

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 5, 2019

resTORbio, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38359

(Commission File Number)

81-3305277
(IRS Employer
Identification No.)

**500 Boylston Street, 13th Floor
Boston, MA**

(Address of principal executive offices)

02116
(Zip Code)

Registrant's telephone number, including area code: (857) 315-5528

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	TORC	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth 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 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition

On November 5, 2019, resTORbio, Inc. announced its financial results for the quarter ended September 30, 2019. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release issued by resTORbio, Inc. on November 5, 2019, furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 5, 2019

resTORbio, Inc.

By: /s/ Chen Schor

Name: Chen Schor

Title: President and Chief Executive Officer

resTORbio Reports Third Quarter 2019 Financial Results and Corporate Update

Top-line data from PROTECTOR 1 study expected by early first quarter of 2020

RTB101 Phase 2b data demonstrating upregulation of innate antiviral immunity presented at IDWeek™ 2019

BOSTON, Massachusetts, November 5, 2019 – resTORbio, Inc. (Nasdaq: TORC), a clinical-stage biopharmaceutical company developing innovative medicines that target the biology of aging to prevent or treat aging-related diseases, today provided a corporate update and reported financial results for the third quarter ended September 30, 2019.

“We made significant progress advancing our clinical programs during the third quarter of 2019. In July, we completed patient recruitment in our Phase 3 PROTECTOR 1 study, the first of two studies in the pivotal PROTECTOR program of our lead candidate RTB101 for improving immune function and reducing the incidence of clinically symptomatic respiratory illness in older adults. Furthermore, we recently presented encouraging data from our Phase 2b trial of RTB101 at IDWeek 2019 showcasing its ability to upregulate anti-viral immunity in older adults and thereby reduce the incidence of illness associated with respiratory tract infections,” said Chen Schor, Co-Founder, President and CEO of resTORbio. “Additionally, our Phase 1b/2a trial of RTB101 in combination with sirolimus in Parkinson’s disease is on track to report data next year. We look forward to continuing our efforts to address aging-related diseases.”

Recent Corporate Highlights

Data from PROTECTOR 1 Trial in Clinically Symptomatic Respiratory Illness Expected by Early First Quarter of 2020: Following early completion of enrollment of 1,024 subjects in PROTECTOR 1 trial, the Company expects to report top-line data by early first quarter of 2020. The PROTECTOR 2 trial, resTORbio’s second Phase 3 clinical trial, is planned to begin in the fourth quarter of 2019, with top-line data from the trial expected in mid-2020.

The PROTECTOR Phase 3 program includes two randomized, double-blind, placebo-controlled clinical trials that will evaluate the safety and efficacy of RTB101 10mg given once daily for 16 weeks during winter cold and flu season to subjects 65 years of age and older, excluding current smokers and individuals with chronic obstructive pulmonary disease. The primary endpoint of both trials is the reduction in the percentage of subjects with clinically symptomatic respiratory illness, defined as illness associated with a respiratory tract infection, or RTI, based on prespecified diagnostic criteria, with or without laboratory confirmation of a pathogen.

Presented Phase 2b Data on RTB101 in Late Breaking Session at IDWeek 2019: In October 2019, resTORbio presented additional data from its randomized, double-blind, placebo-controlled Phase 2b trial of RTB101 for reducing the incidence of RTIs at the Infectious Disease Society of America’s IDWeek. The data highlighted RTB101’s potential to reduce the incidence of RTIs caused by multiple different viruses via upregulation of pan-antiviral immunity. In addition, in post-hoc analyses, RTB101 10mg once daily was observed to reduce the time to alleviation of moderate to severe RTI symptoms by an average of five days as compared to placebo ($p=0.025$) and to reduce the rate of all-cause hospitalization by 56% ($p=0.047$). Overall, RTB101 was well-tolerated with adverse events balanced between the RTB101 10mg once daily and placebo treatment arms.

Phase 1b/2a Trial in Parkinson’s Disease (PD) is Progressing with Data Expected in 2020: Preclinical studies suggest that inhibition of TORC1 may be of potential therapeutic benefit in a number of aging-related neurodegenerative diseases such as PD by stimulating the clearance of misfolded protein aggregates that cause neuronal toxicity. resTORbio’s multicenter, randomized, double-blind, placebo-controlled Phase 1b/2a trial is evaluating the safety and tolerability of RTB101 alone or in combination with sirolimus in patients with mild to moderate PD who are already on standard-of-care therapy, including those with and without glucocerebrosidase mutations. The Company expects data from this trial in 2020.

Third Quarter 2019 Financial Results

- **R&D Expenses:** Research and development (R&D) expenses were \$22.1 million for the three months ended September 30, 2019 compared to \$6.8 million for the three months ended September 30, 2018. The increase was primarily due to the ongoing Phase 3 PROTECTOR program for clinically symptomatic respiratory illness and the ongoing Phase 1b/2a for Parkinson's disease.
- **G&A Expenses:** General and administrative (G&A) expenses were \$3.0 million for the three months ended September 30, 2019 compared to \$2.3 million for the three months ended September 30, 2018. The increase was primarily due to increase in headcount and facilities-related expenses.
- **Net Loss:** Net loss was \$24.4 million, or \$0.68 per share, for the three months ended September 30, 2019 compared to a net loss of \$8.4 million, or \$0.30 per share, for the three months ended September 30, 2018.
- **Cash, Cash Equivalents and Marketable Securities:** Cash, cash equivalents and marketable securities were \$117.3 million as of September 30, 2019, compared to \$108.0 million as of December 31, 2018. The Company expects that its cash, cash equivalents and marketable securities as of September 30, 2019 will be sufficient to fund its operating expenses through 2020.

About RTB101

RTB101 is an oral, selective, and potent TORC1 inhibitor product candidate. TORC1 inhibition has been shown to be of therapeutic benefit in multiple aging-related conditions in preclinical species, including immunosenescence (aging-related decline in immune function). In two Phase 2 clinical trials that enrolled more than 900 older adults, RTB101 was observed to improve immune function by upregulation of pan-antiviral gene expression and to reduce the incidence of RTIs.

About Respiratory Tract Infections in Older Adults

As part of the aging process, the immune system weakens and becomes less effective at detecting and fighting infections such as RTIs. As a result, RTIs are more likely to be of greater severity, prolonged duration, and are more likely to be associated with medical complications in people 65 years of age and older compared to younger adults. In the U.S., RTIs are the fourth leading cause of hospitalization and seventh leading cause of death in people 65 years of age and older. Given that the majority of RTIs are caused by many different types of viruses, most of which lack effective therapies, there remains a significant unmet medical need for an immunotherapy that enhances the ability of the immune system to fight multiple viruses to reduce illness associated with RTIs in older adults.

About Parkinson's Disease in Older Adults

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.

About resTORbio

resTORbio, Inc. is a clinical-stage biopharmaceutical company developing innovative medicines that target the biology of aging to prevent or treat aging-related diseases. resTORbio's lead program selectively inhibits TORC1, an evolutionarily conserved pathway that contributes to the decline in function of multiple organ systems, including immune, neurologic and cardiac function. Learn more about resTORbio, Inc. at www.resTORbio.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Investors are cautioned that statements in this press release which are not strictly historical statements, including, without limitation, express or implied statements or guidance regarding our expectations on the proposed timing, enrollment, trial design and anticipated results of our

PROTECTOR Phase 3 program; our proposed timing and anticipated results of our Phase 1b/2a clinical trial of RTB101 alone or in combination with sirolimus in patients with mild to severe Parkinson's disease; our future plans to develop RTB101 alone or in combination with rapalogs, such as everolimus or sirolimus, including the therapeutic potential and clinical benefits thereof; our expectations on the potential patient populations that may be addressed by our product candidates; our ability to replicate results achieved in our clinical trials in any future trials; our cash position and expected cash runway; our expectations regarding our uses of capital, expenses, future accumulated deficit and other third quarter 2019 financial results and our ability to fund our operations through 2020, constitute forward-looking statements identified by words such as, but not limited to, "believe," "expect," "may," "will," "should," "seek," "anticipate," or "could" and similar words or expressions.

Any forward-looking statements in this statement are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated, including, without limitation, risks associated with: our PROTECTOR Phase 3 program; our ongoing Phase 1b/2a clinical trial of RTB101 alone or in combination with sirolimus in Parkinson's disease; the timing and anticipated results of our clinical trials; the risk that the results of our clinical trials will be predictive of future results in connection with future clinical trials; the timing and outcome of our planned interactions with regulatory authorities; and obtaining, maintaining and protecting our intellectual property; as well as those risks more fully discussed in the section entitled "Risk Factors" in the Annual Report on Form 10-K filed by resTORbio, Inc. with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements are neither historical facts nor assurances of future performance. Instead, they represent our beliefs, expectations, assumptions and views only as of today and should not be relied upon as representing our beliefs, expectations, assumptions and views as of any subsequent date. resTORbio explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

RESTORBIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 22,118	\$ 6,765	\$ 47,523	\$ 26,716
General and administrative	3,043	2,267	8,498	6,629
Total operating expenses	25,161	9,032	56,021	33,345
Loss from operations	(25,161)	(9,032)	(56,021)	(33,345)
Other income, net	725	625	2,203	1,488
Loss before income taxes	(24,436)	(8,407)	(53,818)	(31,857)
Income tax expense	12	—	31	—
Net loss	\$ (24,448)	\$ (8,407)	\$ (53,849)	\$ (31,857)
Net loss per share —basic and diluted	\$ (0.68)	\$ (0.30)	\$ (1.51)	\$ (1.23)
Weighted-average number of common shares used in net loss per share —basic and diluted	36,217	28,047	35,586	25,896

RESTORBIO, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 23,621	\$ 7,042
Marketable securities	93,641	100,986
Prepaid expenses and other current assets	4,019	1,506
Total current assets	121,281	109,534
Restricted cash	245	84
Property and equipment, net	437	321
Total assets	<u>\$ 121,963</u>	<u>\$ 109,939</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 9,973	\$ 2,989
Accrued liabilities	2,220	2,727
Total current liabilities	12,193	5,716
Other liabilities	6	19
Total liabilities	12,199	5,735
Stockholders' equity:		
Common stock	4	3
Additional paid-in capital	234,893	175,635
Accumulated deficit	(125,242)	(71,393)
Accumulated other comprehensive gain (loss)	109	(41)
Total stockholders' equity	109,764	104,204
Total liabilities and stockholders' equity	<u>\$ 121,963</u>	<u>\$ 109,939</u>

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