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): September 19, 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 September 19, 2024, Adicet Bio, Inc. (Adicet or the Company) issued a press release titled "ADI-001 Clinical Biomarker Data Demonstrate Robust Tissue Trafficking and Complete B Cell Depletion in Secondary Lymphoid Tissue," 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 September 19, 2024, the Company announced ADI-001 clinical biomarker data from the Phase 1 GLEAN trial. Notably, ADI-001 demonstrated robust tissue trafficking resulting in high levels of ADI-001, significant chimeric antigen receptor (CAR) T cell activation, and complete CD19+ B cell depletion in secondary lymphoid tissue. A summary of the results is as follows:

- ADI-001 demonstrated significant levels of CAR T cell activation and tissue exposure in lymph node biopsies in the GLEAN trial, with a mean exposure of 236,701 CAR T cells per million across all dose levels, representing a range of 27-64% of total cellular material detected by ddPCR in evaluable biopsies at the 1E9 dose, and exceeding levels previously reported for patients who received autologous alpha-beta CAR T therapies. CAR T cells detected in tissues also demonstrated a robust activation profile, based on situ detection of granzyme B.
- Recent studies have demonstrated depletion of CD19+ plasmablasts, memory B cells and naïve B cells in peripheral blood using anti-CD20 targeted antibodies, however, these CD20-targeted antibody modalities failed to deplete B cells within secondary lymphoid tissues.
- Concurrent with ADI-001 tissue trafficking and activation, complete depletion of CD19+ B cells within analyzed secondary lymphoid tissue was also observed. These results support ADI-001's potential for achieving complete B-cell depletion in peripheral blood and within tissues.

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 the potential safety, tolerability and efficacy of ADI-001 multiple autoimmune indications; the potential for ADI-001 to achieve complete B-cell depletion in peripheral blood and within tissues and differentiation from existing therapies.

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 September 19, 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: September 19, 2024

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

ADI-001 Clinical Biomarker Data Demonstrate Robust Tissue Trafficking and Complete B Cell Depletion in Secondary Lymphoid Tissue

-Results highlight ADI-001's potential as a best-in-class allogeneic cell therapy for autoimmune disease-

-Webcast featuring Dr. Blake Aftab with accompanying presentation available on Company website-

REDWOOD CITY, Calif. & BOSTON – September 19, 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 ADI-001 clinical biomarker data from the Phase 1 GLEAN trial which further reinforces the potential of ADI-001 as a best-in-class allogeneic cell therapy for autoimmune diseases. Notably, ADI-001 demonstrated robust tissue trafficking resulting in high levels of ADI-001, significant chimeric antigen receptor (CAR) T cell activation, and complete CD19+ B cell depletion in secondary lymphoid tissue. These data will be presented by Dr. Blake Aftab, Chief Scientific Officer, at the 9th Annual CAR-TCR Summit on Thursday, September 19, 2024 in Boston, MA.

“These results clearly support the potential of ADI-001 and Adicet’s off-the-shelf gamma delta CAR T cell platform, by demonstrating robust trafficking and complete B cell depletion in tissue, while providing superior exposure of ADI-001 in secondary lymphoid tissue compared to published third-party data reported for alpha-beta CAR T therapies,” said Blake Aftab, Ph.D., Chief Scientific Officer of Adicet Bio. “Together, the totality of our findings provide multiple levels of evidence highlighting the significant advantages of our approach and present a compelling opportunity for ADI-001 to extend B cell targeting into tissues, as we look to address a range of autoimmune diseases in the clinic.”

A summary of the results is reported below:

- ADI-001 demonstrated significant levels of CAR T cell activation and tissue exposure in lymph node biopsies in the GLEAN trial, with a mean exposure of 236,701 CAR T cells per million across all dose levels, representing a range of 27-64% of total cellular material detected by ddPCR in evaluable biopsies at the 1E9 dose, and exceeding levels previously reported for patients who received autologous alpha-beta CAR T therapies. CAR T cells detected in tissues also demonstrated a robust activation profile, based on in situ detection of granzyme B.

- Recently published studies have demonstrated depletion of CD19+ plasmablasts, memory B cells and naïve B cells in peripheral blood using anti-CD20 targeted antibodies, however, these CD20-targeted antibody modalities failed to deplete B cells within secondary lymphoid tissues.
- Concurrent with ADI-001 tissue trafficking and activation, complete depletion of CD19+ B cells within analyzed secondary lymphoid tissue was also observed. These results support ADI-001's potential for achieving complete B-cell depletion in peripheral blood and within tissues.

Adicet is advancing the ADI-001 clinical program in lupus nephritis, systemic lupus erythematosus, systemic sclerosis and anti-neutrophil cytoplasmic autoantibody associated vasculitis (AAV) and expects to report initial clinical data in the first half of 2025.

Company webcast information
A listen-only webcast with an accompanying presentation by Dr. Aftab is accessible under Presentations & Events | Adicet Bio in the Investors section of Adicet Bio's website. The archived webcast will be available for 30 days.

About the GLEAN trial
The Phase 1 GLEAN study was an open-label, multi-center study of ADI-001 enrolling adults diagnosed with B-cell malignancies who have either relapsed, or are refractory to, at least two prior regimens.

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 the potential safety, tolerability and efficacy of ADI-001 multiple autoimmune indications; the potential for ADI-001 to be best-in-class allogenic cell therapy for autoimmune diseases and differentiation from existing therapies; the clinical development of ADI-001 in lupus nephritis, systemic lupus erythematosus, systemic sclerosis and anti-neutrophil cytoplasmic autoantibody associated vasculitis; and the

planned announcement of initial clinical data from ADI-001 in four autoimmune indications in the first half of 2025. 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 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 press release is as of the date of this press release, and Adicet undertakes no duty to update this information unless required by law

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