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 18, 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 November 18, 2024, Adicet Bio, Inc. (Adicet or the Company) issued a press release titled "Adicet Opens Enrollment for ADI-270 Phase 1 Clinical Trial in Metastatic/Advanced Clear Cell Renal Cell Carcinoma," a copy of which is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

On November 18, 2024, the Company also issued a press release titled "Adicet Bio Announces First Lupus Nephritis Patient Dosed in Phase 1 Clinical Trial of ADI-001 in Autoimmune Diseases," a copy of which is furnished herewith as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Item 7.01, including Exhibit 99.1 and 99.2 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 November 18, 2024, the Company announced the opening of enrollment for the Phase 1 clinical trial evaluating ADI-270 in patients with metastatic/advanced clear cell renal cell carcinoma (ccRCC). The Company plans to report preliminary clinical data from this Phase 1 trial of ADI-270 in ccRCC in the first half of 2025.

On November 18, 2024 the Company also announced the first patient dosed in the Phase 1 clinical trial evaluating ADI-001 in lupus nephritis.

Forward-Looking Statements

The disclosure under this Item 8.01 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 Adicet's expectations for its Phase 1 trial of ADI-270 in ccRCC, including plans to report preliminary clinical data in the first half of 2025.

Any forward-looking statements in this Item 8.01 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 crises on the Company's business and financial results, including with respect to disruptions to its 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; that 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 titled "Risk Factors" in Adicet's most recent Quarterly 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 disclosure under this Item 8.01 is as of the date of this Form 8-K, and Adicet undertakes no duty to update this information unless required by law.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press release issued by Adicet Bio, Inc. on November 18, 2024, furnished herewith.
99.2	Press release issued by Adicet Bio, Inc. on November 18, 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 hereunto duly authorized.

ADICET BIO, INC.

Date: November 18, 2024

By: /s/ Nick Harvey
Name: Nick Harvey
Title: Chief Financial Officer

Adicet Opens Enrollment for ADI-270 Phase 1 Clinical Trial in Metastatic/Advanced Clear Cell Renal Cell Carcinoma

First gamma delta CAR T cell therapy with the potential to address solid tumors entering clinical trials

Preliminary Phase 1 clinical data expected in the first half of 2025

REDWOOD CITY, Calif. & BOSTON – November 18, 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 the opening of enrollment for the Phase 1 clinical trial evaluating ADI-270 in patients with metastatic/advanced clear cell renal cell carcinoma (ccRCC).

“Solid tumors represent one of the highest unmet medical needs in oncology and have yet to benefit from the breakthroughs observed with CAR T cell therapies in hematologic malignancies. Emerging data from ADI-270, our armored allogeneic “off the shelf” gamma delta 1 CAR T cell therapy targeting CD70 positive cancers, have shown potential in addressing this gap,” said Chen Schor, President and Chief Executive Officer. “At the recent ASGCT conference, we presented preclinical data in which ADI-270 demonstrated significant tumor infiltration, resistance to the immunosuppressive tumor microenvironment, and potent activity via CAR and innate-mediated targeting, highlighting its potential for treating solid tumors. We look forward to enrolling patients and anticipate sharing preliminary clinical data from the trial in the first half of 2025.”

About the Phase 1 Trial
The Phase 1 multicenter, open-label clinical trial is designed to investigate ADI-270 as monotherapy in adults with relapsed or refractory ccRCC. Following lymphodepletion, patients will be eligible to receive a single dose of ADI-270 with a starting dose level of 3E8 CAR+ cells. Subject to meeting protocol defined criteria, patients enrolled in the trial may be eligible to receive a second dose of ADI-270. The dose escalation and dose expansion portions of the trial will evaluate safety, tolerability, and pharmacokinetics as well as anti-tumor activity as assessed by overall response rate, duration of response and disease control rate.

About ADI-270
ADI-270 is an armored allogeneic “off-the-shelf” gamma delta CAR T cell therapy candidate targeting CD70-positive cancers. CD70 is a compelling target due to its high

expression in both solid and hematological malignancies. ADI-270 is engineered with a third-generation CAR designed to target CD70 using its natural receptor, CD27, as the binding moiety and is further armored with a dominant negative form of the transforming growth factor-β receptor II (dnTGFβRII) to provide functional resilience to the immunosuppressive tumor microenvironment. ADI-270 is also designed to increase exposure and persistence by reducing susceptibility to host vs. graft elimination. These properties of ADI-270 combined with the potent tumor infiltration demonstrated with gamma delta 1 T cells aim to improve clinical responses of RCC patients and other patients with CD70+ tumors.

About Renal Cell Carcinoma
Renal cell carcinoma (RCC) is the most common tumor of the kidney, constituting 80% to 85% of primary renal neoplasms. Clear cell RCCs (ccRCC) are the most common subtype, accounting for 80% of all RCCs. ccRCC is an aggressive subtype arising from renal stem cells commonly arising in the proximal nephron and tubular epithelium, and often metastasizes to the lungs, liver, and bones. Approximately 20% of newly diagnosed cases of RCC are locally advanced or metastatic and up to 30% of patients will develop metastatic disease following nephrectomy. While the 5-year survival rate for localized RCC is 93%, the 5-year survival rate for advanced disease is 15%.

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-270; the potential safety, durability, tolerability and activity of ADI-270; the expected progress, timing and success of the Phase 1 clinical trial of ADI-270 in ccRCC, including expectations for enrollment and plans to report preliminary clinical data in the first half of 2025, and the potential of ADI-270 to become a treatment for solid tumors and ccRCC.

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 geopolitical conflicts and economic conditions on Adicet’s

business and financial results, including with respect to disruptions to Adicet's 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 FDA 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-K and periodic and current reports on Form 10-Q and Form 8-K filed 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.

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Adicet Bio Announces First Lupus Nephritis Patient Dosed in Phase 1 Clinical Trial of ADI-001 in Autoimmune Diseases

Enrollment underway for lupus nephritis (LN) patients

Preliminary clinical data in LN anticipated in 1H25

Initiation of patient enrollment in systemic lupus erythematosus (SLE), systemic sclerosis (SSc), idiopathic inflammatory myopathy (IIM) and stiff person syndrome (SPS) expected in 1Q25; patient enrollment in anti-neutrophil cytoplasmic autoantibody (ANCA) associated vasculitis (AAV) expected in 2H25

REDWOOD CITY, Calif. & BOSTON – November 18, 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 first LN patient has been dosed in the Phase 1 clinical trial evaluating ADI-001 in autoimmune diseases.

“Dosing the first lupus nephritis patient in our Phase 1 trial of ADI-001 marks an important step forward in our mission of improving the lives of patients affected by autoimmune diseases, particularly lupus nephritis,” said Francesco Galimi, M.D., Ph.D., Senior Vice President and Chief Medical Officer of Adicet Bio. “With clinical biomarker data from our study in non-Hodgkin’s lymphoma demonstrating robust tissue trafficking and complete CD19+ B cell depletion in peripheral blood and secondary lymphoid tissue, ADI-001 has the potential to be a transformative off-the-shelf treatment option for several autoimmune diseases. Additionally, the FDA’s Fast Track Designation to ADI-001 in relapsed/refractory class III or class IV LN and the clearance of our investigational IND amendment application of ADI-001 for the treatment of SPS and IIM further serves to emphasize the broad and urgent unmet need for approved therapies to address autoimmune diseases.”

Dr. Galimi continued, “With clinical sites open for enrollment and additional sites that are expected to open in the near future, we anticipate sharing preliminary clinical data from the trial in the first half of 2025. In addition, we look forward to initiating enrollment for SLE, SSc, IIM, and SPS patients in the first quarter of 2025 and for AAV patients in the second half of 2025."

About ADI-001
ADI-001 is an investigational allogeneic gamma delta CAR T cell therapy targeting B-cells via an anti-CD20 CAR. ADI-001 was granted Fast Track Designation by the FDA for the potential treatment of relapsed/refractory class III or class IV lupus nephritis.

About the Phase 1 Trial

The Phase 1 study has four separate arms, enrolling LN and SLE patients into one arm, SSc patients into a second arm, IIM and SPS patients in a third arm and AAV patients into a fourth arm. 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.

For more information about becoming a study site, please email clinicaltrials@adicetbio.com or visit https://www.adicetbio.com/hcp/autoimmune/.

About Adicet Bio, Inc.
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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.

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