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): October 16, 2024

Adicet Bio, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38359**	**81-3305277**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
131 Dartmouth Street, Floor 3 Boston, Massachusetts		**02116**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (650) 503-9095

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:

☐ 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	ACET	The Nasdaq Global 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 7.01 Regulation FD Disclosure.

On October 16, 2024, Adicet Bio, Inc. (the "Company") issued a press release titled "Adicet Bio Announces FDA Clearance of IND Amendment to Evaluate ADI-001 in Idiopathic Inflammatory Myopathy and Stiff Person Syndrome," a copy of which is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01, including 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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On October 16, 2024, the Company announced that the U.S. Food and Drug Administration cleared the Company's Investigational New Drug amendment to evaluate ADI-001 in idiopathic inflammatory myopathy (IIM) and stiff person syndrome (SPS). The Company plans to initiate enrollment for IIM and SPS patients as part of the ongoing Phase 1 trial in autoimmune diseases in the first quarter of 2025. The ADI-001 Phase 1 program in autoimmune diseases will have four separate arms, enrolling lupus nephritis and systemic lupus erythematosus patients into one arm, systemic sclerosis patients into a second arm, anti-neutrophil cytoplasmic autoantibody-associated vasculitis patients into a third arm, and IIM and SPS patients into a fourth arm. The fourth cohort combines several rare autoimmune muscle diseases into a single dose-finding population, including SPS and the following IIM subtypes: dermatomyositis, anti-synthetase syndrome, immune-mediated necrotizing myopathy, polymyositis, and overlap myositis.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press release issued by Adicet Bio, Inc. on October 16, 2024, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 thereunto duly authorized.

ADICET BIO, INC.

Date:	October 16, 2024	By:	/s/ Nick Harvey
		Name:	*Nick Harvey*
		Title:	*Chief Financial Officer*

Adicet Bio Announces FDA Clearance of IND Amendment to Evaluate ADI-001 in Idiopathic Inflammatory Myopathy and Stiff Person Syndrome

ADI-001 clinical development program now addresses six autoimmune diseases

Patient enrollment for idiopathic inflammatory myopathy and stiff person syndrome cohort expected to be initiated in the first quarter of 2025

Company plans to report initial clinical data from Phase 1 study in multiple autoimmune diseases in the first half of 2025

REDWOOD CITY, Calif. & BOSTON – October 16, 2024 – Adicet Bio, Inc. (Nasdaq: ACET), a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for autoimmune diseases and cancer, today announced that the U.S. Food and Drug Administration (FDA) has agreed to an amendment to the Company's Investigational New Drug (IND) application to evaluate ADI-001 in idiopathic inflammatory myopathy (IIM) and stiff person syndrome (SPS) as part of the ongoing Phase 1 trial in autoimmune diseases. The Company plans to initiate enrollment for IIM and SPS patients in the first quarter of 2025. This announcement follows the FDA's recent agreements on amendments to the Company's ADI-001 IND application to evaluate three additional indications beyond lupus nephritis (LN), including systemic lupus erythematosus (SLE), systemic sclerosis (SSc) and anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (AAV).

"The FDA's acceptance of our IND amendment to evaluate ADI-001 in patients with IIM and SPS builds on our recent momentum in autoimmune diseases, expanding our efforts to six autoimmune indications as we aim to bring our differentiated gamma delta T cell therapy candidates to more patients in need of new treatment options," said Chen Schor, President and Chief Executive Officer at Adicet Bio. "Following our recent announcement highlighting clinical biomarker data which demonstrated robust B-cell depletion and preferential trafficking to tissues and organs, we believe in ADI-001's best-in-class potential for the treatment of autoimmune diseases, and we look forward to initiating patient enrollment in IIM and SPS in the first quarter of 2025 in our ongoing Phase 1 clinical program."

The ADI-001 Phase 1 program in autoimmune diseases will have four separate arms, enrolling LN and SLE patients into one arm, SSc patients into a second arm, AAV patients into a third arm, and IIM and SPS patients into a fourth arm. The fourth cohort combines several rare autoimmune muscle diseases into a single dose-finding population, including SPS and the following IIM subtypes: dermatomyositis, anti-synthetase syndrome, immune-mediated necrotizing myopathy, polymyositis, and overlap myositis. Enrolled patients will receive a single dose of ADI-001. The dose-limiting toxicity window is 28 days with response and safety assessments conducted on Day 28 and during the follow up period on months 3, 6, 9, 12, 18 and 24. The primary objectives of the study are to evaluate the safety and tolerability of ADI-001. Secondary objectives include measuring cellular kinetics, pharmacodynamics, changes in autoantibody titers, and appropriate disease activity scores in each indication.

About Idiopathic Inflammatory Myopathy

Idiopathic inflammatory myopathy (IIM, or myositis) refers to a group of rare autoimmune disorders characterized by chronic muscle inflammation and progressive muscle weakness. IIM primarily affects skeletal muscles but can also involve other organs such as the lungs, heart and skin. Five of the main subtypes include dermatomyositis, anti-synthetase syndrome, immune-mediated necrotizing myopathy, polymyositis, and overlap myositis, all of which can lead to significant functional impairment and have the potential to be life-threatening. There is no available cure for IIM and many patients on current treatments have refractory disease and may experience significant side effects.

About Stiff-Person Syndrome

Stiff person syndrome (SPS) is a rare neurological autoimmune disorder characterized by severe muscle stiffness and spasms, primarily affecting the torso and limbs. Muscle stiffness caused by SPS often impairs mobility, making it difficult for patients to walk, bend, or perform daily activities. Muscle spasms can be triggered by sudden stimuli such as loud noises, physical contact, or emotional distress, and can result in a "statue-like" posture when severe. Due to its rarity and overlapping symptoms with other conditions, SPS is frequently misdiagnosed, often as an anxiety disorder or movement disorder. There is currently no available cure for SPS.

About ADI-001
ADI-001 is an investigational allogeneic gamma delta chimeric antigen receptor (CAR) T cell therapy targeting CD20 for the treatment of autoimmune diseases. ADI-001 was granted Fast Track Designation by the FDA for the treatment of relapsed/refractory class III or class IV lupus nephritis (LN), and the ongoing Phase 1 study is also evaluating ADI-001 for the treatment of systemic lupus erythematosus (SLE), systemic sclerosis (SSc), anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (AAV), idiopathic inflammatory myopathy (IIM, or myositis) and stiff person syndrome (SPS). In the Phase 1 GLEAN trial, ADI-001 was shown to target B-cells via an anti-CD20 CAR and demonstrated robust exposure and complete CD19+ B cell depletion both in peripheral blood and secondary lymphoid tissue.

About Adicet Bio, Inc.
Adicet Bio, Inc. is a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for autoimmune diseases and cancer. Adicet is advancing a pipeline of “off-the-shelf” gamma delta T cells, engineered with chimeric antigen receptors (CARs), to facilitate durable activity in patients. For more information, please visit our website at https://www.adicetbio.com.

Forward-Looking Statements
This press release contains “forward-looking statements” of Adicet within the meaning of the Private Securities Litigation Reform Act of 1995 relating to the business and operations of Adicet. 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, but are not limited to, express or implied statements regarding: clinical development of Adicet’s product candidates, including future plans or expectations for ADI-001 and the potential safety, tolerability and efficacy of ADI-001 for the treatment of autoimmune diseases; the potential for ADI-001 to be a best-in-class treatment for autoimmune diseases; the clinical development of

ADI-001 in LN, SLE, SSc and AAV; and the expected progress, timing and success of the Phase 1 clinical study of ADI-001 in IIM and SPS, including timing and expectations for enrollment and future data releases.

Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements, including without limitation, the effect of global economic conditions and public health emergencies on Adicet's business and financial results, including with respect to disruptions to our preclinical and clinical studies, business operations, employee hiring and retention, and ability to raise additional capital; Adicet's ability to execute on its strategy including obtaining the requisite regulatory approvals on the expected timeline, if at all; that positive results, including interim results, from a preclinical or clinical study may not necessarily be predictive of the results of future or ongoing studies; clinical studies may fail to demonstrate adequate safety and efficacy of Adicet's product candidates, which would prevent, delay, or limit the scope of regulatory approval and commercialization; and regulatory approval processes of the U.S. Food and Drug Administration and comparable foreign regulatory authorities are lengthy, time-consuming, and inherently unpredictable; and Adicet's ability to meet production and product release expectations. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Adicet's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Adicet's most recent annual report on Form 10-Q and subsequent filings with the U.S. Securities and Exchange Commission (SEC), as well as discussions of potential risks, uncertainties, and other important factors in Adicet's other filings with the SEC. All information in this press release is as of the date of the release, and Adicet undertakes no duty to update this information unless required by law.

Adicet Bio, Inc.
Investor and Media Contacts

Investors:
Anne Bowdidge
abowdidge@adicetbio.com

Janhavi Mohite
Precision AQ
212-362-1200
janhavi.mohite@precisionaq.com

Media:
Kerry Beth Daly
kbdaly@adicetbio.com