
**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): March 19, 2024

Adicet Bio, 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.)

131 Dartmouth Street, Floor 3
Boston, Massachusetts
(Address of Principal Executive Offices)

02116
(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 March 19, 2024, Adicet Bio, Inc. announced its financial results for the quarter and year ended December 31, 2023. 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

Exhibit No.	Description
99.1	Press Release of Adicet Bio, Inc. dated March 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 hereunto duly authorized.

ADICET BIO, INC.

Date: March 19, 2024

By: /s/ Nick Harvey

Name: *Nick Harvey*

Title: *Chief Financial Officer*



Adicet Reports Fourth Quarter and Full Year 2023 Financial Results and Highlights Recent Company Progress

Expanded clinical pipeline into autoimmune diseases with U.S. Food and Drug Administration (FDA) clearance of Investigational New Drug Application (IND) for ADI-001; initiation of Phase 1 clinical trial in lupus nephritis expected in 2Q 2024

On track to file IND for ADI-270 in renal cell carcinoma in 2Q 2024

Extended projected cash runway into 2H 2026

REDWOOD CITY, Calif. & BOSTON – March 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 reported financial results and operational highlights for the fourth quarter and year ended December 31, 2023.

“We are excited to explore the potential of our gamma delta T cell platform in autoimmune diseases following the FDA’s IND clearance of ADI-001 in lupus nephritis,” said Chen Schor, President and Chief Executive Officer at Adicet Bio. “We believe ADI-001 is ideally suited for the treatment of autoimmune diseases given its robust B-cell depletion consistent with other autologous CAR T therapies tested in autoimmune diseases, its tissue tropism potential in autoimmune diseases, and the safety and efficacy data observed in our Phase 1 study. In addition, ADI-001’s off-the-shelf availability and safety profile has the potential to make cell therapy for autoimmune diseases available to patients in community setting. We look forward to initiating the Phase 1 study in lupus nephritis in the second quarter of 2024 and are on track to expand the program to additional autoimmune indications.”

Mr. Schor continued: “In addition, we are continuing to enroll MCL patients in our ongoing Phase 1 study of ADI-001 in relapsed or refractory non-Hodgkin’s lymphoma. With the completion of the successful capital raise and other net proceeds from stock sales under the at-the-market program in January, extending our cash runway into the second half of 2026, we are well-positioned to continue clinical execution across our pipeline through multiple upcoming milestones.”

Fourth Quarter 2023 and Recent Operational Highlights:

Autoimmune diseases

- **IND clearance for ADI-001 in lupus nephritis.** In December 2023, the FDA cleared the Company's IND application for ADI-001 in lupus nephritis. Adicet plans to initiate a Phase 1 study to evaluate the safety and efficacy of ADI-001 in lupus nephritis during the second quarter of 2024. Preliminary clinical data from the trial are expected in the fourth quarter of 2024 or first quarter of 2025, pending study site activation progression and patient enrollment.
- **Expansion of ADI-001 development in autoimmune diseases.** Adicet expects to expand into additional autoimmune indications in the near future. The Company anticipates providing preliminary clinical data in the fourth quarter of 2024 or first half of 2025, subject to clearance of INDs in those indications as well as successful site initiation and patient enrollment in the relevant clinical protocols.

Hematologic malignancies and solid tumor indications

- **Continuing to advance ADI-001 in Phase 1 GLEAN study in mantle cell lymphoma (MCL).** The Phase 1 study of ADI-001 in relapsed or refractory non-Hodgkin's Lymphoma (NHL) is ongoing, with enrollment focused on the MCL patient population, which demonstrated the greatest clinical benefit in the June 2023 clinical update. Adicet expects to provide a clinical update on safety, efficacy and 6-month complete response data in MCL patients in the second half of 2024.
 - **Advancing ADI-270 preclinical development in solid tumors.** ADI-270 is designed to home to solid tumors, with a highly specific targeting moiety for CD70 and an armoring technology of dominant negative TGF beta receptor to address immunosuppressive factors in the tumor microenvironment. Adicet remains on track to file an IND for ADI-270 in renal cell carcinoma in the second quarter of 2024 and expects to provide clinical data from a Phase 1 study in the first half of 2025, following regulatory clearance and subject to study initiation progress.
 - **Presented persistence and pharmacodynamic data from ADI-001 Phase 1 study at the 65th American Society of Hematology (ASH) Annual Meeting.** In December 2023, Adicet presented new pharmacokinetic and pharmacodynamic data from the Phase 1 study of ADI-001 at the ASH Annual Meeting. The data demonstrated robust dose-dependent expansion and persistence in patients with relapsed or refractory aggressive B-cell NHL. ADI-001's strong exposure and persistence profile observed in the study to date further validates Adicet's gamma delta T cell technology.
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Corporate updates

- **Hired Benjamin Hsu, M.D., Ph.D., as Vice President Clinical Development - Autoimmune.** In March 2024, Adicet appointed Dr. Benjamin Hsu, M.D., Ph.D., as Vice President Clinical Development. Dr. Hsu brings over 20 years of experience in the biotech and pharmaceutical industry with extensive expertise in immunology and rheumatology clinical development. Dr. Hsu will lead the clinical design and execution of the clinical development plan for Adicet's gamma delta T cell therapies for autoimmune diseases.
- **Extended projected cash runway into 2H 2026.** In January 2024, Adicet successfully raised \$91.8 million in net proceeds through an underwritten public offering and received \$19.3 million in net proceeds under its at-the-market (ATM) program.

Financial Results for Fourth Quarter and Full Year 2023:

Three months Ended December 31, 2023

- **Research and Development (R&D) Expenses:** R&D expenses were \$24.8 million for the three months ended December 31, 2023, compared to \$25.0 million during the same period in 2022. The \$0.2 million decrease was primarily driven by a \$2.7 million decrease in expenses related to contract development manufacturing organizations (CDMOs), contract research organizations (CROs) and consultant costs related to our lead product candidate ADI-001. This decrease was partially offset by an increase of \$1.3 million in payroll and personnel expenses, an increase of \$0.7 million in lab expenses and an increase of \$0.6 million in facility and other expenses.
- **General and Administrative (G&A) Expenses:** G&A expenses were \$6.8 million for the three months ended December 31, 2023, compared to \$6.6 million during the same period in 2022. The \$0.2 million increase was primarily driven by an increase of \$0.9 million in payroll and personnel expenses. This increase was partially offset by a \$0.4 million decrease in professional fees and a \$0.4 million decrease in facility and other expenses.
- **Net Loss:** Net loss for the three months ended December 31, 2023 was \$29.5 million, or a net loss of \$0.69 per basic and diluted share, including non-cash stock-based compensation expense of \$4.9 million, as compared to a net loss of \$29.9 million, or a net loss of \$0.72 per basic and diluted share, including non-cash stock-based compensation expense of \$4.3 million during the same period in 2022.

Twelve Months Ended December 31, 2023

- **Research and Development (R&D) Expenses:** R&D expenses were \$106.0 million for the year ended December 31, 2023, compared to \$71.2 million for the year ended December 31, 2022. The \$34.8 million increase was primarily driven by an \$11.5 million increase in payroll and personnel expenses resulting from an increase in overall headcount, a net \$10.7 million increase in expenses related to CDMOs, CROs and consultant costs related to our lead product candidate ADI-001, a \$8.5 million increase in facility and other expenses and a \$4.1 million increase in lab expenses.
- **General and Administrative (G&A) Expenses:** G&A expenses were \$26.5 million for the year ended December 31, 2023, compared to \$26.3 million for the year ended December 31, 2022. The \$0.2 million increase was primarily driven by a \$3.3 million increase in payroll and personnel expenses, which includes an increase in stock-based compensation of \$1.2 million, salaries and benefits of \$1.0 million and contractor fees of \$0.9 million and an increase in recruiting fees of \$0.3 million. These increases were primarily due to increased headcount for the period. The overall increase was partially offset by a \$2.6 million decrease in facilities and other related expenses.
- **Goodwill Impairment:** Goodwill was impaired by \$19.5 million during the year ended December 31, 2023 following the results of an interim impairment test conducted during the period. This represented the entire remaining balance of goodwill.
- **Net Loss:** Net loss for the year ended December 31, 2023 was \$142.7 million, or a net loss of \$3.31 per basic and diluted share, including non-cash stock-based compensation expense of \$20.3 million, as compared to a net loss of \$69.8 million, or a net loss of \$1.70 per basic and diluted share, including non-cash stock-based compensation expense of \$17.1 million during the same period in 2022.
- **Cash Position:** Cash and cash equivalents were \$159.7 million as of December 31, 2023, compared to \$257.7 million as of December 31, 2022. Subsequent to December 31, 2023, the Company received \$91.8 million of net proceeds from an underwritten public offering and \$19.3 million of net proceeds under its ATM program. The Company expects that its cash and cash equivalents as of December 31, 2023, together with the proceeds raised subsequent to year end, 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 submission or timing of clearance of INDs in autoimmune diseases, and the potential safety, durability, tolerability and efficacy of these product candidates; 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 plan to expand into other autoimmune indications in the future; the Company's expectations regarding regulatory filings and clearances, including the submission of an IND for ADI-270 in renal cell carcinoma in the second quarter of 2024; 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 annual report on Form 10-K and our periodic 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, INC.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Revenue—related party	\$ —	\$ —	\$ —	\$ 24,990
Operating expenses:				
Research and development	24,759	25,015	106,043	71,246
General and administrative	6,807	6,550	26,533	26,295
Goodwill impairment	—	—	19,462	—
Total operating expenses	<u>31,566</u>	<u>31,565</u>	<u>152,038</u>	<u>97,541</u>
Loss from operations	(31,566)	(31,565)	(152,038)	(72,551)
Interest income	2178	2,179	9,978	3,760
Interest expense	—	(26)	(25)	(80)
Other expense, net	(101)	(463)	(573)	(919)
Loss before income tax provision	<u>(29,489)</u>	<u>(29,875)</u>	<u>(142,658)</u>	<u>(69,790)</u>
Income tax provision	—	—	—	—
Net loss	<u>\$ (29,489)</u>	<u>\$ (29,875)</u>	<u>\$ (142,658)</u>	<u>\$ (69,790)</u>
Net loss per share, basic and diluted	<u>\$ (0.69)</u>	<u>\$ (0.72)</u>	<u>\$ (3.31)</u>	<u>\$ (1.70)</u>
Weighted-average common shares used in computing net loss per share, basic and diluted	<u>43,035,315</u>	<u>41,651,298</u>	<u>43,042,405</u>	<u>41,080,286</u>

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

	<u>December 31,</u>	<u>December 31,</u>
	<u>2023</u>	<u>2022</u>
Cash and cash equivalents	\$ 159,711	\$ 257,656
Working capital	142,985	241,331
Total assets	207,295	330,690
Accumulated deficit	(380,772)	(238,114)
Total stockholders' equity	170,175	292,338

