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): August 13, 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 2.02 Results of Operations and Financial Condition.

On August 13, 2024, Adicet Bio, Inc. announced its financial results for the quarter ended June 30, 2024. 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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release of Adicet Bio, Inc. dated August 13, 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: August 13, 2024

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

Adicet Reports Second Quarter 2024 Financial Results and Provides Business Updates

ADI-001 autoimmune clinical development expanded beyond lupus nephritis (LN) to include systemic lupus erythematosus (SLE), systemic sclerosis (SSc) and anti-neutrophil cytoplasmic autoantibody (ANCA) associated vasculitis (AAV), following recent U.S. Food and Drug Administration (FDA) Investigational New Drug (IND) clearances

IND clearance for ADI-270 for the treatment of patients with relapsed/refractory renal cell carcinoma (RCC)

FDA Fast Track Designation granted for two product candidates

Strong balance sheet with $224.1 million in cash and cash equivalents as of June 30, 2024

REDWOOD CITY, Calif. & BOSTON – August 13, 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 reported financial results and operational highlights for the second quarter ended June 30, 2024.

“We believe ADI-001 has best-in-class potential for autoimmune diseases and we are excited about the opportunity to expand ADI-001 clinical development beyond LN to include patients with SLE, SSc and AAV. We have initiated startup activities at multiple clinical sites and expect to begin enrolling patients with LN in our Phase 1 study in the third quarter of 2024,” said Chen Schor, President and Chief Executive Officer at Adicet Bio. “Looking ahead, with the ADI-270 IND cleared for RCC, and Fast Track Designation in hand, we expect to initiate the Phase 1 trial of ADI-270 in patients with RCC, the most common type of kidney cancer, in the fourth quarter of 2024. This progress underscores the unique potential of our gamma delta 1 CAR T cell platform in both autoimmune diseases and solid tumors.”

Second Quarter 2024 and Recent Operational Highlights:

Autoimmune diseases

- ***Fast Track Designation for ADI-001 in relapsed/refractory class III or class IV LN.*** In June 2024, the FDA granted ADI-001 Fast Track Designation for the potential treatment of relapsed/refractory class III or class IV LN. The Company has initiated startup activities at multiple clinical sites and plans to commence

enrollment in its Phase 1 clinical trial of ADI-001 in lupus nephritis in the third quarter of 2024, with preliminary clinical data expected in the first half of 2025, subject to site initiation and patient enrollment.

- ***Expansion of clinical development of ADI-001 beyond LN to include SLE, SSc and AAV.*** The Company recently received clearance for its IND to include three additional indications: SLE, SSc and AAV. In connection with the Company's Phase 1 clinical trial of ADI-001 in autoimmune disease, enrollment of SLE, SSc and AAV patients is expected to commence in the second half of 2024. Clinical data from the Company's Phase 1 clinical trial of ADI-001 in SLE, SSc and AAV patients are anticipated during the first half of 2025, subject to site initiation and patient enrollment expectations.

Hematologic malignancies and solid tumor indications

- ***IND clearance and FDA Fast Track Designation for ADI-270.*** Adicet received FDA clearance of its IND application for ADI-270 in RCC and the FDA also granted Fast Track Designation for ADI-270 for the potential treatment of patients with metastatic/advanced clear cell RCC who have been treated with an immune checkpoint inhibitor and a vascular endothelial growth factor inhibitor. Contingent upon study initiation progress, the Company intends to initiate the Phase 1 clinical trial of ADI-270 in RCC patients in the fourth quarter of 2024 and present preliminary clinical data from the study in the first half of 2025, subject to site initiation and patient enrollment.

- ***Presentation of preclinical data from ADI-270 at the 2024 European Hematology Association (EHA) Hybrid Congress.*** In June 2024, Adicet presented promising preclinical data supporting ADI-270's robust anti-tumor activity in an encore poster presentation at the EHA Hybrid Congress.

- ***Enrollment of mantle cell lymphoma (MCL) patients ongoing in ADI-001 Phase 1 GLEAN study.*** Adicet is continuing to enroll MCL patients in the Phase 1 trial evaluating ADI-001 in relapsed or refractory non-Hodgkin's Lymphoma. The Company plans to provide a clinical update in the fourth quarter of 2024.

Financial Results for Second Quarter 2024:

- **Research and Development (R&D) Expenses:** R&D expenses were $25.9 million for the three months ended June 30, 2024, compared to $28.4 million during the same period in 2023. The decrease in research and development expenses was primarily due to a net $1.9 million decrease in expenses related to contract development and manufacturing organization and other externally

conducted research and development as well as a $0.6 million decrease in payroll and personnel expenses resulting from a decrease in overall headcount.

- **General and Administrative (G&A) Expenses:** G&A expenses were $6.9 million for the three months ended June 30, 2024, compared to $6.5 million during the same period in 2023. The increase in general and administrative expenses was primarily due to an increase in stock-based compensation of $0.7 million. The increase was partially offset by a $0.2 million decrease in recruiting fees as well as a $0.1 million decrease in consultant fees.

- **Net Loss:** Net loss for the three months ended June 30, 2024 was $29.9 million, or a net loss of $0.33 per basic and diluted share, including non-cash stock-based compensation expense of $6.0 million, as compared to a net loss of $32.4 million, or a net loss of $0.75 per basic and diluted share, including non-cash stock-based compensation expense of $5.0 million during the same period in 2023.

- **Cash Position:** Cash and cash equivalents were $224.1 million as of June 30, 2024, compared to $159.7 million as of December 31, 2023. The Company expects that current cash and cash equivalents as of June 30, 2024, will be sufficient to fund its operating expenses into the second half of 2026.

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: preclinical and clinical development of Adicet’s product candidates, including future plans or expectations for ADI-001 and ADI-270, including the potential safety, durability, tolerability and efficacy of these product candidates as well as their potential promising profiles; the potential for ADI-001 to be best-in-class for autoimmune diseases; the progress, timing and success of the Company’s ongoing and planned Phase 1 clinical trials of ADI-001 in autoimmune diseases and cancer, including expectations for site activation, enrollment and data readouts; the Company’s clinical trial of ADI-270 in metastatic/advanced ccRCC, including expectations for site

enrollment and data readouts; and expectations regarding the Company's uses of capital, expenses and financial results, including the expected cash runway.

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 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 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 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, INC.
Consolidated Statements of Operations Information
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	25,901	28,362	49,797	55,118
General and administrative	6,948	6,528	13,922	13,093
Total operating expenses	32,849	34,890	63,719	68,211
Loss from operations	(32,849)	(34,890)	(63,719)	(68,211)
Interest income	2,999	2,615	5,917	5,279
Interest expense	—	(4)	(2)	(23)
Other expense, net	(51)	(124)	(113)	(329)
Loss before income tax provision	(29,901)	(32,403)	(57,917)	(63,284)
Income tax provision	—	—	—	—
Net loss	$ (29,901)	$ (32,403)	$ (57,917)	$ (63,284)
Net loss per share, basic and diluted	$ (0.33)	$ (0.75)	$ (0.68)	$ (1.47)
Weighted-average common shares used in computing net loss per share, basic and diluted	90,632,045	42,957,035	84,848,146	42,957,242

ADICET BIO, INC.
Consolidated Balance Sheets Information
(in thousands)
(Unaudited)

	June 30,	December 31,
	2024	2023
Cash and cash equivalents	$ 224,069	$ 159,711
Working capital	210,449	142,985
Total assets	268,842	207,295
Accumulated deficit	(438,689)	(380,772)
Total stockholders' equity	235,111	170,175