the amount paid, resTORbio will pay for such audit.

8.9 **No Projections.** Novartis and resTORbio acknowledge that nothing in this Agreement will be construed as representing an estimate or projection of anticipated sales of any Product, and that the Milestones and Net Sales levels set forth above or elsewhere in this Agreement or that have otherwise been discussed by the Parties are merely intended to define the Milestone Payments and royalty obligations to Novartis in the event such Milestones or Net Sales levels are achieved. *resTORbio MAKES NO REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY COMMERCIALIZE ANY PRODUCT OR, IF COMMERCIALIZED, THAT ANY PARTICULAR NET SALES LEVEL OF SUCH PRODUCT WILL BE ACHIEVED.*

8.10 **Adjustment to Milestone Payments.** The Parties will collaborate in good faith to maximize the chances of the material supply as described in Section 6.1 as soon as practical.

If the material is not made available to resTORbio by April 3, 2017 (after resTORbio provides all information reasonably required by Novartis within not later than March 24, 2017), then resTORbio will receive a non-refundable credit of USD\$[\*\*\*] to be applied against any milestone payments under Section 8.3 or 8.4 of this Agreement.

## 9. INTELLECTUAL PROPERTY.

9.1 **Inventions and Know-How.** All inventions, whether or not reduced to practice, and Know- How arising from resTORbio's activities under this Agreement, including any Patent Rights covering such inventions, will be owned by resTORbio, subject to the licenses to Novartis and its Affiliates to RAD001 Improvements set forth in Section 2.3.

9.2 **Ownership of Results and Data.** All data and results arising from resTORbio's activities under this Agreement, including but not limited to Development, clinical and regulatory data and Information generated for regulatory purposes relating to a Product will be owned by resTORbio.

### 9.3 Patent Prosecution.

- (a) *[Reserved]*
- (b) resTORbio will have the sole right to control Prosecution and Maintenance of all RAD001 Patents, BEZ235 Patents, and BEZ235/RAD001 Combination Patents (the "Licensed Patents") at resTORbio's expense, using counsel reasonably acceptable to Novartis. resTORbio will keep Novartis informed of important issues relating to the Prosecution and Maintenance of the Novartis Patents, and will furnish to Novartis copies of documents relevant to such Prosecution and Maintenance in sufficient time, but no later than 14 days, prior to the filing of such document to allow for review and comment by Novartis and resTORbio will reasonably consider all of such comments. Novartis will cooperate with and assist resTORbio in the Prosecution and Maintenance of the Novartis Patents including by (i) making its relevant scientists and scientific records reasonably available and (ii) signing and delivering (or using reasonable efforts to have signed and delivered), subject to reimbursement of out of pocket costs by resTORbio, all documents reasonably necessary in connection with such Prosecution and Maintenance. resTORbio will notify Novartis of any decision not to continue to pay the expenses of Prosecution and Maintenance of any Novartis Patent, which notice must be delivered at least sixty (60) days prior to any payment due date. In such event, Novartis, at its sole discretion and expense, shall have the right to continue Prosecution and Maintenance of such Novartis Patent in such country and, thereafter, such Novartis Patent shall no longer be considered a Novartis Patent licensed to resTORbio in such country. In the event that Novartis undertakes such Prosecution and Maintenance, resTORbio will provide Novartis all reasonable assistance and cooperation in relation thereto, including providing any necessary powers of attorney and any other required documents or instruments.

### 9.4 Third Party Infringement.

- (a) Each Party will promptly notify the other of any infringement in the Field by a Third Party of any of the Novartis Patent or misappropriation of any Novartis Know-How in the Field of which it becomes aware, including any filing of an Abbreviated New Drug Application in the United States or such similar filing under applicable law in jurisdictions other than the United States. Each Party shall provide the other Party with all available evidence supporting such infringement, suspected infringement, unauthorized use or misappropriation or suspected unauthorized use or misappropriation (collectively, "Third Party Infringement").
- (b) resTORbio will have the first right to bring and control any legal action in connection with the Third Party Infringement relating to any Novartis Patent in the Field at its own expense as it reasonably determines appropriate, and Novartis will have the right, at its own expense, to be represented in any such action by counsel of its own choice. If resTORbio fails to bring an action or proceeding with respect to, or to terminate, infringement of any Novartis Patent

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(i) within ninety (90) days following the notice of alleged infringement (or twenty (20) days after resTORbio receives the relevant ANDA notification), or

(ii) prior to twenty (20) days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, Novartis will have the right to bring and control any such action at its own expense and by counsel of its own choice, and resTORbio will have the right, at its own expense, to be represented in any such action by counsel of its own choice; *provided, however*, that if resTORbio notifies Novartis in writing prior to twenty (20) days before such time limit for the filing of any such action that resTORbio intends to file such action before the time limit, then resTORbio will be obligated to file such action before the time limit, and Novartis will not have the right to bring and control such action.

(c) At the request of the Party controlling the Third Party Infringement claim, the other Party will provide assistance in connection therewith, including by executing reasonably appropriate documents, access to such Party's premises and employees, cooperating reasonably in discovery and joining as a party to the action if required.

(d) In connection with any such proceeding, resTORbio will not enter into any settlement admitting the invalidity of, or otherwise impairing Novartis' rights in, the Novartis Technology without the prior written consent of Novartis, which will not be unreasonably withheld or delayed.

(e) Any recoveries resulting from such an action relating to a Third Party Infringement will be first applied against payment of each Party's costs and expenses in connection therewith. In the event that resTORbio brought such action, any remainder will be retained by resTORbio; *provided, however*, any such amount will be considered Net Sales hereunder and will be subject to a royalties and sales milestones (as applicable) to Novartis under this Agreement. In the event that Novartis brought such action, the remainder will be retained by Novartis.

9.5 **Patent Invalidity Claim.** If a Third Party at any time asserts a claim that any Novartis Patent is invalid or otherwise unenforceable (an "Invalidity Claim"), whether as a defense in an infringement action brought by a Party pursuant to Section 9.4, in a declaratory judgment action or any patent office proceeding anywhere in the world (e.g., inter-partes review or European opposition) or otherwise, resTORbio shall have the first right, but not the obligation, to defend such Invalidity Claim and Novartis shall cooperate with resTORbio in preparing and formulating a response to such Invalidity Claim. If resTORbio does not defend an Invalidity Claim brought against a Novartis Patent, Novartis may defend such Invalidity Claim and the coordination provisions of Section 9.4(c) will apply to such Invalidity Claim, *mutatis mutandis* as they apply to Third Party Infringement suits. Neither Party may, without the consent of the other Party, settle or compromise any Invalidity Claim in any manner which would (a) have an adverse effect on such other Party's rights or obligations hereunder or (b) be an admission of liability on behalf of the other Party (*provided, however*, that the Party initiating such suit may settle such suit without such consent if such settlement involves only the receipt of money from, or the payment of money to, such Third Party and the Party settling such suit makes all such

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payments to such Third Party). To the extent such Invalidity Claim is raised as a defense in an infringement action brought by a Party pursuant to Section 9.4, the expense provisions of Section 9.4 will apply and counsel to the Party controlling the infringement action shall act as the ministerial liaison with the court.

9.6 **Trademarks.** resTORbio will have the right to brand the Products using resTORbio related trademarks and any other trademarks and trade names it determines appropriate for the Products, which may vary by country or within a country ("Product Marks"). resTORbio will own all rights in the Product Marks and register and maintain the Product Marks in the countries and regions it determines reasonably necessary. In no event will resTORbio use any Novartis trademarks (including but not limited to ZORTESS CERTICAN, AFINITOR, or VOTUBIA) in connection with the research, Development, or Commercialization of Compounds or Products under this Agreement

9.7 **Patent Extensions.**

- (a) If requested by resTORbio, Novartis will cooperate in obtaining patent term restoration (under but not limited to the Drug Price Competition and Patent Term Restoration Act), supplemental protection certificates or their equivalents, and patent term extensions with respect to the Novartis Patents in any country and/or region where applicable. Novartis will provide all reasonable assistance requested by resTORbio, including permitting resTORbio to proceed with applications for such in the name of Novartis, if deemed appropriate by resTORbio, and executing documents and providing any relevant information to resTORbio.
- (b) As between the Parties, resTORbio will in its sole discretion determine which, if any, Novartis Patents it will apply to extend; *provided, however*, that resTORbio will give Novartis 45 days' notice before doing so and reasonably consider any input from Novartis with respect to the extension of any Novartis Patents.

**10. CONFIDENTIALITY**

10.1 **Duty of Confidence.**

- (a) Subject to the other provisions of this Section 10, all Information disclosed by a Party or its Affiliates under this Agreement will be maintained in confidence and otherwise safeguarded by the recipient Party. The recipient Party may only use the Information for the purposes of this Agreement and pursuant to the rights granted to the recipient Party under this Agreement. Subject to the other provisions of this Section 10, each Party will hold as confidential such Information of the other Party or its Affiliates in the same manner and with the same protection as such recipient Party maintains its own confidential information. Subject to the other provisions of this Section 10, a recipient Party may only disclose Information of the other Party to employees, agents, contractors, consultants and advisers of the Party and its Affiliates and sublicensees and to Third Parties to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; *provided* that such Persons are bound to maintain the confidentiality of the Information in a manner consistent with the confidentiality provisions of this Agreement.

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- (b) With respect to Novartis' obligations under this Section 10, all Novartis Know-How, to the extent relating to Compounds and Products in the Field, will be considered Information of resTORbio during the Term of the Agreement and Novartis will maintain in confidence and otherwise safeguard such Novartis Know-How as such in accordance with this Section 10 (it being understood that the exceptions in Sections 10.2(b) and (c) will not apply to Novartis with respect to Novartis Know-How); *provided, however*, that for the avoidance of doubt, all Know-How owned or Controlled by either Party about RAD001 generally and/or RAD001 outside the Field shall be deemed to be Information of Novartis.

10.2 **Exceptions.** The obligations under this Section 10 will not apply to any information to the extent the recipient Party can demonstrate by competent evidence that such information:

- (a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the recipient Party or its Affiliates;
- (b) was known to, or was otherwise in the possession of, the recipient Party or its Affiliates prior to the time of disclosure by the disclosing Party or any of its Affiliates;
- (c) is disclosed to the recipient Party or an Affiliate on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the disclosing Party or any of its Affiliates; or
- (d) is independently developed by or on behalf of the recipient Party or its Affiliates, as evidenced by its written records, without reference to the Information disclosed by the disclosing Party or its Affiliates under this Agreement.

Specific aspects or details of Information will not be deemed to be within the public domain or in the possession of the recipient Party merely because the Information is embraced by more general information in the public domain or in the possession of the recipient Party.

Further, any combination of Information will not be considered in the public domain or in the possession of the recipient Party merely because individual elements of such Information are in the public domain or in the possession of the recipient Party unless the combination and its principles are in the public domain or in the possession of the recipient Party.

10.3 **Authorized Disclosures.**

- (a) In addition to disclosures allowed under Section 10.1 and 10.2, either Party may disclose Information belonging to the other Party or its Affiliates to the extent such disclosure is necessary in the following instances: (i) filing or prosecuting Patent Rights as permitted by this Agreement; (ii) in connection with

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Regulatory Filings for Products; **(iii)** prosecuting or defending litigation as permitted by this Agreement; **(iv)** complying with applicable court orders or governmental regulations; **(v)** in connection with an offering of securities or securities law disclosure requirements if counsel determines that such disclosure is required; or **(vi)** to the extent otherwise necessary or appropriate in connection with exercising the license and other rights granted to it hereunder.

- (b)** In addition, resTORbio and its Affiliates and sublicensees may disclose Information of Novartis to Third Parties as may be necessary or useful in connection with the Development, manufacture or Commercialization of the Compounds and/or Product(s) as permitted by this Agreement, including in connection with subcontracting transactions; *provided, however*, that to the extent such Information relates to RAD001 (alone or in combination) and is not otherwise permitted under Section 5.1, any such disclosure shall be subject to Novartis' written approval (which will not be unreasonably withheld or delayed more than 30 days).
- (c)** In addition, either Party may disclose the terms of this Agreement and Information pertaining to Products in connection with an assignment or potential assignment of this Agreement, a loan, financing or investment transaction, or an acquisition, merger, consolidation or similar transaction (or for such Persons to determine their interest in performing such activities or entering into such transactions), in each case on the condition that any Third Parties to whom such disclosures are made agree to be bound by confidentiality and non-use obligations no less rigorous than those contained in this Agreement.
- (d)** In the event the recipient Party is required to disclose Information of the disclosing Party by law or in connection with bona fide legal process, such disclosure will not be a breach of this Agreement; provided that the recipient Party **(i)** informs the disclosing Party as soon as reasonably practicable of the required disclosure; **(ii)** limits the disclosure to the required purpose; and **(iii)** at the disclosing Party's request and expense, assists in an attempt to object to or limit the required disclosure.

10.4 **Ongoing Obligation for Confidentiality.** Upon early termination of this Agreement for any reason, each Party and its Affiliates will immediately return to the other Party or destroy any Information disclosed by the other Party, except for one copy which may be retained in its confidential files for archive purposes.

## 11. TERM AND TERMINATION

11.1 **Term.** The term of this Agreement will commence upon the Effective Date and continue on a country-by-country basis until the expiry of the Royalty Term in such country, unless earlier terminated as permitted by this Agreement.



**11.2 Termination for Cause.**

- (a) If either Novartis or resTORbio is in material breach of any material obligation hereunder, the non-breaching Party may give written notice to the breaching Party specifying the claimed particulars of such breach, and in the event such material breach is not cured within sixty (60) days after such notice, the non-breaching Party will have the right (but not the obligation) thereafter to terminate this Agreement immediately by giving written notice to the breaching Party to such effect; *provided, however*, that if such breach is capable of being cured but cannot be cured within such sixty (60) day period and the breaching Party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching Party will have an additional thirty (30) days (or such longer period agreed upon by the Parties) to cure such breach. Any termination by any Party under this Section and the effects of termination provided herein will be without prejudice to any damages or other legal or equitable remedies to which it may be entitled
- (b) If resTORbio does not receive total equity or other non-dilutive (including grants and partnerships or sublicenses, but excluding debt instruments) financing of at least USD\$15 million by the third anniversary of the Effective Date, then Novartis will have the right, at its discretion, to terminate this Agreement upon 90 days' advance to resTORbio, unless during such 90 day period, resTORbio receives such equity or other non-dilutive financing.

**11.3 Insolvency.** If an Insolvency Event occurs, (a) resTORbio will give immediate (not longer than three business days') notice to Novartis of such occurrence, and (b) Novartis will have the right to immediately terminate this Agreement by written notice to resTORbio.

**11.4 Termination by resTORbio Without Cause.** resTORbio may terminate this Agreement without cause at any time after the Effective Date in its entirety or on a Product-by-Product or country-by-country basis at any time on sixty (60) days' prior written notice.

**11.5 Partial Termination for Failure to Use Commercially Reasonable Efforts on a RAD001 Product.** If resTORbio does not use, or ceases to use, Commercially Reasonable Efforts to research, Develop, and Commercialize a Product incorporating RAD001 for a period of three years, but is otherwise not in breach of its obligation to research, Develop, and Commercialize a Product under Article 7 (*e.g.*, resTORbio is using Commercially Reasonable Efforts to research, Develop, and Commercialize a BEZ235-only Product), then Novartis will have the right to terminate the licenses and rights set forth in this Agreement with respect to RAD001 (*i.e.*, the license grants by Novartis to resTORbio, all rights of reference granted by Novartis to resTORbio relating to RAD001, all rights to RAD001 supply, *etc.*) by delivering written notice to resTORbio; *provided, however* that all other aspects of this Agreement (including the license grants to BEZ235 and all rights of reference to BEZ235) as well as the license to Novartis to RAD001 Improvements will survive such a termination.

**11.6 Rights in Bankruptcy.** The Parties acknowledge that this Agreement constitutes an executory contract under Section 365 of the Code for the license of "intellectual property" as defined under Section 101 of the Code and constitutes a license of "intellectual property" for purposes of any similar laws in any other country. The Parties further acknowledge that resTORbio, as licensee of such rights under this Agreement, will retain and may fully exercise all of its protections, rights and elections under the Code, including, but not limited to, Section 365(n) of the Code, and any similar laws in any other country. In the event of the commencement of a bankruptcy proceeding by or against Novartis under the Code and any similar laws in any other country, resTORbio will be entitled to a complete duplicate of

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(or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and the same, if not already in its possession, will be promptly delivered to it **(a)** upon any such commencement of a bankruptcy proceeding upon its written request therefor, unless Novartis elects to continue to perform all of its obligations under this Agreement, or **(b)** if not delivered under (a) above, following the rejection of this Agreement by or on behalf of Novartis upon written request therefor by resTORbio. All rights, powers and remedies of resTORbio provided for in this Section 11.6 are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including, without limitation, under the Code and any similar laws in any other country).

## 12. EFFECT OF TERMINATION

12.1 **Termination by resTORbio for Cause.** Upon termination of this Agreement by resTORbio pursuant to Section 11.2:

- (a)** the licenses and other rights granted by Novartis to resTORbio under the Novartis Technology and the covenant not to sue set forth in Section 2.4 will terminate and resTORbio shall not have any rights to use or exercise any rights under the Novartis Technology; and
- (b)** except as set forth in this Section and in Section 12.3, the rights and obligations of the Parties hereunder will terminate as of the date of such termination.

12.2 **Termination by Novartis for Cause or by resTORbio Without Cause.** Upon termination of this Agreement by Novartis pursuant to Section 11.2 or Section 11.3 or by resTORbio pursuant to Section 11.4:

- (a)** all licenses and other rights granted by Novartis to resTORbio under the Novartis Technology will terminate and resTORbio shall not have any rights to use or exercise any rights under the Novartis Technology
- (b)** the license to RAD001 Improvements will remain in full force and effect;
- (c)** the provisions of Article 9 will terminate;
- (d)** within thirty (30) days of termination, resTORbio will provide to Novartis a fair and accurate summary report of the status of the Development, manufacture and Commercialization of all Compounds and Products in the Field in each country through the effective date of termination;
- (e)** resTORbio will grant, and hereby does grant, to Novartis and its Affiliates, solely for the Development, manufacture and Commercialization of Products in the Field, a perpetual, irrevocable, exclusive, worldwide, fully paid-up license, with the right to grant sublicenses, under all Patent Rights and Know-How Controlled by resTORbio and its Affiliates and sublicensees as of the effective date of termination, that are specifically related to the Development, manufacture and Commercialization of Products in the Field;

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- (f) to the extent permitted by applicable law, resTORbio will transfer to Novartis or its designee, solely for the Development, manufacture and Commercialization of Products in the Field, all right, title, and interest in and to all preclinical and clinical data, and all other supporting data, including pharmacology, toxicology, chemistry and biology data, and documented technical and other information or materials Controlled by resTORbio and its Affiliates and sublicensees to the extent related to the Development, manufacture and Commercialization of Products in the Field; *provided* that resTORbio may retain a single copy of such items for its records as required by applicable law;
- (g) to the extent permitted by applicable law, resTORbio will transfer to Novartis or its designee all Regulatory Filings, Regulatory Approvals (including reimbursement and pricing approvals), the contents of any global safety database, records of all interactions with Regulatory Authorities, in each case to the extent related to Products in the Field, that resTORbio and its Affiliates and sublicensees Control as of the effective date of such termination. If resTORbio is restricted under applicable law from transferring ownership of any of the foregoing items to Novartis or its designee, resTORbio will grant, and hereby does grant, to Novartis (or its designee) a right of reference or use to such item. resTORbio will take all permitted actions reasonably necessary to effect such transfer or grant of right of reference or use to Novartis or its designee;
- (h) to the extent reasonably requested by Novartis, resTORbio will transfer to Novartis any license agreements or other contracts between resTORbio or any of its Affiliates and any Third Party that are specific to the Products in the Field (including, as applicable, clinical trial and manufacturing agreements), to the extent such agreements are in effect as of the effective date of termination and such assignment or transfer is permitted at no cost or expense to resTORbio, and to facilitate introductions of Novartis to the applicable subcontractors, licensors, manufacturing vendors, clinical trial sites, clinical trial investigators and the like;
- (i) Novartis will have the right to purchase from resTORbio all of the inventory of the Products held by resTORbio and its Affiliates and sublicensees as of the effective date of termination at a price equal to resTORbio's actual manufacturing cost, determined in accordance with Accounting Standards, but only if such Products meet the applicable release specifications;
- (j) for a period of six (6) months following the effective date of termination, resTORbio will provide such assistance as may be reasonably necessary to transfer manufacturing documents and materials that are used by resTORbio and its Affiliates and sublicensees (or their subcontractor(s)) in the manufacture of Products, and cooperate with Novartis in reasonable respects to transfer to Novartis, or Novartis' designated contract manufacturer, the manufacturing technologies (including all relevant Know-How) that are used in the manufacture of the Products;
- (k) Novartis will pay to resTORbio, on a Product-by-Product basis for each Product for which a Phase III Clinical Trial had been Initiated prior to the effective date of termination, royalties on Net Sales of such Product by or under the authority

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of Novartis, its Affiliates or licensees or sublicensees, at fifty percent (50%) of the rates set forth in Section 8 in accordance with the same schedule and other terms and conditions as resTORbio would have otherwise been obligated to pay royalties to Novartis for Products under Article 8, *mutatis mutandis* (including, for the avoidance of doubt, provisions relating to reductions in royalty rates arising from a loss of Patent Rights, set offs for in-licensed Third Party intellectual property, *etc.*);

- (l) except as set forth in this Section and in Section 12.3, the rights and obligations of the Parties hereunder will terminate as of the date of such termination;
- (m) Novartis will thereafter indemnify, defend and hold resTORbio and the resTORbio Indemnitees harmless in the manner forth in Section 14.2(a) as if Novartis were resTORbio and the resTORbio Indemnitees were the Novartis Indemnitees, *mutatis mutandis* for all claims arising after the effective date of such termination, and resTORbio's indemnification obligations under that Section 14.2(a) shall thereupon cease for claims arising after the effective date of such termination; and
- (n) Section 2.4 will terminate.

12.3 **Survival.** Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the provisions of Article 1, 11, 12, 14, and 16 will survive expiration or termination of this Agreement. The provisions of Article 10 (Confidentiality) will survive the termination or expiration of this Agreement for a period of ten (10) years.

12.4 **Termination Not Sole Remedy.** Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies will remain available except as agreed to otherwise herein. For the avoidance of doubt, nothing in this Agreement shall obligate a Party to terminate this Agreement in the event that the other Party breaches any obligation of this Agreement, and failure to terminate this Agreement shall not prohibit or modify the recovery of damages pursuant to Section 16.5.

12.5 **Termination of RAD001 License Only.** If Novartis terminates the license with respect to RAD001 only pursuant to Section 11.5, then the provisions of Section 12.2(a) through 12.2(o) will apply, but only with respect to RAD001.

### 13. REPRESENTATIONS, WARRANTIES AND COVENANTS

13.1 **Representations and Warranties by Each Party.** Each Party represents and warrants to the other as of the Effective Date that:

- (a) it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;
- (b) it has full corporate power and authority to execute, deliver, and perform this Agreement, and has taken all corporate action required by law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

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- (c) this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles and public policy constraints (including those pertaining to limitations and/or exclusions of liability, competition laws, penalties and jurisdictional issues including conflicts of laws);
- (d) all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained;
- (e) the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and will not **(i)** conflict with or result in a breach of any provision of its organizational documents; **(ii)** result in a breach of any agreement to which it is a party; or **(iii)** violate any law; and
- (f) neither such Party nor, to the actual knowledge of such Party, any employee, agent or subcontractor of such Party involved or to be involved in the Development of the Compounds or the Products has been debarred under Subsection (a) or (b) of Section 306 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 335a).

### 13.2 Covenants by resTORbio.

- (a) No Person who is known by resTORbio **(a)** to have been debarred under Subsection (a) or (b) of Section 306 of said Act, or **(b)** to be on any of the FDA clinical investigator enforcement lists (including, but not limited to, the **(i)** Disqualified/Totally Restricted List, **(ii)** Restricted List and **(iii)** Adequate Assurances List), will be employed by or on behalf of resTORbio or its Affiliates or otherwise participate in the performance of any activities hereunder; and
- (b) resTORbio will maintain, general liability insurance with limits not less than those reasonably suited to address claims that could reasonably arise from the Development and Commercialization of pharmaceutical products (and in any event with combined limits of not less than \$1,000,000 per occurrence and \$1,000,000 per accident for bodily injury, including death, and property damage). At Novartis' written request, resTORbio will provide Novartis with evidence of resTORbio's insurance. resTORbio will name Novartis as an additional insured party under such insurance policy, and will provide to Novartis at least 30 days prior written notice of any change or cancellation to resTORbio's insurance program.

**13.3 Representations and Warranties by Novartis.** Novartis represents and warrants to resTORbio as of the Effective Date that:

- (a) *Exhibit B* sets forth a true and correct list of all Novartis Patents as of the Effective Date having claims covering the Compounds or the Products in the Field;
- (b) Novartis is the sole and exclusive owner, or exclusive licensee of all of the Novartis Patents free from encumbrances; *provided, however*, that University of Pennsylvania co-owns or has rights to certain Patent Rights relating to the use of BEZ235 and RAD001 in conjunction with CAR-T cell therapies;
- (c) Novartis has the right to grant to resTORbio the licenses under the Novartis Technology that it purports to grant hereunder;
- (d) Novartis has the right to use and disclose and to enable resTORbio to use and disclose (in each case under appropriate conditions of confidentiality) the Novartis Know-How free from encumbrances;
- (e) Novartis has filed and prosecuted patent applications within the Novartis Patents in good faith and complied with all duties of disclosure with respect thereto;
- (f) Novartis has not granted to any Third Party, including any academic organization or agency, any rights to the Compounds or Products in the Field; *provided, however*, that Novartis has granted rights to the University of Pennsylvania to use BEZ235 and RAD001 in connection with CAR-T cell therapies;
- (g) Novartis has not received any written notice alleging that the Development, registration, manufacture, use or Commercialization of the Compounds or Products infringes the Patent Rights or misappropriates the Know-How of any Third Party; *provided, however*, that no representation or warranty is given with respect to RAD001 alone (*i.e.*, other than in combination with BEZ235).
- (h) Novartis has not initiated or been involved in any proceedings or Claims in which it alleges that any Third Party is or was infringing or misappropriating any Novartis Technology relating to BEZ235 or BEZ235 in combination with RAD001, nor have any such proceedings been threatened by Novartis, nor does Novartis have any actual knowledge of a valid basis for any such proceedings; *provided, however*, that for the avoidance of doubt, no representation or warranty is given with respect to RAD001 alone (*i.e.*, other than in combination with BEZ235).
- (i) Novartis has taken precautions, consistent with its usual business practice, to preserve the confidentiality of the Novartis Know-How;
- (j) Novartis has not entered into a government funding relationship that would result in rights to any Compounds or Products residing in the US Government, National Institutes of Health, National Institute for Drug Abuse or other agency, and the licenses granted hereunder are not subject to overriding obligations to the US Government as set forth in Public Law 96 517 (35 U.S.C. 200-204), as amended, or any similar obligations under the laws of any other country; and

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- (k) (i) Novartis has not granted any Third Party rights that would otherwise interfere or be inconsistent with resTORbio's rights hereunder, (ii) there are no agreements or arrangements to which Novartis or any of its Affiliates is a party relating to the Products, Compounds, Novartis Patents, or Novartis Know-How that would materially limit the rights granted to resTORbio under this Agreement or that materially restrict or will result in a material restriction on resTORbio's ability to Develop, manufacture or Commercialize the Compounds and the Products in the Field, and (iii) Novartis shall not following the Effective Date grant, any license, sublicense or other right to exploit any rights that would prevent it from granting the licenses granted to resTORbio under this Agreement in the Field.

13.4 **Covenants of Novartis.** Novartis covenants that:

- (a) it will not grant any interest in the Novartis Patents or Novartis Know-How which is inconsistent with the terms and conditions of this Agreement; and
- (b) if, at any time after execution of this Agreement, it becomes aware that it or any employee, agent or subcontractor of Novartis who participated in the Development or manufacture of a Compound or Product is on, or is being added to the FDA Debarment List or any of the three FDA Clinical Investigator Restriction Lists referenced in Section 13.1(f), it will provide written notice of this to resTORbio within five (5) days of its becoming aware of this fact.

13.5 **No Other Warranties.** Except as expressly provided in this Article 13, the Novartis Technology is licensed hereunder "as is". Nothing in this Agreement shall be construed as a representation made or warranty given by Novartis that it will be successful in prosecuting any Novartis Patents, that any patents will issue based on pending applications or that any such pending applications or patents issued thereon will be valid. *EXCEPT AS EXPRESSLY STATED IN THIS SECTION 13, (A) NO REPRESENTATION, CONDITION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF NOVARTIS OR NOVARTIS; AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE HEREBY EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON- INFRINGEMENT.*

14. **INDEMNIFICATION; LIABILITY**

14.1 **Indemnification by Novartis.** Novartis will indemnify and hold resTORbio, its Affiliates, and their respective officers, directors and employees ("resTORbio Indemnitees") harmless from and against any Claims against them to the extent arising or resulting from the breach of any of the covenants, warranties or representations made by Novartis to resTORbio under this Agreement; *provided, however*, that Novartis will not be obliged to so indemnify, defend and hold harmless the resTORbio Indemnitees for any Claims for which resTORbio has an obligation to indemnify Novartis Indemnitees pursuant to Section 14.2 or to the extent that such Claims arise from the breach, negligence or willful misconduct of resTORbio or the resTORbio Indemnitees.

14.2 **Indemnification by resTORbio.** resTORbio will indemnify and hold Novartis, its Affiliates, and their respective officers, directors and employees (“Novartis Indemnitees”) harmless from and against any Claims against them to the extent arising or resulting from:

- (a) actions by resTORbio, its Affiliates and sublicensees, and their respective employees, agents and subcontractors, in connection with the Development, manufacture or Commercialization of the Compounds or Products, including, for the avoidance of doubt, all product liability claims (whether arising during Development or Commercialization) relating to any Compound or Product (whether pursuant to design defect, manufacturing defect, failure to notify, or otherwise); or
- (b) the breach of any of the covenants, warranties, or representations made by resTORbio to Novartis under this Agreement;

*provided, however*, that resTORbio will not be obliged to so indemnify, defend and hold harmless the Novartis Indemnitees for any Claims for which Novartis has an obligation to indemnify resTORbio Indemnitees pursuant to Section 14.1 or to the extent that such Claims arise from the breach, negligence or willful misconduct of Novartis or the Novartis Indemnitees.

14.3 **Indemnification Procedure.**

- (a) For the avoidance of doubt, all indemnification claims in respect of a resTORbio Indemnitee or Novartis Indemnitee will be made solely by resTORbio or Novartis, respectively.
- (b) A Party seeking indemnification hereunder (“Indemnified Party”) will notify the other Party (“Indemnifying Party”) in writing reasonably promptly after the assertion against the Indemnified Party of any Claim or fact in respect of which the Indemnified Party intends to base a claim for indemnification hereunder (“Indemnification Claim Notice”), but the failure or delay to so notify the Indemnifying Party will not relieve the Indemnifying Party of any obligation or liability that it may have to the Indemnified Party, except to the extent that the Indemnifying Party demonstrates that its ability to defend or resolve such Claim is adversely affected thereby. The Indemnification Claim Notice will contain a description of the claim and the nature and amount of the Claim (to the extent that the nature and amount of such Claim is known at such time). Upon the request of the Indemnifying Party, the Indemnified Party will furnish promptly to the Indemnifying Party copies of all correspondence, communications and official documents (including court documents) received or sent in respect of such Claim.
- (c) Subject to the provisions of Sections (d) and (e) below, the Indemnifying Party will have the right, upon written notice given to the Indemnified Party within thirty (30) days after receipt of the Indemnification Claim Notice to assume the defense and handling of such Claim, at the Indemnifying Party’s sole expense, in which case the provisions of Section 14.3(d) below will govern. The assumption of the defense of a Claim by the Indemnifying Party will not be construed as acknowledgement that the Indemnifying Party is liable to



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indemnify any indemnitee in respect of the Claim, nor will it constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party's claim for indemnification. In the event that it is ultimately decided that the Indemnifying Party is not obligated to indemnify or hold an Indemnitee harmless from and against the Claim, the Indemnified Party will reimburse the Indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any losses incurred by the Indemnifying Party in its defense of the Claim. If the Indemnifying Party does not give written notice to the Indemnified Party, within thirty (30) days after receipt of the Indemnification Claim Notice, of the Indemnifying Party's election to assume the defense and handling of such Claim, the provisions of Section 14.3(e) below will govern.

- (d) Upon assumption of the defense of a Claim by the Indemnifying Party: (i) the Indemnifying Party will have the right to and will assume sole control and responsibility for dealing with the Claim; (ii) the Indemnifying Party may, at its own cost, appoint as counsel in connection with conducting the defense and handling of such Claim any law firm or counsel reasonably selected by the Indemnifying Party; (iii) the Indemnifying Party will keep the Indemnified Party informed of the status of such Claim; and (iv) the Indemnifying Party will have the right to settle the Claim on any terms the Indemnifying Party chooses; *provided, however*, that it will not, without the prior written consent of the Indemnified Party, agree to a settlement of any Claim which could lead to liability or create any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to indemnification hereunder or which admits any wrongdoing or responsibility for the claim on behalf of the Indemnified Party. The Indemnified Party will cooperate with the Indemnifying Party and will be entitled to participate in, but not control, the defense of such Claim with its own counsel and at its own expense. In particular, the Indemnified Party will furnish such records, information and testimony, provide witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation will include access during normal business hours by the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Claim, and making the Indemnified Party, the Indemnitees and its and their employees and agents available on a mutually convenient basis to provide additional information and explanation of any records or information provided.
- (e) If the Indemnifying Party does not give written notice to the Indemnified Party as set forth in Section 14.3(c) or fails to conduct the defense and handling of any Claim in good faith after having assumed such, the Indemnified Party may, at the Indemnifying Party's expense, select counsel reasonably acceptable to the Indemnifying Party in connection with conducting the defense and handling of such Claim and defend or handle such Claim in such manner as it may deem appropriate. In such event, the Indemnified Party will keep the Indemnifying Party timely apprised of the status of such Claim and will not settle such Claim without the prior written consent of the Indemnifying Party, which consent will not be unreasonably withheld. If the Indemnified Party defends or handles such Claim, the Indemnifying Party will cooperate with the Indemnified Party, at the Indemnified Party's request but at no expense to the Indemnified Party, and will be entitled to participate in the defense and handling of such Claim with its own counsel and at its own expense.

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- 14.4 **Mitigation of Loss.** Each Indemnified Party will take and will procure that its Affiliates take all such reasonable steps and action as are necessary or as the Indemnifying Party may reasonably require in order to mitigate any Claims (or potential losses or damages) under this Section 14. Nothing in this Agreement will or will be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.
- 14.5 **Special, Indirect and Other Losses.** *NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR FOR ANY ECONOMIC LOSS OR LOSS OF PROFITS SUFFERED BY THE OTHER PARTY, EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS SECTION 14.*

## 15. PUBLICATIONS AND PUBLICITY

### 15.1 Publications.

- (a) Each Party and its Affiliates shall have the right to make disclosures pertaining to a Compound or Product to Third Parties in publications in accordance with the following procedure: The publishing Party will provide the non-publishing Party with an advance copy of the proposed publication, and the other Party will then have thirty (30) days prior to submission of any publication in which to recommend any changes it reasonably believes are necessary to preserve any Patent Rights or Know-How Controlled by or licensed to the non-publishing Party in whole or in part to the non-publishing Party. If the non-publishing Party informs the publishing Party that such Publication, in the non-publishing Party's reasonable judgment, could be expected to have a material adverse effect on any patentable invention owned by or licensed, in whole or in part, to the non-publishing Party (other than pursuant to a license granted under this Agreement), or on any Know-How which is Information of the non-publishing Party, or which could have a material adverse effect on the Development or Commercialization of a Product, the publishing Party shall delay or prevent such publication as follows: (i) with respect to a patentable invention, such publication shall be delayed sufficiently long (not to exceed sixty (60) days) to permit the timely preparation and filing of a patent application; and (ii) with respect to Know-How which is Information of such non-publishing Party or which could have a material adverse effect on the Development or Commercialization of a Product, such Know-How or Information shall be deleted from the publication.
- (b) For the avoidance of doubt, resTORbio or any of its Affiliates may, without any required consents from Novartis publish or have published information about clinical trials related to the Products, including the results of such clinical trials, as required by applicable law or regulation.

### 15.2 Publicity.

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- (a) Neither Party will use the name, symbol, trademark, trade name or logo of the other Party or its Affiliates in any press release, publication or other form of public disclosure without the prior written consent of the other Party in each instance except for those disclosures for which consent has already been obtained.
- (b) resTORbio may issue a press release, in the form attached as *Exhibit F*, having provided notice to Novartis within two (2) business days ahead of the release, to announce the execution of this Agreement. Except as required by judicial order or applicable law, or as set forth below, neither Party shall make any public announcement concerning this Agreement beyond the scope of the initial press release without the prior written consent of the other Party. For the avoidance of doubt, (i) resTORbio may issue press releases and other public statements as it deems appropriate in connection with the Development and Commercialization of Products under this Agreement (so long as such release is not issued as a joint release with Novartis, Novartis' name is not in the title of such release, and no quotes from Novartis personnel are included), and (ii) Novartis may issue press releases and other public statements required by securities law disclosure requirements in connection with the achievement of Milestones under this Agreement.
- (c) Either Party may also disclose the existence and terms of this Agreement in confidence to its attorneys and advisors, and to potential acquirors (and their respective professional advisors), in connection with a potential merger, acquisition or reorganization and to existing and potential investors or lenders of such Party, as a part of their due diligence investigations, or to existing and potential sublicensees or to permitted sublicensees and assignees, or to any other Person described in Section 10.3(c) or this 15.2(c), in each case under an agreement to keep the terms of this Agreement confidential under terms of confidentiality and non-use substantially no less rigorous than the terms contained in this Agreement and to use such information solely for the purpose permitted pursuant to Section 10.3(c) or this 15.2(c).
- (d) Notwithstanding the foregoing, each Party may make any disclosures required of it to comply with any duty of disclosure it may have pursuant to law or governmental regulation or pursuant to the rules of any recognized stock exchange. If a disclosure required by law, governmental regulation or the rules of any recognized stock exchange, the Parties will coordinate with each other with respect to the timing, form and content of such required disclosure. If so requested by the other Party, the Party subject to such obligation will use commercially reasonable efforts to obtain an order protecting to the maximum extent possible the confidentiality of such provisions of this Agreement as reasonably requested by the other Party. If the Parties are unable to agree on the form or content of any required disclosure, such disclosure will be limited to the minimum required as determined by the disclosing Party in consultation with its legal counsel. Without limiting the foregoing, each Party will consult with the other Party on the provisions of this Agreement, together with exhibits or other attachments attached hereto, to be redacted in any filings made by Novartis or resTORbio with the Securities and Exchange Commission (or other regulatory body) or as otherwise required by law.

## 16. GENERAL PROVISIONS

- 16.1 **Assignment.** Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that either Party may **(i)** assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates; or **(ii)** assign this Agreement in its entirety to a successor to all or substantially all of its business or assets to which this Agreement relates. Any permitted assignee will assume all obligations of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment). Any attempted assignment in contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.
- 16.2 **Extension to Affiliates.** resTORbio will have the right to extend the rights, immunities and obligations granted in this Agreement to one or more of its Affiliates. All applicable terms and provisions of this Agreement will apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to resTORbio. resTORbio will remain primarily liable for any acts or omissions of its Affiliates.
- 16.3 **Severability.** Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then this Agreement will be construed as if such provision were not contained herein and the remainder of this Agreement will be in full force and effect, and the Parties will use their commercially reasonable efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties.
- 16.4 **Governing Law and Jurisdiction.** This Agreement will be governed by and construed under the laws of the Commonwealth of Massachusetts, USA, without giving effect to the conflicts of laws provision thereof. The United Nations Convention on Contracts for the International Sale of Goods (1980) will not apply to the interpretation of this Agreement.
- 16.5 **Dispute Resolution.**
- (a) In the event of a dispute under this Agreement, the Parties will refer the dispute to the Alliance Managers for discussion and resolution. If the Alliance Managers are unable to resolve such a dispute within thirty (30) days of the dispute being referred to them, either Party may require that the Parties forward the matter to the Senior Officers (or designees with similar authority to resolve such dispute), who will attempt in good faith to resolve such dispute. If the Senior Officers cannot resolve such dispute within thirty (30) days of the matter being referred to them, either Party will be free to initiate the arbitration proceeding outlined in Section 16.5(b) to resolve the matter.
  - (b) Any unresolved disputes between the Parties relating to, arising out of or in any way connected with this Agreement or any term or condition hereof, or the performance by either Party of its obligations hereunder, whether before or after termination of this Agreement, will be resolved by final and binding arbitration. Whenever a Party decides to institute arbitration proceedings, it will give written notice to that effect to the other Party. Arbitration will be held in Boston,

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RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED

Massachusetts, USA, in accordance with the commercial arbitration rules of the International Chamber of Commerce (“ICC”). The arbitration will be conducted by a panel of three arbitrators appointed in accordance with ICC rules; *provided* that each Party will within fifteen (15) days after the institution of the arbitration proceedings appoint an arbitrator, and such arbitrators will together, within thirty (30) days, select a third arbitrator as the chair of the arbitration panel, and each arbitrator will have significant experience in the biopharmaceutical industry. If the two initial arbitrators are unable to select a third arbitrator within such thirty (30) day period, the third arbitrator will be appointed in accordance with ICC rules. The arbitrators will render their opinion within forty-five (45) days of the final arbitration hearing. No arbitrator (nor the panel of arbitrators) will have the power to award punitive damages or to award costs and expenses of the proceeding or reasonable attorney’s fees to any Party under this Agreement and such award is expressly prohibited. Decisions of the panel of arbitrators will be final and binding on the Parties. Judgment on the award so rendered may be entered in any court of competent jurisdiction.

- 16.6 **Force Majeure.** In the event that either Party is prevented from performing its obligations under this Agreement as a result of any contingency beyond its reasonable control (“Force Majeure”), including but not limited to, any actions of governmental authorities or agencies, war, hostilities between nations, civil commotions, riots, national industry strikes, lockouts, sabotage, shortages in supplies, energy shortages, fire, floods and acts of nature such as typhoons, hurricanes, earthquakes, or tsunamis, the Party so affected will not be responsible to the other Party for any delay or failure of performance of its obligations hereunder, for so long as Force Majeure prevents such performance. In the event of Force Majeure, the Party immediately affected thereby will give prompt written notice to the other Party specifying the Force Majeure event complained of, and will use commercially reasonable efforts to resume performance of its obligations. Notwithstanding the foregoing, if such a Force Majeure induced delay or failure of performance continues for a period of more than three (3) consecutive months, either Party may terminate this Agreement upon written notice to the other Party.
- 16.7 **Waivers and Amendments.** The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver will be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.
- 16.8 **Relationship of the Parties.** Nothing contained in this Agreement will be deemed to constitute a partnership, joint venture, or legal entity of any type between Novartis and resTORbio, or to constitute one as the agent of the other. Moreover, each Party will not construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party will act solely as an independent contractor, and nothing in this Agreement will be construed to give any Party the power or authority to act for, bind, or commit the other.

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16.9 **Notices.** All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when: **(a)** delivered by hand (with written confirmation of receipt); or **(b)** when received by the addressee, if sent by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses set forth below (or to such other addresses as a Party may designate by notice):

If to resTORbio:

resTORbio, Inc.  
501 Boylston Street, Suite 6102  
Boston, Massachusetts 02116 USA  
Attn: Chief Executive Officer with

a required copy to:

Choate, Hall & Stewart LLP  
Two International Place  
Boston, MA 02110 USA  
Attn: Robert A. Licht, Esq.

If to Novartis:

Novartis International Pharmaceutical Ltd  
Lichtstrasse 35  
CH-4056 Basel  
Switzerland

with a required copy to:

Novartis Institutes for BioMedical Research, Inc.  
250 Massachusetts Avenue  
Cambridge, MA 02139 USA  
Attn: General Counsel

16.10 **Further Assurances.** resTORbio and Novartis will execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary to carry out the intent and purposes of this Agreement.

16.11 **Compliance with Law.** Each Party will perform its obligations under this Agreement in accordance with all applicable laws. No Party will, or will be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any applicable law.

16.12 **No Third Party Beneficiary Rights.** The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they will not be construed as conferring any rights to any Third Party (including any third party beneficiary rights).

16.13 **Expenses.** Except as otherwise expressly provided in this Agreement, each Party will pay the fees and expenses of its respective lawyers and other experts and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution and delivery of this Agreement.

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- 16.14 **Entire Agreement.** This Agreement, together with its Exhibits and schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter, including the Prior Confidentiality Agreement. In the event of any conflict between a substantive provision of this Agreement and any Exhibit or schedule hereto, the substantive provisions of this Agreement will prevail.
- 16.15 **Counterparts.** This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (.pdf) sent by electronic mail shall be deemed to be original signatures.
- 16.16 **Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

*[Signature Page Follows]*

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*License Agreement - Signature Page*

IN WITNESS WHEREOF, the Parties, intending to be bound, have caused this Agreement to be executed by their duly authorized representatives.

**NOVARTIS INTERNATIONAL**

**resTORbio, INC.**

**PHARMACEUTICAL LTD.**

By: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_



[\*\*\*] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH  
CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL  
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*License Agreement—Signature Page*

IN WITNESS WHEREOF, the Parties, intending to be bound, have caused this Agreement to be executed by their duly authorized representatives.

**NOVARTIS INTERNATIONAL**

**RESTORBIO, INC.**

**PHARMACEUTICAL LTD.**

By: /s/ Felix R. Ehrat  
Name: Felix R. Ehrat  
Title: Group General Counsel

By: /s/ Chen Schor  
Name: Chen Schor  
Title: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

COMPOUNDSBEZ235:

The chemical name of BEZ235 is:

[\*\*\*]

The molecular formula of the freebase is [\*\*\*]. The molar mass of the freebase is [\*\*\*] g·mol<sup>-1</sup>. The structural formula of the freebase is:

[\*\*\*]

RAD001:

everolimus, an inhibitor of mammalian target of rapamycin (mTOR), is an antineoplastic agent.

The chemical name of everolimus is

[\*\*\*].

The molecular formula is [\*\*\*] and the molecular weight is [\*\*\*]. The structural formula is:

[\*\*\*]

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EXHIBIT B-1—[\*\*\*]

<u>Case reference</u>	<u>Internal Title</u>	<u>Country</u>	<u>Filing Number</u>	<u>Grant Number</u>	<u>Name</u>
[***]	[***]	[***]	[***]		[***]
[***]	[***]	[***]	[***]		[***]
[***]	[***]	[***]	[***]		[***]
[***]	[***]	[***]	[***]		[***]
[***]	[***]	[***]	[***]		[***]
[***]	[***]	[***]	[***]		[***]
[***]	[***]	[***]	[***]		[***]
[***]	[***]	[***]	[***]		[***]
[***]	[***]	[***]	[***]		[***]





















Exhibit B-3—[\*\*\*]

<u>Case reference</u>	<u>Internal Title</u>	<u>Country</u>	<u>Filing Number</u>	<u>Grant Number</u>	<u>Name</u>
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
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[***]	[***]	[***]	[***]	[***]	[***]
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[***]	[***]	[***]	[***]	[***]	[***]
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Exhibit B-3—[\*\*\*]

<u>Case reference</u>	<u>Internal Title</u>	<u>Country</u>	<u>Filing Number</u>	<u>Grant Number</u>	<u>Name</u>
[***]	[***]	[***]	[***]		[***]
[***]	[***]	[***]	[***]		[***]
[***]	[***]	[***]	[***]		[***]
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[***]	[***]	[***]	[***]		[***]
[***]	[***]	[***]	[***]		[***]

Exhibit B-3 – [\*\*\*]

<u>Case reference</u>	<u>Internal Title</u>	<u>Country</u>	<u>Filing Number</u>	<u>Grant Number</u>	<u>Name</u>
[***]	[***]	[***]	[***]		[***]
[***]	[***]	[***]	[***]		[***]
[***]	[***]	[***]	[***]		[***]
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[***]	[***]	[***]	[***]		[***]
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**EXHIBIT C**

[\*\*\*]

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**BUSINESS SERVICES, PERSONNEL AND  
INFORMATION MANAGEMENT AGREEMENT**

This Business Services, Personnel and Information Management Agreement (“Agreement”) is entered into to be effective as of August 1, 2016 (the “Effective Date”) by and between resTORbio, Inc., a Delaware Corporation (the “Operating Company”), PureTech Management, Inc., a Delaware corporation (the “PTM”), PureTech Health LLC, a Delaware limited liability company (“PureTech”) and PureTech Health plc, a UK public limited company (“PTH plc”).

WHEREAS, PureTech is in the business of creating companies and providing, among other things, management expertise, strategic advice, accounting and administrative support, computer and telecommunications services and office infrastructure to certain of its operating companies;

WHEREAS, PTM is in the business of providing personnel services to PureTech and certain of PureTech’s operating companies;

WHEREAS, the Operating Company desires to (i) engage PureTech to provide (or continue to provide), among other things, management expertise, strategic advice, accounting and administrative support, computer and telecommunications services and office infrastructure (collectively, the “Business Services”) and (ii) engage PTM to provide personnel services (the “Personnel Services”);

WHEREAS, from time to time, PureTech and PTH plc may share certain information with the Operating Company, and the Operating Company may wish to, or may be required to, make certain information public, and the parties have agreed to enter into this Agreement to, among other things, set out the means by which the sharing of such information is to be controlled and (where relevant) restricted by the Operating Company and/or PTH plc.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants set forth herein, the sufficiency of which consideration is acknowledged to be sufficient, the parties agree as set forth below.

Section 1. Term.

This Agreement shall commence as of the Effective Date and shall continue in full force and effect until terminated by either party giving at least thirty (30) calendar days written notice to the other except in respect of Sections 5, 6, 7 and 8 which shall survive any termination of this Agreement.

Section 2. Business Services.

PureTech shall provide Business Services to the Operating Company at such times and in such forms as reasonably requested by Operating Company and agreed to by PureTech.

Section 3. Personnel Services.

(a) Provision of Personnel. PTM shall provide such Personnel Services to the Operating Company as are requested by the Operating Company from time to time to carry on the operations of the Operating Company and agreed by PureTech.

(b) Payments for PTM Personnel Services. PTM shall be liable and responsible for all payments in connection with the Personnel Services owed to employees, governments and Other third parties including, without limitation, salaries, wages and other compensation, and shall pay any and all contributions, employer taxes, and assessments which may be required to be paid in respect of unemployment insurance, workers' compensation, social security, Medicare, tax withholding, and other Obligations; provided such payments have been made in advance to PTM in accordance with Section 6 hereof.

(c) Benefits for PTM Personnel. PTM shall also be responsible for providing, and shall pay the cost of, the benefit plans and prerequisites offered to all similarly situated personnel covered by the Personnel Services, in each case to the extent and in accordance with each applicable employee's employment or services agreement; provided that the payments for such costs have been made in advance to PTM in accordance with Section 6 hereof.

(d) Records. PTM shall have sole responsibility for keeping all records pertaining to the Personnel Services provided by it to the Operating Company. PTM shall, upon request by the Operating Company, provide to the Operating Company or its designated agent(s) access to such records and shall provide to the Operating Company or its designated agent(s) copies of such records upon request.

Section 4. Compliance with Laws.

At all times, PTM shall comply with all laws, regulations, ordinances, and other legal requirements applicable to it including, without limitation, the obtaining of workers' compensation insurance as such may be required by law.

Section 5. Information Management.

(a) Definitions. For purposes of this Section 5, the following definitions shall apply:

- (i) "Act" means the Companies Act 2006.
- (ii) "Accounts" means, in respect of any financial year or other period in respect of which accounts are prepared in accordance with the relevant provisions of the Companies Act 2006, the audited or unaudited accounts of any party to this Agreement;

- (iii) “Business Day” means a day (which for this purpose shall be from 9:00am to 5:30pm Eastern Standard Time) on which banks are open for commercial business in the United States of America other than a Saturday or a Sunday;
- (iv) “Disclose” or “Disclosure” means the disclosure of Information to a person other than a party to this Agreement;
- (v) “Company Disclosure Requirements” means any relevant disclosure obligations imposed on a company by the United States Securities and Exchange Commission, the Food and Drug Administration, the Act, or any other such relevant, equivalent or successor body from time to time;
- (vi) “Information” means, to the extent not otherwise Public Information:
  - (1) in the case of information provided by or relating to PureTech and/or PTH plc, any information whatsoever concerning PureTech and/or PTH plc that is not Public Information; and
  - (2) in the case of information relating to the Operating Company, any information, publication, e-mail, text message or announcement relating to the Operating Company’s products, research, clinical studies, strategy, business, customer relationships or supplier relationships, whether actual, potential, or otherwise, its Accounts, any information pertaining to or is reasonably likely to cause any actual or prospective material change in its financial position, prospects or business, and any other material matter concerning or relating to the Operating Company.
- (vii) “Public Information” means information that (1) is or becomes generally available to the public other than as a result of its Disclosure by the Operating Company in breach of this Agreement; or (2) pursuant to a written statement by PureTech and/or PTH plc, is not to be construed as “Information”;
- (viii) “Required Disclosure” means any Disclosure made pursuant to the Company Disclosure Requirements.

(b) Operating Company Obligations. The Operating Company hereby agrees that (i) it shall introduce and maintain appropriate control systems to protect the Information; and (ii) subject to Section 5(c), it shall not Disclose Information other than as permitted in accordance with this Agreement.



(c) Required Disclosures by Operating Company.

- (i) Nothing in this Agreement shall prevent the Operating Company from making a Required Disclosure, provided that the Operating Company complies with the provisions of Section 5(c)(ii).
- (ii) To the extent that the Operating Company is required to make a Required Disclosure, the Operating Company shall not make such Required Disclosure until PureTech has approved the Draft Required Disclosure (as defined below) and the Operating Company has at its own cost: (1) prepared and delivered to PureTech and PTH plc, not less than 10 Business Days prior to the date of the Required Disclosure, written notice of the Required Disclosure, including a copy of the proposed form of Required Disclosure (the "Draft Required Disclosure"), the reason for the proposed Required Disclosure, and any other information or documentation as would be necessary for PureTech to identify the nature, content and extent of the proposed Required Disclosure; (2) provided PureTech and PTH plc with such information and access to the officers, employees and premises of the Operating Company as PureTech and/or PureTech plc may reasonably require in connection with evaluating such Required Disclosure; and (3) directed the Operating Company's auditors to provide to PureTech and/or PTH plc such information as PureTech may reasonably request in connection with evaluating such Required Disclosure.
- (iii) The Operating Company shall not disclose Information to third parties unless such third party has executed a non-disclosure agreement subjecting such disclosure to customary confidentiality and non-use obligations. In addition, each of the Operating Company's its directors, officers and employees shall execute non-disclosure agreements containing customary confidentiality and non-use obligations upon their engagement by the Operating Company.

(d) Financial Statements. The Operating Company shall provide to PureTech and PTH PLC such financial and other information as reasonably determined by PureTech or PTH plc to be necessary or appropriate in the preparation of PTH plc's Accounts. Such information shall be provided in a manner and at such times as PureTech or PTH PLC shall require in their sole and absolute discretion.

(e) Announcements. No announcement concerning this Agreement or any matter referred to herein shall be made by the Operating Company without the prior written approval of PureTech and/or PTH plc, except for such announcements as may be required by the Company Disclosure Requirements.

(f) Termination. This Section 5 shall terminate upon the date on which PureTech holds less than ten percent (10%) of then outstanding voting power of the Operating Company.

Section 6. Payments.

(a) Business Services. PureTech shall periodically invoice the Operating Company for the Business Services provided by PureTech to the Operating Company and out-of-pocket expenses reasonably incurred by PureTech in connection with the provision of such Business Services, Such invoices shall be paid to PureTech via check or wire transfer; provided, however, that if PureTech so elects, in its sole and absolute discretion, such invoices may be paid in the form of a convertible promissory note issued by the Operating Company, or conversion of such outstanding indebtedness into equity of the Operating Company, on such terms as may be agreed by the Operating Company and PureTech.

(b) Personnel Services. The Operating Company shall pay PTM an amount equal to:

- (i) the direct costs (including, without limitation, the cost of all wages, salaries, compensation, benefits, contributions (including 401(k) contributions) and taxes) and assessments of the PTM Personnel provided to the Operating Company calculated on a pro rata basis for the time actually spent by PTM Personnel in service for the Operating Company, plus
- (ii) any amounts in respect of severance, notice or similar payments paid or owed by PTM to any PTM Personnel.

All amounts due pursuant to this Section 6(b) shall be paid to PTM via check or wire transfer sufficiently prior to the date on which PTM is required to make such payments to PTM Personnel. Upon any termination of this Agreement, the Operating Company shall be obligated to pay all amounts that accrued pursuant to this Section 6(b) prior to the effective date of any such termination and (ii) all amounts in respect of severance, notice or similar payments paid or owed by PTM to any PTM Personnel. The payment obligations contained herein shall survive any termination of this Agreement.

Section 7. Liability.

(a) Indemnification of PTM and PureTech. The Operating Company shall indemnify and hold PTM, PureTech and PTH plc, and each of their respective directors, officers, employees, trustees, contractors, subcontractors, and agents (collectively, the "Indemnitees") harmless against any and all claims (including any employment related claims against any such Indemnities) for loss, damage, or injuries ("Losses") to the extent such Losses arise out of or relate to the Business Services or the Personnel Services or any breaches of this Agreement; provided that the Operating Company shall not be liable for any Losses arising out of the gross negligence or bad faith of PTM, PureTech or PTH plc. Such indemnity shall include all costs and expenses incurred by the Indemnitees in connection with such cause of action, including reasonable attorney's fees and any costs of settlement. The rights and obligations of this Section shall survive termination or expiration of the Agreement.

(b) Interruption of Service. PTM shall not be liable to the Operating Company for any loss of business or other damage caused to the Operating Company by any personnel provided in connection with any Personnel Services or arising out of any interruption of service due to a labor strike or other reason beyond the control of PTM.

Section 8. Miscellaneous Provisions.

(a) Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts. Any dispute arising hereunder which cannot be settled by the parties shall first be referred to a mediator and, if such mediation proves unsuccessful, shall be referred to a court located in Boston, Massachusetts.

(b) Assignment. This Agreement and the rights and obligations set forth herein may not be delegated, assigned, or subcontracted by the Operating Company to any person or entity which is not a party without first obtaining the written consent of PTM, PureTech and PTH plc to this Agreement.

(c) Independent Contractor. The parties agree that the relationship of each of PureTech and PTM, on the one hand, to the Operating Company, on the other hand, is that of an independent contractor. Neither PureTech nor PTM shall act as the agent of the Operating Company or execute any instrument purporting to bind the Operating Company. The Operating Company shall not act as the agent of PureTech or PTM and shall not execute any instrument purporting to bind PureTech or PTM. Notwithstanding the foregoing, PTM Personnel to the Operating Company may enter into contracts, agreements, and other instruments binding on the Operating Company if authorized to do so as part of their customary responsibilities for the Operating Company and if approved by the Operating Company.

*[remainder of the page intentionally left blank]*

IN WITNESS WHEREOF, this Agreement is effective as of the Effective Date set forth above.

RESTORBIO, INC.

By: /s/ Chen Schor

Name: Chen Schor

Title: President & CEO

PURETECH MANAGEMENT, INC.

By: /s/ Stephen Muniz

Name: Stephen Muniz

Title: COO

PURETECH HEALTH LLC

By: /s/ Stephen Muniz

Name: Stephen Muniz

Title: COO

PURETECH HEALTH PLC

By: /s/ Stephen Muniz

Name: Stephen Muniz

Title: COO

[Signature Page to Business Services, Personnel and Information Management Agreement]

March 31, 2017

Chen Schor

Dear Mr. Schor:

This letter agreement (the "Agreement") confirms our agreement regarding your employment with resTORbio, Inc. (the "Company") and shall be effective as of the date first written above.

**1. Employment Period.** Your employment under this Agreement will commence on April, 4, 2017 (the "Start Date") and continue until terminated in accordance with Section 5 (the "Employment Period"). You will be employed on an at-will basis, which means that you may resign and the Company may terminate your employment at any time for any reason or for no reason.

**2. Position and Duties.** During the Employment Period, you will be employed by the Company in accordance with the terms and conditions set forth herein on a full-time basis as its President and Chief Executive Officer, and in such capacity you agree to perform all duties that are required by your position and such other duties as may reasonably be assigned to you from time to time by the Board of Directors (the "Board") of the Company that are consistent with your position. During the Employment Period, you shall report to the Board. You agree that you will devote your full business time to the advancement of the business and interests of the Company and to the discharge of your duties and responsibilities. During the Employment Period, you shall be free to serve as a director of other corporations so long as such activities do not interfere with your duties under this Agreement.

**3. Compensation and Benefits.** During the Employment Period, as compensation for all services performed by you for the Company, the Company will provide you the following pay and benefits:

(a) **Base Salary.** The Company will pay you a base salary at the rate of \$361,000.00 per year, less required withholding, payable in accordance with the regular payroll practices of the Company, and subject to increase by the Board in its discretion ("Base Salary"). The board of directors of the Company will consider in good faith appropriate annual increases to your salary, consistent with market. Notwithstanding the foregoing, your then current Base Salary shall be increased by no less than 5% immediately no later than the earlier of your eligibility for the SP2 bonus described in Section 3(c)(iii) below or the second anniversary of the Start Date.

(b) **Annual Bonus Compensation.** During your employment with the Company, you will be considered annually for a bonus targeted at 40% of your Base Salary subject to achieving reasonably obtainable Company and individual performance targets set by you and the Board each year. Any such bonus is entirely discretionary in nature and subject to the rules of the cash bonus scheme, which may be varied from time to time. Any bonus due hereunder will be payable by March 15th of the fiscal year that begins immediately following the fiscal year for which the bonus was earned. Your annual bonus eligibility will commence with your start date and be pro-rated for any partial year of service. Notwithstanding the foregoing, for the period of January 1, 2017 to the Start Date you will be eligible for a bonus targeted at 40% of your current Base Salary, which such bonus shall be subject to the same restrictions and payable at the same time as your annual bonus for the 2017 fiscal year. No payment will be made under any annual cash bonus scheme if, on or before the payment date, you have given notice of termination of employment or you are no longer employed by the Company, except as set forth in Section 5(a) below.

(c) **Additional Bonuses.** In addition to your annual bonuses, you also shall be eligible for the following bonuses, each of which shall be payable only once if earned:

(i) **FPD Bonus.** \$18,000 payable within 30 days after the first subject is dosed in a Phase II study following pre-IND meeting or call with the U.S. Food and Drug Administration (or written feedback to a pre-IND briefing book from the FDA) and as long as such dosing of subject per this paragraph occurs by the first anniversary of the Start Date.

(ii) **FSFIA Bonus.** \$18,000 payable within 30 days after the Company enrolls the first subject following interim analysis review by committee defined by the Phase II study protocol and as long as such subject per this paragraph was enrolled by the second anniversary of the Start Date.

(iii) **SP2 Bonus.** \$36,000 payable within 30 days after the Company achieves the primary end point with a p value equal to or less than 0.05 in a Phase II study as long as such achievement occurs by the third anniversary of the Start Date. In the event that the bonuses described in Sections 3(c)(i) and (ii) above have not been earned at the time this bonus is earned and becomes due, then you shall receive those bonuses at the same time.

(d) **Participation in Insurance and Employee Benefit Plans.** During the Employment Period, you will be entitled to participate in all employee benefit plans in effect for employees of the Company generally. Your participation will be subject to the terms of the applicable plan documents and generally applicable Company policies. The benefits made available by the Company, and the rules, terms and conditions for participation in such benefit plans, may be changed by the Company at any time without advance notice. The Company shall maintain Directors and Officers Liability insurance coverage with commercially reasonable terms during the Employment Period.

(e) **Vacations.** During the Employment Period, you will be entitled to four (4) weeks of vacation per year, in addition to holidays observed by the Company. Vacation may be taken at such times and intervals as you will determine, subject to the business needs of the Company as reasonably determined by the Board, with one (1) weeks of carry-forward of unused vacation time from one year to the next.

(f) **Business Expenses.** During the Employment Period, the Company will pay or reimburse you for all reasonable out of pocket business expenses incurred or paid by you in the performance of your duties and responsibilities for the Company, subject to any maximum annual limit and other restrictions on such expenses set by the Board and to such reasonable substantiation and documentation as it may specify from time to time.

#### **4. Confidential Information and Restricted Activities.**

(a) **Confidential Information.** During the Employment Period, you will learn of confidential information and you may develop confidential information on behalf of the Company. In addition, you understand that the Company will receive from third parties confidential or proprietary information ("Third Party Information") subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. As a condition to your employment with the Company, you are required to execute on the date hereof a Non-Disclosure Agreement in the form attached hereto as Exhibit A setting forth the policies and procedures of the Company for protecting confidential information and Third Party Information. You understand that the restrictions set forth therein will continue to apply after your employment terminates regardless of the reason for such termination.

(b) **Protection of Documents.** All documents, records and files, in any media of whatever kind and description, embodying or containing confidential information or Third Party Information, and any copies, in whole or in part, thereof (the "Documents"), whether or not prepared by you will be the sole and exclusive property of the Company. You agree to safeguard all Documents and to surrender to the Company at the time your employment terminates, or at such earlier time or times as the Board, or its designee may specify, all Documents then in your possession or control.

(c) **Non-Competition Restrictions.** You agree that the following restrictions on your activities during and after your employment are necessary and reasonable to protect the goodwill, confidential information and other legitimate interests of the Company from unfair competition:

(i) During the Employment Period and for 6 months after the Employment Period ends for any reason (the “Restricted Period”), you will not, directly or indirectly, on behalf of any individual or entity other than the Company, perform services in any capacity (whether as an owner, employee, partner, independent contractor or otherwise, whether with or without compensation) directly or indirectly in all or any portion of any business that the Company conducts or is developing (the “Business”) as of the date of such termination; provided, however, that ownership of less than 5% of the outstanding stock of any publicly traded company will not by itself be deemed to be a violation of this provision.

(ii) During the Restricted Period, you will not directly or indirectly, and will not assist directly or indirectly any other Person to (A) solicit, hire or engage in any capacity any employee of the Company (or any Person who was an employee of the Company within 6 months of the date of your termination) or solicit or seek to persuade any employee of the Company to discontinue such employment, or (B) call on, solicit, induce, influence or encourage any customer of the Company or independent contractor providing services to the Company to terminate or diminish its relationship with the Company.

(d) **Inventions and Patents; Third Party Information.** Any discoveries, ideas, inventions, improvements, enhancements, processes, methods, techniques, developments, software, and works of authorship, whether patentable or not, which you create, make, conceive or reduce to practice, either alone or jointly with others, during your employment by the Company, whether or not during normal working hours or on the premises of the Company or an affiliate (all of which are collectively referred to in this Agreement as “Developments”), will be works-made-for-hire and the Company will be deemed the sole owner throughout the universe of any and all rights of whatsoever nature therein, whether or not now or hereafter known, existing, contemplated, recognized or developed, with the right to use the same in perpetuity in any manner the Company determines in its sole discretion without any further payment to you whatsoever. If, for any reason, any of such Developments will not legally be a work-for-hire and/or there are any rights which do not accrue to the Company under the preceding sentence, then you hereby irrevocably assign and agree to assign any and all of your right, title and interest thereto, including, without limitation, any and all copyrights, patents, trade secrets, trademarks and/or other rights of whatsoever nature therein, whether or not now or hereafter known, existing, contemplated, recognized or developed to the Company, and the Company will have the right to use the same in perpetuity throughout the universe in any manner the Company determines without any further payment to you whatsoever. You will, from time to time, as may be requested by the Company and at the Company’s expense, do any and all things which the Company may deem useful or desirable to establish or document the Company’s exclusive ownership of any and all rights in any such results and proceeds, including, without limitation, the execution of appropriate copyright and/or patent applications or assignments. To the extent you have any rights in the Developments that cannot be assigned in the manner described above, you unconditionally and irrevocably waive the enforcement of such rights. This Section 4(d) is subject to, and will not be deemed to limit, restrict or constitute any waiver by the Company of any rights of ownership to which the Company may be entitled by operation of law by virtue of the Company being your employer.



(e) You agree not to incorporate any discoveries, ideas, inventions, improvements, enhancements, processes, methods, techniques, developments, software, and works of authorship, whether patentable or not, which were created, made, conceived or reduced to practice by you prior to your employment by the Company and which are owned by you, which relate directly or indirectly to the current or anticipated future business of the Company (collectively, "Prior Developments") into any Company product, material, process or service without prior written consent of an officer of the Company. If you do incorporate any Prior Development into any Company product, material, process or service, you hereby grant to the Company a non-exclusive, worldwide, perpetual, transferable, irrevocable, royalty-free, fully-paid right and license to make, have made, use, offer for sale, sell, import, reproduce, modify, prepare derivative works, display, perform, transmit, distribute and otherwise exploit such Prior Development and to practice any method related thereto.

(f) **Cooperation.** You agree to cooperate, in a reasonable and appropriate manner, with the Company and its attorneys, both during and after the termination of your employment, in connection with any litigation or other proceeding arising out of or relating to matters in which you were involved prior to the termination of your employment to the extent the Company pays all Company-approved expenses you incur and reasonable hourly consulting fees in connection with such cooperation.

**5. Termination of Employment.** Your employment under this Agreement and the Employment Period may only be terminated as set forth in this Section 5.

(a) **Termination by the Company for Cause or by You for Good Reason.**

(i) Cause. The Company may terminate the Employment Period and your employment at any time, with or without Cause. The following, as determined by the Board in its reasonable judgment, will constitute "Cause" for termination: (A) your breach of any material provision of this Agreement and the continuation such breach for a period of 30 days after written notice to you of such breach and a request for reasonable cure or other appropriate corrective action; or (B) engagement in theft, embezzlement, fraud, dishonesty or misappropriation of any of the Company's property.

(ii) Good Reason. You may terminate the Employment Period and your employment with or without Good Reason. "Good Reason" shall be deemed to exist if any of the following conditions occur without your consent: (A) a material reduction of your Compensation or Benefits; (B) a

material adverse change of your title, authority, duties, or responsibilities; or (C) the relocation of your principal place of employment more than 50 miles from its current location; provided, however, that in each case you provide written notice to the Company within 90 days of the event constituting Good Reason of your intention to terminate your employment for Good Reason. Such termination shall be effective 30 days from the Company's receipt of such notice if the Company has not fully cured such act(s) or failure(s) within 15 days from the Company's receipt of such notice.

(iii) Payments in the Event of Termination without Cause by the Company, and Termination by You for Good Reason. If your employment is terminated by the Company without Cause in accordance with Section 5(a)(i), including without limitation any termination without Cause before or following a "Change of Control", as defined below, or you terminate your employment for Good Reason in accordance with Section 5(a)(ii), you will be entitled to: (A) your Accrued Obligations, as defined below, and (B) a lump sum payment equal to six (6) months of your then current Base Salary if such termination occurs within the first twelve (12) months of your employment or, if such termination occurs thereafter, a lump sum payment equal to twelve (12) months of your then current Base Salary (the "Base Severance Amount"); and (C) continued coverage under the Company's health and dental plans on the same terms as prior to such termination until the earlier of (x) the expiration of the period for which you receive severance pursuant to Section 5(a)(iii)(B), and (y) the date you commence new employment which offers health coverage that would disqualify you from continued COBRA coverage pursuant to law. Payment of the Base Severance Amount and health insurance continuation pursuant to this Section 5(a)(iii) is contingent upon your execution and non-revocation of a general release of claims in favor of the Company in form reasonably satisfactory to the Company. The Base Severance Amount shall be paid in accordance with the Company's normal payroll procedures.

If your employment is terminated by the Company without Cause following Change of Control or you terminate your employment for Good Reason following Change of Control then you will be eligible to your Annual Bonus Compensation pro rated for partial years of service.

(iv) Once the release required by Section 5(a)(iii) is executed and delivered, then the following will apply to the payments required under this Section 5:

(A) Any such cash payment to be provided that is not nonqualified deferred compensation subject to Section 409A will commence or be made upon the first regularly scheduled payroll date immediately after the date the release is executed and no longer subject to revocation (the "Release Effective Date").

(B) Any such cash payment to be provided that is nonqualified deferred compensation subject to Section 409A will commence or be made upon the sixtieth (60th) day following your termination of employment.

The first cash payment made pursuant to this Section 5(a)(iv), if any, will include payment of all amounts that otherwise would have been due prior to the Release Effective Date under Section 5 had such payments commenced immediately upon your termination of employment; and any payments made thereafter will continue as otherwise provided herein.

(b) **Termination by Death or Disability.** Your employment will automatically terminate in the event of your death during employment. In the event you become disabled during employment and, as a result, are unable to continue to perform substantially all of your duties and responsibilities under this Agreement notwithstanding the provision of any reasonable accommodation, the Company will continue to pay your Base Salary (upon exhaustion of any available sick time and if you are not then eligible for short term or long term disability benefits) in accordance with normal payroll practices of the Company and will continue to provide you benefits in accordance with Section 3(d) above, to the extent permitted by plan terms, for up to ninety days of disability during any period of 365 consecutive calendar days. If you are unable to return to work after 90 days of disability, the Company may terminate your employment, upon notice to you. If any question will arise as to whether you are disabled to the extent that you are unable to perform substantially all of your duties and responsibilities for the Company, you will, at the Company's request, submit to a medical examination by a physician selected by the Company to whom you or your guardian, if any, has no reasonable objection to determine whether you are so disabled and such determination will for the purposes of this Agreement be conclusive of the issue. In the event of termination of your employment by reason of death or disability in accordance with this Section 5(b), the Company (i) will pay you or your estate your Accrued Obligations.

(c) **All Other Methods of Termination.** In the event of termination of your employment by the Company for Cause, or by you without Good Reason, the Company (i) will pay you your Accrued Obligations and will have no obligation to pay you severance benefits.

## 6. Matters Related to Termination.

(a) **Benefit Plan Termination.** Except for any right you may have under the federal law known as “COBRA”, applicable state law, or this Agreement to continue participation in the Company’s group health and dental plans, benefits will terminate in accordance with the terms of the applicable benefit plans based on the date of termination of your employment.

(b) **Survival.** Provisions of this Agreement will survive any termination if so provided in this Agreement or if necessary or desirable to accomplish the purposes of other surviving provisions, including without limitation your obligations under Section 4 of this Agreement. Upon termination by either you or the Company, all rights, duties and obligations of you and the Company to each other will cease, except as otherwise expressly provided in this Agreement.

**7. Definitions.** For purposes of this Agreement, the following definitions will apply:

“**Accrued Obligations**” means (i) any Base Salary earned but not paid through the date of termination; (ii) any compensation deferred by you prior to your termination of employment and not paid by the Company (all of which will be paid in accordance with the terms of and at the time provided in the underlying deferral arrangement); (iii) any amounts or benefits owing to you under the then applicable benefit plans of the Company; (iv) any of the Additional Bonuses earned, that have not been paid prior to the date of termination; and (v) any amounts owing to you for reimbursement of expenses.

“**Change of Control**” means any of the following: (i) a merger or consolidation of the Company with or into any other corporation or other entity in which the Company is not the surviving entity; (ii) a sale, lease, exchange or other transfer (in one transaction or a related series of transactions) of all or substantially all of the Company’s assets; (iii) the acquisition by any person or any group of persons, acting together in any transaction or related series of transactions, of such quantity of the Company’s voting securities as causes such person, or group of persons, to own beneficially, directly or indirectly, as of the time immediately after such transaction or series of transactions, 50% or more of the combined voting power of the voting securities of the Company; or (iv) the liquidation or dissolution of the Company.

“**Person**” means an individual, a corporation, a limited liability company, an association, a partnership, an estate, a trust or any other entity or organization, other than the Company.

“**Section 409A**” means Section 409A of the Internal Revenue Code of 1986, as amended from time to time, and the regulations and guidance issued thereunder.

**8. Governing Law.** This Agreement, the rights and obligations of the parties hereto, and any claims or disputes relating thereto, will be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (without regard to its choice of law provisions). Each of the parties agrees that any dispute between the parties will be resolved only in the state or federal courts of the Commonwealth of Massachusetts.

**9. Representations.** You represent and warrant to the Company that you are not subject to any contract, agreement, judgment, order or decree of any kind, or any restrictive agreement of any character, that restricts your ability to perform your obligations under this Agreement or that would be breached by you upon your performance of your duties pursuant to this Agreement.

**10. Withholding.** All payments made by the Company under this Agreement will be reduced by any tax or other amounts required to be withheld by the Company under applicable law.

**11. Assignment.** This Agreement will inure to the benefit of and be binding upon you and the Company, and each of our respective successors, executors, administrators, heirs and assigns. You may not assign this Agreement without the prior written consent of the Company.

**12. Miscellaneous.**

(a) This Agreement sets forth your entire agreement with the Company and supersedes all prior and contemporaneous communications, agreements and understandings, written or oral, with respect to the subject matter hereof. This Agreement may not be modified or amended, and no breach will be deemed to be waived, unless agreed to in writing by you and the Board or an expressly authorized representative of the Board. The headings and captions in this Agreement are for convenience only and in no way define or describe the scope or content of any provision of this Agreement. This Agreement may be executed in two or more counterparts, each of which will be an original and all of which together will constitute one and the same instrument.

(b) Notwithstanding any other payment schedule provided herein, if you are identified on the date of termination as a “specified employee” within the meaning of Section 409A(a)(2)(B), then any payment that is considered nonqualified deferred compensation subject to Section 409A, as determined by the Company in its sole discretion, and payable on account of a “separation from service,” will be made on the date that is the earlier of (A) the expiration of the six (6)-month period beginning on the date of your “separation from service”, and (B) your death (the “Delay Period”) to the extent required under Section 409A. Upon the expiration of the Delay Period, all payments delayed pursuant to this subsection (whether they would have otherwise been payable in a single sum or in installments in the absence of such delay) will be paid to you in a lump sum, and all remaining payments due under this Agreement will be paid or provided in accordance with the normal payment dates specified for them herein.

(c) For purposes of Section 409A, your right to receive any installment payment pursuant to this Agreement will be treated as a right to receive a series of separate and distinct payments.

(d) Notwithstanding any other provision in this Agreement to the contrary, in no event shall any payment under this Agreement that constitutes "Non-Qualified Deferred Compensation" for purposes of Section 409A be subject to offset by any other agreement unless otherwise permitted by Section 409A.

**13. Severability.** If any provision of this Agreement is illegal, invalid or unenforceable for any reason whatsoever, such provision will be fully severable, and this Agreement will be construed and enforced as if such illegal, invalid or unenforceable provision were not a part of this Agreement with the remaining provisions of this Agreement remaining in full force and effect and unaffected by the illegal, invalid or unenforceable provision or by its severance from this Agreement.

**14. Notices.** Any notices provided for in this Agreement will be in writing and will be effective immediately when delivered in person or three days after such notice is deposited in the United States mail, postage prepaid, and addressed to you at your last known address on the books of the Company or, in the case of the Company, to it at its principal place of business, attention Board or to such other address as either party may specify by notice to the other actually received.

**15. Defend Trade Secrets Act of 2016 Notice.** Notwithstanding any provision in this Agreement, an individual shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, provided that such filing is made under seal. Further, an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, provided that the individual (A) files any document containing the trade secret under seal and (B) does not disclose the trade secret, except pursuant to court order.

\* \* \* \* \*

If the foregoing is acceptable to you, please sign this letter in the space provided below. At the time you sign and return it this letter will take effect as a binding agreement between you and the Company on the basis, and subject to the conditions, set forth above. The enclosed copy is for your records.

Sincerely yours,

resTORbio, Inc.

By: /s/ David Steinberg

Name: David Steinberg

Title: Board Member

Accepted and Agreed:

/s/ Chen Schor

Chen Schor

Date: March 31, 2017

*[Signature Page to Employment Letter]*

**Exhibit A**

**NON-DISCLOSURE AGREEMENT**

This Non-Disclosure Agreement (this "Agreement") is made as of this \_\_ day of \_\_\_\_\_, 2017 by and between resTORbio, Inc., a Delaware corporation (hereinafter referred to collectively with its Affiliates as the "Company"), and Chen Schor (the "Employee").

The Company desires to employ the Employee to provide services to the Company. In consideration of the employment or the continued employment of the Employee by the Company, the Company and the Employee agree as follows:

1. Condition of Employment.

The Employee acknowledges that Employee's employment and/or the continuance of that employment with the Company is contingent upon Employee's agreement to become a party to and adhere to the provisions of this Agreement. The Employee further acknowledges that the nature of the Company's business is such that protection of its proprietary and confidential information and the proprietary and confidential information of its Affiliates is critical to the survival and success of the Company's business.

2. Proprietary and Confidential Information.

a. The Employee agrees that all information and know-how, whether or not in writing, of a private, secret or confidential nature concerning the Company's or any Affiliate's business or financial affairs (collectively, "Proprietary Information") is and shall be the exclusive property of the Company (or any person or entity designated by the Company). By way of illustration, but not limitation, Proprietary Information may include discoveries, ideas, inventions, products, product improvements, product enhancements, processes, methods, techniques, formulas, compositions, compounds, negotiation strategies and positions, projects, developments, plans (including business and marketing plans), research data, clinical data, financial data (including sales costs, profits, pricing methods), personnel data, computer programs (including software used pursuant to a license agreement), computer software code, computer games, customer, prospect and supplier lists, and contacts at or knowledge of customers or prospective customers of the Company or any Affiliate, and the names of, contact information of, and any other data concerning, existing and prospective Affiliates and existing and prospective investors of such Affiliates. The Employee shall not disclose any Proprietary Information to any person or entity other than employees of the Company or use the same for any purposes (other than in the performance of Employee's duties as an employee of the Company) without written approval by an officer of the Company, either during or after Employee's employment with the Company. The Employee shall use the Employee's best efforts to prevent unauthorized publication or disclosure of any of the Company's Proprietary Information.



b. The Employee agrees that all files, documents, letters, memoranda, reports, records, data, sketches, drawings, models, laboratory notebooks, program listings, computer equipment or devices, computer programs or other written, photographic, or other tangible or intangible material containing Proprietary Information, whether created by the Employee or others, which shall come into Employee's custody or possession, shall be and are the exclusive property of the Company to be used by the Employee only in the performance of Employee's duties for the Company and shall not be copied or removed from the Company premises except in the pursuit of the business of the Company. All such materials or copies thereof and all tangible property of the Company in the custody or possession of the Employee shall be delivered to the Company, upon the earlier of (i) a request by the Company or (ii) termination of Employee's employment for any reason. After such delivery, the Employee shall not retain any such materials or copies thereof or any such tangible property.

c. The Employee agrees that Employee's obligation not to disclose or to use information and materials of the types set forth in paragraphs 2(a) and 2(b) above, and Employee's obligation to return materials and tangible property, set forth in paragraph 2(b) above, also extends to such types of information, materials and tangible property of Affiliates, customers of the Company or suppliers to the Company or other third parties who may have disclosed or entrusted the same to the Company or to the Employee in the course of the Company's business.

### 3. Scope of Disclosure Restrictions.

Nothing in this Agreement or elsewhere prohibits the Employee from reporting possible violations of state or federal law or regulation to any government agency, regulator, or legal authority, or making other disclosures that are protected under the whistleblower provisions of state or federal law or regulation. The Employee is not required to notify the Company that the Employee has made any such reports or disclosures; provided, however, that nothing herein authorizes the disclosure of information the Employee obtained through a communication that was subject to the attorney-client privilege, unless disclosure of the information would otherwise be permitted by an applicable law or rule. Further, pursuant to the Defend Trade Secrets Act: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."

#### 4. Non-Disparagement.

The Employee shall not, either during Employee's employment with the Company or thereafter, make or encourage others to make any statement or release any information that is intended to, or reasonably could be foreseen to, disparage, defame or embarrass the Company or any of its Affiliates or their respective employees, officers, directors, partners, members or stockholders.

#### 5. Miscellaneous.

a. Equitable Remedies. The Employee acknowledges that the restrictions contained in this Agreement are necessary for the protection of the business and goodwill of the Company and are considered by the Employee to be reasonable for such purpose. The Employee agrees that any breach or threatened breach of this Agreement is likely to cause the Company substantial and irrevocable damage which is difficult to measure. Therefore, in the event of any such breach or threatened breach, the Employee agrees that the Company, in addition to such other remedies which may be available, shall have the right to obtain an injunction from a court restraining such a breach or threatened breach without posting bond and the right to specific performance of the provisions of this Agreement and the Employee hereby waives the adequacy of a remedy at law as a defense to such relief.

b. Disclosure of this Agreement. The Employee hereby authorizes the Company to notify others, including but not limited to the Affiliates and any of the Employee's future employers or prospective business associates, of the terms and existence of this Agreement and the Employee's continuing obligations to the Company hereunder.

c. Not Employment Contract. The Employee acknowledges that this Agreement does not constitute a contract of employment, does not imply that the Company will continue Employee's employment for any period of time and does not change the at-will nature of Employee's employment.

d. Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of both parties and their respective successors and assigns, including any corporation with which, or into which, the Company may be merged or which may succeed to the Company's assets or business, provided, however, that the obligations of the Employee are personal and shall not be assigned by Employee. The Employee expressly consents to be bound by the provisions of this Agreement for the benefit of the Company or any Affiliate thereof to whose employ the Employee may be transferred without the necessity that this Agreement be re-signed at the time of such transfer.

e. Severability. In case any provision of this Agreement shall be invalid, illegal or otherwise unenforceable, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby.

f. Waivers. No delay or omission by the Company in exercising any right under this Agreement will operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion.

g. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (without reference to the conflicts of laws provisions thereof). Any action, suit, or other legal proceeding which is commenced to resolve any matter arising under or relating to any provision of this Agreement shall be commenced only in a court of the Commonwealth of Massachusetts (or, if appropriate, a federal court located within Massachusetts), and the Company and the Employee each consents to the jurisdiction of such a court. The Company and the Employee each hereby irrevocably waive any right to a trial by jury in any action, suit or other legal proceeding arising under or relating to any provision of this Agreement.

h. Entire Agreement; Amendment. This Agreement supersedes all prior agreements, written or oral, between the Employee and the Company relating to the subject matter of this Agreement. This Agreement may not be modified, changed or discharged in whole or in part, except by an agreement in writing signed by the Employee and the Company. The Employee agrees that any change or changes in Employee's duties, salary or compensation after the signing of this Agreement shall not affect the validity or scope of this Agreement.

i. Captions. The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

THE EMPLOYEE ACKNOWLEDGES THAT HE/SHE HAS CAREFULLY READ THIS AGREEMENT AND UNDERSTANDS AND AGREES TO ALL OF THE PROVISIONS IN THIS AGREEMENT.

*[Remainder of the Page Intentionally Left Blank]*

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year set forth above.

WITNESS our hands and seals:

RESTORBIO, INC.

ACKNOWLEDGED AND AGREED:

By: \_\_\_\_\_  
Name: David Steinberg  
Title: Board Member

\_\_\_\_\_ Chen Schor

March 31, 2017

Joan Mannick, M.D.

Dear Dr. Mannick:

This letter agreement (the "Agreement") confirms our agreement regarding your employment with resTORbio, Inc. (the "Company") and shall be effective as of the date first written above.

**1. Employment Period.** Your employment under this Agreement will commence on *[date]* and continue until terminated in accordance with Section 5 (the "Employment Period"). You will be employed on an at-will basis, which means that you may resign and the Company may terminate your employment at any time for any reason or for no reason. Your anticipated start date is April 4, 2017 (the "Start Date").

**2. Position and Duties.** During the Employment Period, you will be employed by the Company in accordance with the terms and conditions set forth herein on a full-time basis as its Chief Medical Officer, and in such capacity you agree to perform all duties that are required by your position and such other duties as may reasonably be assigned to you from time to time by the Chief Executive Officer (the "CEO") and Board of Directors (the "Board") of the Company that are consistent with your position. During the Employment Period, you shall report to the CEO. You agree that you will devote your full business time to the advancement of the business and interests of the Company and to the discharge of your duties and responsibilities. During the Employment Period, you shall be free to serve as a director of other corporations so long as such activities do not interfere with your duties under this Agreement.

**3. Compensation and Benefits.** During the Employment Period, as compensation for all services performed by you for the Company, the Company will provide you the following pay and benefits:

(a) **Base Salary.** The Company will pay you a base salary at the rate of \$318,250.00 per year, less required withholding, payable in accordance with the regular payroll practices of the Company, and subject to increase by the Board in its discretion ("Base Salary"). The board of directors of the Company will consider in good faith appropriate annual increases to your salary, consistent with market. Notwithstanding the foregoing, your then current Base Salary shall be increased by no less than 5% immediately no later than the earlier of your eligibility for the SP2 bonus described in Section 3(c)(iii) below or the second anniversary of your employment.

(b) **Annual Bonus Compensation.** During your employment with the Company, you will be considered annually for a bonus targeted at 35% of your Base Salary subject to achieving reasonably obtainable Company and individual performance targets set by you and the CEO or the Board each year. Any such bonus is entirely discretionary in nature and subject to the rules of the cash bonus scheme, which may be varied from time to time. Any bonus due hereunder will be payable by March 15th of the fiscal year that begins immediately following the fiscal year for which the bonus was earned. Your annual bonus eligibility will commence with your start date and be pro-rated for any partial year of service. Notwithstanding the foregoing, for the period of January 1, 2017 to the Start Date you will be eligible for a bonus targeted at 23.33% of your current Base Salary, which such bonus shall be subject to the same restrictions and payable at the same time as your annual bonus for the 2017 fiscal year. No payment will be made under any annual cash bonus scheme if, on or before the payment date, you have given notice of termination of employment or you are no longer employed by the Company, except as set forth in Section 5(a) below.

(c) **Additional Bonuses.** In addition to your annual bonuses, you also shall be eligible for the following bonuses, each of which shall be payable only once if earned:

(i) **FPD Bonus.** \$15,000 payable within 30 days after the first subject is dosed in a Phase II study following pre-IND meeting or call with the U.S. Food and Drug Administration (or written feedback to a pre-IND briefing book from the FDA) and as long as such dosing of subject per this paragraph occurs by the first anniversary of the Start Date.

(ii) **FSFIA Bonus.** \$15,000 payable within 30 days after the Company enrolls first subject following interim analysis review by committee defined by the Phase II study protocol and as long as such subject per this paragraph was enrolled by the second anniversary of the Start Date.

(iii) **SP2 Bonus.** \$30,000 payable within 30 days after the Company achieves the primary end point with a p value equal to or less than 0.05 in a Phase II study as long as such achievement occurs by the third anniversary of the Start Date. In the event that the bonuses described in Sections 3(c)(i) and (ii) above have not been earned at the time this bonus is earned and becomes due, then you shall receive those bonuses at the same time.

(d) **Participation in Insurance and Employee Benefit Plans.** During the Employment Period, you will be entitled to participate in all employee benefit plans in effect for employees of the Company generally. Your participation will be subject to the terms of the applicable plan documents and generally applicable Company policies. The benefits made available by the Company, and the rules, terms and conditions for participation in such benefit plans, may be changed by the Company at any time without advance notice. The Company shall maintain Directors and Officers Liability insurance coverage with commercially reasonable terms during the Employment Period.

(e) **Vacations.** During the Employment Period, you will be entitled to four (4) weeks of vacation per year, in addition to holidays observed by the Company. Vacation may be taken at such times and intervals as you will determine, subject to the business needs of the Company as reasonably determined by the Board, with one (1) weeks of carry-forward of unused vacation time from one year to the next.

(f) **Business Expenses.** During the Employment Period, the Company will pay or reimburse you for all reasonable out of pocket business expenses incurred or paid by you in the performance of your duties and responsibilities for the Company, subject to any maximum annual limit and other restrictions on such expenses set by the Board and to such reasonable substantiation and documentation as it may specify from time to time.

#### **4. Confidential Information and Restricted Activities.**

(a) **Confidential Information.** During the Employment Period, you will learn of confidential information and you may develop confidential information on behalf of the Company. In addition, you understand that the Company will receive from third parties confidential or proprietary information ("Third Party Information") subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. As a condition to your employment with the Company, you are required to execute on the date hereof a Non-Disclosure Agreement in the form attached hereto as Exhibit A setting forth the policies and procedures of the Company for protecting confidential information and Third Party Information. You understand that the restrictions set forth therein will continue to apply after your employment terminates regardless of the reason for such termination.

(b) **Protection of Documents.** All documents, records and files, in any media of whatever kind and description, embodying or containing confidential information or Third Party Information, and any copies, in whole or in part, thereof (the "Documents"), whether or not prepared by you will be the sole and exclusive property of the Company. You agree to safeguard all Documents and to surrender to the Company at the time your employment terminates, or at such earlier time or times as the CEO, or his or her designee may specify, all Documents then in your possession or control.

(c) **Non-Competition Restrictions.** You agree that the following restrictions on your activities during and after your employment are necessary and reasonable to protect the goodwill, confidential information and other legitimate interests of the Company from unfair competition:

(i) During the Employment Period and for 6 months after the Employment Period ends for any reason (the “Restricted Period”), you will not, directly or indirectly, on behalf of any individual or entity other than the Company, perform services in any capacity (whether as an owner, employee, partner, independent contractor or otherwise, whether with or without compensation) directly or indirectly in all or any portion of any business that the Company conducts or is developing (the “Business”) as of the date of such termination; provided, however, that ownership of less than 5% of the outstanding stock of any publicly traded company will not by itself be deemed to be a violation of this provision.

(ii) During the Restricted Period, you will not directly or indirectly, and will not assist directly or indirectly any other Person to (A) solicit, hire or engage in any capacity any employee of the Company (or any Person who was an employee of the Company within 6 months of the date of your termination) or solicit or seek to persuade any employee of the Company to discontinue such employment, or (B) call on, solicit, induce, influence or encourage any customer of the Company or independent contractor providing services to the Company to terminate or diminish its relationship with the Company.

(d) **Inventions and Patents; Third Party Information.** Any discoveries, ideas, inventions, improvements, enhancements, processes, methods, techniques, developments, software, and works of authorship, whether patentable or not, which you create, make, conceive or reduce to practice, either alone or jointly with others, during your employment by the Company, whether or not during normal working hours or on the premises of the Company or an affiliate (all of which are collectively referred to in this Agreement as “Developments”), will be works-made-for-hire and the Company will be deemed the sole owner throughout the universe of any and all rights of whatsoever nature therein, whether or not now or hereafter known, existing, contemplated, recognized or developed, with the right to use the same in perpetuity in any manner the Company determines in its sole discretion without any further payment to you whatsoever. If, for any reason, any of such Developments will not legally be a work-for-hire and/or there are any rights which do not accrue to the Company under the preceding sentence, then you hereby irrevocably assign and agree to assign any and all of your right, title and interest thereto, including, without limitation, any and all copyrights, patents, trade secrets, trademarks and/or other rights of whatsoever nature therein, whether or not now or hereafter known, existing, contemplated, recognized or developed to the Company, and the Company will have the right to use the same in perpetuity throughout the universe in any manner the Company determines without any further payment to you whatsoever. You will, from time to time, as may be requested by the Company and at the Company’s expense, do any and all things which the Company may deem useful or desirable to establish or document the Company’s exclusive ownership of any and all rights in any such results and proceeds, including, without limitation, the execution of appropriate copyright and/or patent applications or assignments. To the extent you have any rights in



the Developments that cannot be assigned in the manner described above, you unconditionally and irrevocably waive the enforcement of such rights. This Section 4(d) is subject to, and will not be deemed to limit, restrict or constitute any waiver by the Company of any rights of ownership to which the Company may be entitled by operation of law by virtue of the Company being your employer.

(e) You agree not to incorporate any discoveries, ideas, inventions, improvements, enhancements, processes, methods, techniques, developments, software, and works of authorship, whether patentable or not, which were created, made, conceived or reduced to practice by you prior to your employment by the Company and which are owned by you, which relate directly or indirectly to the current or anticipated future business of the Company (collectively, "Prior Developments") into any Company product, material, process or service without prior written consent of an officer of the Company. If you do incorporate any Prior Development into any Company product, material, process or service, you hereby grant to the Company a non-exclusive, worldwide, perpetual, transferable, irrevocable, royalty-free, fully-paid right and license to make, have made, use, offer for sale, sell, import, reproduce, modify, prepare derivative works, display, perform, transmit, distribute and otherwise exploit such Prior Development and to practice any method related thereto.

(f) **Cooperation.** You agree to cooperate, in a reasonable and appropriate manner, with the Company and its attorneys, both during and after the termination of your employment, in connection with any litigation or other proceeding arising out of or relating to matters in which you were involved prior to the termination of your employment to the extent the Company pays all Company-approved expenses you incur and reasonable hourly consulting fees in connection with such cooperation.

**5. Termination of Employment.** Your employment under this Agreement and the Employment Period may only be terminated as set forth in this Section 5.

(a) **Termination by the Company for Cause or by You for Good Reason.**

(i) Cause. The Company may terminate the Employment Period and your employment at any time, with or without Cause. The following, as determined by the Board in its reasonable judgment, will constitute "Cause" for termination: (A) your breach of any material provision of this Agreement and the continuation such breach for a period of 30 days after written notice to you of such breach and a request for reasonable cure or other appropriate corrective action; or (B) engagement in theft, embezzlement, fraud, dishonesty or misappropriation of any of the Company's property.

(ii) Good Reason. You may terminate the Employment Period and your employment with or without Good Reason. "Good Reason" shall be deemed to exist if any of the following conditions occur without your consent: (A) a material reduction of your Compensation or Benefits; (B) a material adverse change of your title, authority, duties, or responsibilities; or (C) the relocation of your principal place of employment more than 50 miles from its current location; provided, however, that in each case you provide written notice to the Company within 90 days of the event constituting Good Reason of your intention to terminate your employment for Good Reason. Such termination shall be effective 30 days from the Company's receipt of such notice if the Company has not fully cured such act(s) or failure(s) within 15 days from the Company's receipt of such notice.

(iii) Payments in the Event of Termination without Cause by the Company, and Termination by You for Good Reason. If your employment is terminated by the Company without Cause in accordance with Section 5(a)(i), including without limitation any termination without Cause before or following a "Change of Control", as defined below, or you terminate your employment for Good Reason in accordance with Section 5(a)(ii), you will be entitled to: (A) your Accrued Obligations, as defined below, and (B) a lump sum payment equal to six (6) months of your then current Base Salary if such termination occurs within the first twelve (12) months of your employment or, if such termination occurs thereafter, a lump sum payment equal to nine (9) months of your then current Base Salary (the "Base Severance Amount"); and (C) continued coverage under the Company's health and dental plans on the same terms as prior to such termination until the earlier of (x) the expiration of the period for which you receive severance pursuant to Section 5(a)(iii)(B), and (y) the date you commence new employment which offers health coverage that would disqualify you from continued COBRA coverage pursuant to law. Payment of the Base Severance Amount and health insurance continuation pursuant to this Section 5(a)(iii) is contingent upon your execution and non-revocation of a general release of claims in favor of the Company in form reasonably satisfactory to the Company. The Base Severance Amount shall be paid in accordance with the Company's normal payroll procedures.

If your employment is terminated by the Company without Cause following Change of Control or you terminate your employment for Good Reason following Change of Control then you will be eligible to your Annual Bonus Compensation pro rated for partial years of service.

(iv) Once the release required by Section 5(a)(iii) is executed and delivered, then the following will apply to the payments required under this Section 5:

(A) Any such cash payment to be provided that is not nonqualified deferred compensation subject to Section 409A will commence or be made upon the first regularly scheduled payroll date immediately after the date the release is executed and no longer subject to revocation (the "Release Effective Date").

(B) Any such cash payment to be provided that is nonqualified deferred compensation subject to Section 409A will commence or be made upon the sixtieth (60th) day following your termination of employment.

The first cash payment made pursuant to this Section 5(a)(iv), if any, will include payment of all amounts that otherwise would have been due prior to the Release Effective Date under Section 5 had such payments commenced immediately upon your termination of employment; and any payments made thereafter will continue as otherwise provided herein.

(b) **Termination by Death or Disability.** Your employment will automatically terminate in the event of your death during employment. In the event you become disabled during employment and, as a result, are unable to continue to perform substantially all of your duties and responsibilities under this Agreement notwithstanding the provision of any reasonable accommodation, the Company will continue to pay your Base Salary (upon exhaustion of any available sick time and if you are not then eligible for short term or long term disability benefits) in accordance with normal payroll practices of the Company and will continue to provide you benefits in accordance with Section 3(d) above, to the extent permitted by plan terms, for up to ninety days of disability during any period of 365 consecutive calendar days. If you are unable to return to work after 90 days of disability, the Company may terminate your employment, upon notice to you. If any question will arise as to whether you are disabled to the extent that you are unable to perform substantially all of your duties and responsibilities for the Company, you will, at the Company's request, submit to a medical examination by a physician selected by the Company to whom you or your guardian, if any, has no reasonable objection to determine whether you are so disabled and such determination will for the purposes of this Agreement be conclusive of the issue. In the event of termination of your employment by reason of death or disability in accordance with this Section 5(b), the Company (i) will pay you or your estate your Accrued Obligations.

(c) **All Other Methods of Termination.** In the event of termination of your employment by the Company for Cause, or by you without Good Reason, the Company (i) will pay you your Accrued Obligations and will have no obligation to pay you severance benefits.

## 6. Matters Related to Termination.

(a) **Benefit Plan Termination.** Except for any right you may have under the federal law known as “COBRA”, applicable state law, or this Agreement to continue participation in the Company’s group health and dental plans, benefits will terminate in accordance with the terms of the applicable benefit plans based on the date of termination of your employment.

(b) **Survival.** Provisions of this Agreement will survive any termination if so provided in this Agreement or if necessary or desirable to accomplish the purposes of other surviving provisions, including without limitation your obligations under Section 4 of this Agreement. Upon termination by either you or the Company, all rights, duties and obligations of you and the Company to each other will cease, except as otherwise expressly provided in this Agreement.

**7. Definitions.** For purposes of this Agreement, the following definitions will apply:

“**Accrued Obligations**” means (i) any Base Salary earned but not paid through the date of termination; (ii) any compensation deferred by you prior to your termination of employment and not paid by the Company (all of which will be paid in accordance with the terms of and at the time provided in the underlying deferral arrangement); (iii) any amounts or benefits owing to you under the then applicable benefit plans of the Company; (iv) any of the Additional Bonuses earned, that have not been paid prior to the date of termination; and (v) any amounts owing to you for reimbursement of expenses.

“**Change of Control**” means any of the following: (i) a merger or consolidation of the Company with or into any other corporation or other entity in which the Company is not the surviving entity; (ii) a sale, lease, exchange or other transfer (in one transaction or a related series of transactions) of all or substantially all of the Company’s assets; (iii) the acquisition by any person or any group of persons, acting together in any transaction or related series of transactions, of such quantity of the Company’s voting securities as causes such person, or group of persons, to own beneficially, directly or indirectly, as of the time immediately after such transaction or series of transactions, 50% or more of the combined voting power of the voting securities of the Company; or (iv) the liquidation or dissolution of the Company.

“**Person**” means an individual, a corporation, a limited liability company, an association, a partnership, an estate, a trust or any other entity or organization, other than the Company.

“**Section 409A**” means Section 409A of the Internal Revenue Code of 1986, as amended from time to time, and the regulations and guidance issued thereunder.

**8. Governing Law.** This Agreement, the rights and obligations of the parties hereto, and any claims or disputes relating thereto, will be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (without regard to its choice of law provisions). Each of the parties agrees that any dispute between the parties will be resolved only in the state or federal courts of the Commonwealth of Massachusetts.

**9. Representations.** You represent and warrant to the Company that you are not subject to any contract, agreement, judgment, order or decree of any kind, or any restrictive agreement of any character, that restricts your ability to perform your obligations under this Agreement or that would be breached by you upon your performance of your duties pursuant to this Agreement.

**10. Withholding.** All payments made by the Company under this Agreement will be reduced by any tax or other amounts required to be withheld by the Company under applicable law.

**11. Assignment.** This Agreement will inure to the benefit of and be binding upon you and the Company, and each of our respective successors, executors, administrators, heirs and assigns. You may not assign this Agreement without the prior written consent of the Company.

**12. Miscellaneous.**

(a) This Agreement sets forth your entire agreement with the Company and supersedes all prior and contemporaneous communications, agreements and understandings, written or oral, with respect to the subject matter hereof. This Agreement may not be modified or amended, and no breach will be deemed to be waived, unless agreed to in writing by you and the CEO or an expressly authorized representative of the Board. The headings and captions in this Agreement are for convenience only and in no way define or describe the scope or content of any provision of this Agreement. This Agreement may be executed in two or more counterparts, each of which will be an original and all of which together will constitute one and the same instrument.

(b) Notwithstanding any other payment schedule provided herein, if you are identified on the date of termination as a “specified employee” within the meaning of Section 409A(a)(2)(B), then

any payment that is considered nonqualified deferred compensation subject to Section 409A, as determined by the Company in its sole discretion, and payable on account of a “separation from service,” will be made on the date that is the earlier of (A) the expiration of the six (6)-month period beginning on the date of your “separation from service”, and (B) your death (the “Delay Period”) to the extent

required under Section 409A. Upon the expiration of the Delay Period, all payments delayed pursuant to this subsection (whether they would have otherwise been payable in a single sum or in installments in the absence of such delay) will be paid to you in a lump sum, and all remaining payments due under this Agreement will be paid or provided in accordance with the normal payment dates specified for them herein.

(c) For purposes of Section 409A, your right to receive any installment payment pursuant to this Agreement will be treated as a right to receive a series of separate and distinct payments.

(d) Notwithstanding any other provision in this Agreement to the contrary, in no event shall any payment under this Agreement that constitutes "Non-Qualified Deferred Compensation" for purposes of Section 409A be subject to offset by any other agreement unless otherwise permitted by Section 409A.

**13. Severability.** If any provision of this Agreement is illegal, invalid or unenforceable for any reason whatsoever, such provision will be fully severable, and this Agreement will be construed and enforced as if such illegal, invalid or unenforceable provision were not a part of this Agreement with the remaining provisions of this Agreement remaining in full force and effect and unaffected by the illegal, invalid or unenforceable provision or by its severance from this Agreement.

**14. Notices.** Any notices provided for in this Agreement will be in writing and will be effective immediately when delivered in person or three days after such notice is deposited in the United States mail, postage prepaid, and addressed to you at your last known address on the books of the Company or, in the case of the Company, to it at its principal place of business, attention CEO, or to such other address as either party may specify by notice to the other actually received.

**15. Defend Trade Secrets Act of 2016 Notice.** Notwithstanding any provision in this Agreement, an individual shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, provided that such filing is made under seal. Further, an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, provided that the individual (A) files any document containing the trade secret under seal and (B) does not disclose the trade secret, except pursuant to court order.

\* \* \* \* \*

If the foregoing is acceptable to you, please sign this letter in the space provided below. At the time you sign and return it this letter will take effect as a binding agreement between you and the Company on the basis, and subject to the conditions, set forth above. The enclosed copy is for your records.

Sincerely yours,

resTORbio, Inc.

By: /s/ Chen Schor

Name: Chen Schor

Title: Chief Executive Officer

Accepted and Agreed:

/s/ Joan Mannick

Joan Mannick, M.D.

Date: March 31, 2017

*[Signature Page to Employment Letter]*

**Exhibit A**

**NON-DISCLOSURE AGREEMENT**

This Non-Disclosure Agreement (this "Agreement") is made as of this \_\_ day of \_\_\_\_\_, 2017 by and between resTORbio, Inc., a Delaware corporation (hereinafter referred to collectively with its Affiliates as the "Company"), and Joan Mannick (the "Employee").

The Company desires to employ the Employee to provide services to the Company. In consideration of the employment or the continued employment of the Employee by the Company, the Company and the Employee agree as follows:

1. Condition of Employment.

The Employee acknowledges that Employee's employment and/or the continuance of that employment with the Company is contingent upon Employee's agreement to become a party to and adhere to the provisions of this Agreement. The Employee further acknowledges that the nature of the Company's business is such that protection of its proprietary and confidential information and the proprietary and confidential information of its Affiliates is critical to the survival and success of the Company's business.

2. Proprietary and Confidential Information.

a. The Employee agrees that all information and know-how, whether or not in writing, of a private, secret or confidential nature concerning the Company's or any Affiliate's business or financial affairs (collectively, "Proprietary Information") is and shall be the exclusive property of the Company (or any person or entity designated by the Company). By way of illustration, but not limitation, Proprietary Information may include discoveries, ideas, inventions, products, product improvements, product enhancements, processes, methods, techniques, formulas, compositions, compounds, negotiation strategies and positions, projects, developments, plans (including business and marketing plans), research data, clinical data, financial data (including sales costs, profits, pricing methods), personnel data, computer programs (including software used pursuant to a license agreement), computer software code, computer games, customer, prospect and supplier lists, and contacts at or knowledge of customers or prospective customers of the Company or any Affiliate, and the names of, contact information of, and any other data concerning, existing and prospective Affiliates and existing and prospective investors of such Affiliates. The Employee shall not disclose any Proprietary Information to any person or entity other than employees of the Company or use the same for any purposes (other than in the performance of Employee's duties as an employee of the Company) without written approval by an officer of the Company, either during or after Employee's employment with the Company. The Employee shall use the Employee's best efforts to prevent unauthorized publication or disclosure of any of the Company's Proprietary Information.



b. The Employee agrees that all files, documents, letters, memoranda, reports, records, data, sketches, drawings, models, laboratory notebooks, program listings, computer equipment or devices, computer programs or other written, photographic, or other tangible or intangible material containing Proprietary Information, whether created by the Employee or others, which shall come into Employee's custody or possession, shall be and are the exclusive property of the Company to be used by the Employee only in the performance of Employee's duties for the Company and shall not be copied or removed from the Company premises except in the pursuit of the business of the Company. All such materials or copies thereof and all tangible property of the Company in the custody or possession of the Employee shall be delivered to the Company, upon the earlier of (i) a request by the Company or (ii) termination of Employee's employment for any reason. After such delivery, the Employee shall not retain any such materials or copies thereof or any such tangible property.

c. The Employee agrees that Employee's obligation not to disclose or to use information and materials of the types set forth in paragraphs 2(a) and 2(b) above, and Employee's obligation to return materials and tangible property, set forth in paragraph 2(b) above, also extends to such types of information, materials and tangible property of Affiliates, customers of the Company or suppliers to the Company or other third parties who may have disclosed or entrusted the same to the Company or to the Employee in the course of the Company's business.

### 3. Scope of Disclosure Restrictions.

Nothing in this Agreement or elsewhere prohibits the Employee from reporting possible violations of state or federal law or regulation to any government agency, regulator, or legal authority, or making other disclosures that are protected under the whistleblower provisions of state or federal law or regulation. The Employee is not required to notify the Company that the Employee has made any such reports or disclosures; provided, however, that nothing herein authorizes the disclosure of information the Employee obtained through a communication that was subject to the attorney-client privilege, unless disclosure of the information would otherwise be permitted by an applicable law or rule. Further, pursuant to the Defend Trade Secrets Act: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."

#### 4. Non-Disparagement.

The Employee shall not, either during Employee's employment with the Company or thereafter, make or encourage others to make any statement or release any information that is intended to, or reasonably could be foreseen to, disparage, defame or embarrass the Company or any of its Affiliates or their respective employees, officers, directors, partners, members or stockholders.

#### 5. Miscellaneous.

a. Equitable Remedies. The Employee acknowledges that the restrictions contained in this Agreement are necessary for the protection of the business and goodwill of the Company and are considered by the Employee to be reasonable for such purpose. The Employee agrees that any breach or threatened breach of this Agreement is likely to cause the Company substantial and irrevocable damage which is difficult to measure. Therefore, in the event of any such breach or threatened breach, the Employee agrees that the Company, in addition to such other remedies which may be available, shall have the right to obtain an injunction from a court restraining such a breach or threatened breach without posting bond and the right to specific performance of the provisions of this Agreement and the Employee hereby waives the adequacy of a remedy at law as a defense to such relief.

b. Disclosure of this Agreement. The Employee hereby authorizes the Company to notify others, including but not limited to the Affiliates and any of the Employee's future employers or prospective business associates, of the terms and existence of this Agreement and the Employee's continuing obligations to the Company hereunder.

c. Not Employment Contract. The Employee acknowledges that this Agreement does not constitute a contract of employment, does not imply that the Company will continue Employee's employment for any period of time and does not change the at-will nature of Employee's employment.

d. Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of both parties and their respective successors and assigns, including any corporation with which, or into which, the Company may be merged or which may succeed to the Company's assets or business, provided, however, that the obligations of the Employee are personal and shall not be assigned by Employee. The Employee expressly consents to be bound by the provisions of this Agreement for the benefit of the Company or any Affiliate thereof to whose employ the Employee may be transferred without the necessity that this Agreement be re-signed at the time of such transfer.

e. Severability. In case any provision of this Agreement shall be invalid, illegal or otherwise unenforceable, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby.

f. Waivers. No delay or omission by the Company in exercising any right under this Agreement will operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion.

g. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (without reference to the conflicts of laws provisions thereof). Any action, suit, or other legal proceeding which is commenced to resolve any matter arising under or relating to any provision of this Agreement shall be commenced only in a court of the Commonwealth of Massachusetts (or, if appropriate, a federal court located within Massachusetts), and the Company and the Employee each consents to the jurisdiction of such a court. The Company and the Employee each hereby irrevocably waive any right to a trial by jury in any action, suit or other legal proceeding arising under or relating to any provision of this Agreement.

h. Entire Agreement; Amendment. This Agreement supersedes all prior agreements, written or oral, between the Employee and the Company relating to the subject matter of this Agreement. This Agreement may not be modified, changed or discharged in whole or in part, except by an agreement in writing signed by the Employee and the Company. The Employee agrees that any change or changes in Employee's duties, salary or compensation after the signing of this Agreement shall not affect the validity or scope of this Agreement.

i. Captions. The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

THE EMPLOYEE ACKNOWLEDGES THAT HE/SHE HAS CAREFULLY READ THIS AGREEMENT AND UNDERSTANDS AND AGREES TO ALL OF THE PROVISIONS IN THIS AGREEMENT.

*[Remainder of the Page Intentionally Left Blank]*

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year set forth above.

WITNESS our hands and seals:

RESTORBIO, INC.

ACKNOWLEDGED AND AGREED:

By: \_\_\_\_\_  
Name: Chen Schor  
Title: Chief Executive Officer

\_\_\_\_\_  
Joan Mannick

resTORbio, Inc.  
501 Boylston Street, Suite 6102  
Boston, Massachusetts 02116

October 5, 2017

John McCabe

Dear John:

We are pleased to offer you the position of Vice President, Finance at resTORbio, Inc. (“resTORbio” or the “Company”). This is an exciting time for resTORbio, and we believe that your skills and experience can greatly assist in moving the company forward. Your anticipated full time start date is October 23, 2017 (the “Start Date”). Should you decide to accept this offer, the terms of your employment will be as follows:

1. Position. You will be employed on an at-will basis, which means that you may resign and the Company may terminate your employment or change your job title and duties at any time for any reason or for no reason. You agree to devote your entire business time, attention, skills and best efforts to the performance of your duties hereunder following the Start Date and agree that you will not, following the Start Date, be employed by or otherwise engaged in any other business activity requiring any of your business time.

2. Compensation.

(a) Salary. Your salary will be \$20,833.33 per month (“Base Salary”), payable periodically on the same schedule as other employees of the Company generally but not less frequently than on a monthly basis.

(b) Equity. As soon as practicable following the execution of this Agreement, and subject to the approval of the Company’s Board of Directors you shall be granted an incentive stock option (the “Option”) under resTORbio’s Stock Incentive Plan (the “Plan”) to purchase 82,535 of shares of Common Stock. The Option shall vest over four years from the Start Date with 1/4 of the shares underlying such option vesting on the first year anniversary of such Start Date and the remaining 3/4 of such shares vesting in 6 equal semi-annual installments following such first year anniversary, provided that you are engaged by the Company on each such vesting date. The Option shall have an exercise price equal to the fair market value of the Common Stock on the date of grant and shall be subject to the provisions set forth in the Plan and the Form of Incentive Stock Option Agreement previously approved by the Board.

(c) Performance Bonus. Beginning with the 2017 calendar year and for each calendar year thereafter during which you are employed by ResTORbio, you will be eligible to receive, in the sole discretion of the Company, a performance bonus of up to thirty percent (30%) of the Base Salary paid to you during such calendar year (the “Performance Bonus”). This bonus will be prorated for the appropriate portion of 2017 for which you are employed by the Company. Any Performance Bonus with respect to a calendar year shall be paid between January 1 and March 15 of the immediately following calendar year and in no event shall you be eligible for a Performance Bonus with respect to a

calendar year if you separate from service with the Company prior to the end of such calendar year, except as set forth in Section 6(c) below. Annual performance goals will be mutually agreed in advance between you and your immediate supervisor and performance by you against these goals will be the basis of determining the amount of the Performance Bonus to be awarded.

3. Expense Reimbursement. In accordance with the Company's policies and procedures, you will be entitled to reimbursement of all reasonable and properly documented expenses incurred by you in the performance of your duties that are approved by the Company.

4. Fringe Benefits. During your employment with the Company, you will be entitled to the benefits of such group medical, dental, disability and retirement benefits, if any, as the Company shall make generally available from time to time to its employees (the "Benefits"), provided you are eligible under (and subject to all provisions of) the plan documents governing those programs. The Benefits made available by the Company, and the rules, terms and conditions for participation in such benefit plans, may be changed by the Company at any time without advance notice.

5. Vacation. In addition to ten (10) holidays per year on which the Company's offices are closed, you will be entitled to eighteen (18) days paid vacation or sick leave each calendar year during your employment, accruing ratably each month. A maximum of five (5) days of unused vacation may be carried forward from year to year; provided that in no event may any vacation days be carried forward for more than one year.

6. Payments Upon Termination of Employment.

(a) *Termination for Any Reason.* In the event your employment with the Company terminates for any reason, the Company shall pay to you (i) any Base Salary, accrued vacation pay and expense reimbursement, accrued but unpaid as of the date of termination, and (ii) the awarded but unpaid portion, if any, of the Performance Bonus for any prior year.

(b) *Termination by the Company without Cause or by you for Good Reason (No Change in Control).* Upon termination of your employment with the Company by the Company without Cause (as defined below) or upon your resignation from employment for Good Reason (as defined below) following the first anniversary of the Start Date where there has not been a Change in Control (as defined below), contingent upon your execution and delivery of a general release reasonably satisfactory to the Company within forty-five (45) days after your termination date releasing the Company, its officers, agents, stockholders and affiliates from any liability for any matter other than for payments under this Section 6 and contractual obligations under other written agreements (the "Release"), you shall be entitled to (i) payment of an amount equal to three (3) months of your Base Salary then in effect, to be paid over a like number of months consistent with the Company's normal payroll schedule, commencing within sixty (60) days after your termination date, and (ii) continued coverage under the Company's health and dental plans on the same terms as prior to such termination until the earlier of (x) the expiration of the three (3) month period for which you are entitled to receive severance, and (y) the date you commence new employment which offers health coverage that would disqualify you from continued COBRA coverage pursuant to law; provided, however, that in the event of your material breach of any of the Related Agreements, you shall not be entitled to any of the foregoing benefits and all such obligations shall terminate and be of no further force or effect.

(c) *Termination by the Company without Cause or by you for Good Reason (Change in Control)*. Upon termination of your employment with the Company by the Company without Cause or upon your resignation from employment for Good Reason within twelve (12) months after a Change in Control, contingent upon your execution and delivery of a Release within forty-five (45) days after your termination date, you shall be entitled to (i) payment of an amount equal to six (6) months of your Base Salary then in effect, to be paid over a like number of months consistent with the Company's normal payroll schedule, commencing within sixty (60) days after your termination date, (ii) up to 50% of your annual Performance Bonus for the year in which such termination occurs, pro-rated to reflect the month in which the termination occurs, such amount to be payable in a lump-sum within sixty (60) days of such termination, and (iii) continued coverage under the Company's health and dental plans on the same terms as prior to such termination until the earlier of (x) the expiration of the six (6) month period for which you are entitled to receive severance, and (y) the date you commence new employment which offers health coverage that would disqualify you from continued COBRA coverage pursuant to law; provided, however, that in the event of your material breach of any of the Related Agreements, then the Company's obligation to pay such severance amounts and the Performance Bonus and to provide such coverage shall terminate and be of no further force or effect.

(d) *Accelerated Vesting of Equity Following a Change in Control*. Upon termination of your employment with the Company by the Company without Cause or upon your resignation from employment for Good Reason following a Change in Control, contingent upon your execution and delivery of the Release within forty-five (45) days after your termination date, any outstanding equity or equity-based awards granted to you by the Company shall become fully vested and exercisable as of your termination date.

For the purposes hereof, "Change in Control" shall mean the first to occur of any of the following, provided that for any distribution that is subject to Section 409A of the Internal Revenue Code of 1986, as amended ("Code"), a Change in Control under this Agreement shall be deemed to occur only if such event also satisfies the requirements under Treas. Regs. Section 1.409A-(i)(5):

(a) any Person (as defined below) becomes the "beneficial owner" (as defined in Rule 13d-3 of the United States Securities Exchange Act of 1934, as amended (the "Exchange Act")), directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the total voting power represented by the Company's then-outstanding voting securities; provided, however, that the acquisition of additional securities by any one Person who is considered to own more than fifty percent (50%) of the total voting power of the securities of the Company will not be considered a Change in Control;

(b) the consummation of the sale, transfer or disposition by the Company of all or substantially all of the Company's assets; or

(c) the consummation of a merger or consolidation of the Company with any other corporation, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its parent) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity or its parent outstanding immediately after such merger or consolidation.

For purposes hereof, "Cause" shall mean the good faith determination of the Company that any one or more of the following events has occurred: (i) conviction of any felony, (ii) deliberate neglect of, willful misconduct in connection with the performance of, or refusal to perform reasonable and lawful duties reasonably assigned to you pursuant to the terms hereof, (iii) material breach of any of the provisions of this Agreement or the Related Agreements (as defined below) or (iv) any fraudulent conduct materially detrimental to the reputation of the Company.

For the purposes hereof, "Good Reason" shall mean, in the context of a resignation by you, a resignation that occurs within thirty (30) days following you first having knowledge of any material adverse change in your compensation, title or authority, or any material breach of this Agreement by the Company, provided that in the case of a material breach, Good Reason shall only exist where you have provided the Company with written notice of the breach and, if the breach is reasonably capable of being cured within a period of ten (10) business days, the Company has failed to so cure such breach within ten (10) business days.

For the purposes hereof, "Person" shall mean (a) a natural person, sole proprietorship, partnership, corporation, association, limited liability company, trust, unincorporated organization, government entity or any other legal entity; and (b) any group deemed to be a "person" within the meaning of Section 13(d) or 14(d) of the Exchange Act. Persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company.

Except as set forth in this Section 6, nothing in this letter shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company.

7. Related Agreements. As a condition to your employment with the Company, you are required to execute on the date hereof a Noncompetition and Nonsolicitation Agreement and an Invention and Non-Disclosure Agreement (the "Related Agreements").

8. No Conflict. You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing (or that purports to prevent) you from entering into employment with or carrying out your responsibilities for the Company, or which is in any way inconsistent with the terms of this letter.

9. Company Policies and Procedures. As an employee of the Company, you will be required to comply with all Company policies and procedures. Violations of the Company's policies may lead to immediate termination of your employment. Further, the Company's premises, including all workspaces, furniture, documents, and other tangible materials, and all information technology resources of the Company (including computers, data and other electronic files, and all internet and email) are subject to oversight and inspection by the Company at any time. Company employees should have no expectation of privacy with regard to any Company premises, materials, resources, or information.



10. Miscellaneous. This Agreement shall not be construed as an agreement, either expressed or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at will, under which, both you and the Company remain free to terminate the employment relationship, with or without Cause, at any time, with or without notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and the Chief Executive Officer, which expressly states the intention to modify the at-will nature of your employment. Similarly, nothing in this letter shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company. This Agreement shall be construed and enforced in accordance with and governed by the laws of the Commonwealth of Massachusetts (without giving effect to any conflicts or choice of laws provisions thereof that would cause the application of the domestic substantive laws of any other jurisdiction). You and the Company each hereby irrevocably waive any right to a trial by jury in any action, suit or other legal proceeding arising under or relating to any provision of this Agreement. The terms and conditions of your proposed employment with the Company in this Agreement supersede any and all prior written and verbal discussions concerning conditions of employment.

If you agree with the provisions of this letter, please sign in the space provided below and return it to Spencer Ball, by October 6, 2017. If you do not accept this offer by October 6, 2017, this offer will be revoked.

Very truly yours,

resTORbio, Inc.

By: /s/ Chen Schor

Chen Schor  
Chief Executive Officer

ACKNOWLEDGED AND AGREED:

/s/ John McCabe

John McCabe