

**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 08, 2023

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.)

200 Berkeley Street, 19th Floor
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 November 8, 2023, Adicet Bio, Inc. announced its financial results for the quarter ended September 30, 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, 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.	<u>Description</u>
99.1	Press Release of Adicet Bio, Inc. dated November 8, 2023, 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 8, 2023

By: /s/ Nick Harvey

Name: *Nick Harvey*

Title: *Chief Financial Officer*



Adicet Reports Third Quarter 2023 Financial Results and Provides Business Updates

Initiated ADI-001 Phase 1 EXPAND cohort in post chimeric antigen receptor (CAR) T large B cell lymphoma (LBCL)

Continuing to enroll mantle cell lymphoma (MCL) patients in ADI-001 Phase 1 study

Prioritizing ADI-270 for solid tumor applications; on track to file ADI-270 Investigational New Drug Application (IND) in 1H 2024

REDWOOD CITY, Calif. & BOSTON – November 8, 2023 – Adicet Bio, Inc. (Nasdaq: ACET), a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for cancer, today reported financial results and operational highlights for the third quarter ended September 30, 2023.

“Clinical and translational medicine data for our lead asset ADI-001 in NHL has provided us with valuable insights, which has guided us as we initiated the EXPAND cohort in post CAR T LBCL and continue to enroll MCL patients to the clinical study. For patients with these advanced cancers, the prognosis remains poor and patients are in need of new, more effective and better tolerated therapies,” said Chen Schor, President and Chief Executive Officer at Adicet Bio.

“In addition, over the past several months, we have conducted a strategic review of our pipeline to focus our resources on programs with the greatest potential for differentiation and long-term value creation,” Mr. Schor added. “On the preclinical front, we are prioritizing the development of ADI-270 as our lead preclinical candidate in renal cell carcinoma and other solid tumor indications. ADI-270 has demonstrated a highly differentiated profile stemming from its unique engineering, including targeting via a CAR that incorporates CD27, addition of dominant negative TGF beta receptor armoring, complimentary innate anti-tumor activity of the gamma delta 1 T cells and tissue tropism to solid tumors. We remain on track to file an IND for ADI-270 in the first half of 2024. With a focused organization and clear priority for advancing a pipeline with the highest probability of success, we believe we are well positioned for long-term success as leaders in the allogeneic T cell therapy field.”

Recent Operational Highlights:

- **Advanced ADI-001 Development.** The Company is advancing the development of ADI-001, the Company's investigational therapy targeting CD20 for the potential treatment of relapsed or refractory B-cell non-Hodgkin's lymphoma
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(NHL). In November, Adicet initiated an expansion cohort (EXPAND) to evaluate ADI-001 in patients with post CAR T LBCL and continues to enroll MCL patients in the Company's ongoing Phase 1 study of ADI-001. Recently, the Company expanded manufacturing capabilities of ADI-001 by transferring the manufacturing process to an additional contract development and manufacturing organization (CDMO) that is capable of operating at a larger scale of production. Subject to data readouts and regulatory feedback, the Company will evaluate options to advance ADI-001 into a potentially pivotal single arm Phase 2 study in post CAR T LBCL and/or MCL patients under an accelerated approval pathway. Adicet continues to expect that it will provide a clinical update from the Phase 1 study in NHL patients in the second half of 2024.

- **Prioritized ADI-270 Development for Solid Tumors.** Adicet has reprioritized its preclinical pipeline to focus on the development of ADI-270 as its lead preclinical candidate for renal cell carcinoma, with potential in other solid tumor indications. The Company has completed a pre-IND meeting for ADI-270 with the U.S. Food and Drug Administration and received positive feedback to support an IND filing in the first half of 2024. 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. The Company expects to file an IND application for ADI-270 in the first half of 2024. Adicet has paused preclinical development of ADI-925 to prioritize corporate resources on IND-enabling activities for ADI-270.
- ***Presented new preclinical data at the International Conference on Molecular Targets and Cancer Therapeutics.*** In October 2023, Adicet presented new preclinical data building on the potential of Adicet's allogeneic gamma delta platform as a promising approach to target prostate cancer. Details of Adicet's lead optimization process and differentiated prostate specific membrane antigen (PSMA) binding moiety were presented at the conference. Data demonstrated intrinsic targeting of patient-derived tumors by gamma delta T cells. Additionally, Adicet's novel mode of targeting PSMA demonstrated selective binding to conformational epitopes and superior function compared to clinically relevant benchmarks.
- ***Presented three posters at the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting.*** Earlier in November, Adicet presented three poster presentations highlighting the therapeutic value of its broad pipeline of CAR gamma delta T cell product candidates, including ADI-001, at SITC.

Financial Results for Third Quarter 2023:

- **Research and Development (R&D) Expenses:** R&D expenses were \$26.2 million for the three months ended September 30, 2023, compared to \$16.6
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million during the same period in 2022. The \$9.6 million increase is primarily driven by a \$4.8 million increase in expenses related to CDMOs and other externally conducted research and development as well as a \$2.4 million increase in payroll and personnel expenses resulting from an increase in overall headcount. There was also a \$2.0 million increase in allocated facility expenses and a \$0.4 million increase in lab expenses.

- **General and Administrative (G&A) Expenses:** G&A expenses were \$6.6 million for the three months ended September 30, 2023, compared to \$6.4 million during the same period in 2022. The \$0.2 million increase is primarily driven by an increase in stock-based compensation of \$0.6 million and an increase in contractor fees of \$0.2 million. The increase was partially offset by a \$0.4 million decrease in allocated facility and other costs.
- **Goodwill Impairment:** Goodwill was impaired by \$19.5 million during the three months ended September 30, 2023 following the results of an impairment test conducted during the period. This represented the entire remaining balance of goodwill.
- **Net Loss:** Net loss for the three months ended September 30, 2023 was \$49.9 million, or a net loss of \$1.16 per basic and diluted share, including non-cash goodwill impairment expense of \$19.5 million and non-cash stock-based compensation expense of \$5.6 million. Net loss was \$22.0 million during the same period in 2022, or a net loss of \$0.53 per basic and diluted share, including non-cash stock-based compensation expense of \$4.2 million.
- **Cash Position:** Cash and cash equivalents were \$183.3 million as of September 30, 2023, compared to \$257.7 million as of December 31, 2022. The Company expects that current cash and cash equivalents as of September 30, 2023, will be sufficient to fund its operating expenses into the first half of 2025.

About Adicet Bio, Inc.

Adicet Bio, Inc. is a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for cancer. Adicet is advancing a pipeline of "off-the-shelf" gamma delta T cells, engineered with chimeric antigen receptors (CARs) to enhance selective tumor targeting and facilitate innate and adaptive anti-tumor immune response for 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 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, ADI-270 and Adicet's preclinical development pipeline; the potential safety, durability, tolerability and efficacy of ADI-001 and Adicet's other product candidates; the expected progress, timing and success of the Phase 1 study of ADI-001 in relapsed/refractory NHL patients, including expectations around a clinical update in the second half of 2024; the expectations regarding the submission of an IND for ADI-270 in the first half of 2024; the plan to transition ADI-001 into a potentially pivotal Phase 2 study, subject to data readouts and regulatory feedback; the expected timing of additional data in post-CAR T LBCL and MCL patients in the second half of 2024; expectations for Adicet's additional CDMO and its production capabilities; and Adicet's growth as a company, the contributions of its directors and executive officers, and expectations regarding its 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 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 and Comprehensive Income (Loss)
(in thousands, except share and per share amounts)
(Unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	2023	2022	2023	2022
Revenue—related party	\$ —	\$ —	\$ —	\$ 24,990
Operating expenses:				
Research and development	26,167	16,570	81,284	46,231
General and administrative	6,633	6,415	19,726	19,745
Goodwill impairment	19,462	—	19,462	—
Total operating expenses	<u>52,262</u>	<u>22,985</u>	<u>120,472</u>	<u>65,976</u>
Loss from operations	(52,262)	(22,985)	(120,472)	(40,986)
Interest income	2,520	1,224	7,800	1,581
Interest expense	(1)	(18)	(25)	(54)
Other expense, net	(142)	(217)	(472)	(456)
Loss before income tax provision	<u>(49,885)</u>	<u>(21,996)</u>	<u>(113,169)</u>	<u>(39,915)</u>
Income tax provision	—	—	—	—
Net loss	<u>\$ (49,885)</u>	<u>\$ (21,996)</u>	<u>\$ (113,169)</u>	<u>\$ (39,915)</u>
Net loss per share, basic and diluted	<u>\$ (1.16)</u>	<u>\$ (0.53)</u>	<u>\$ (2.63)</u>	<u>\$ (0.98)</u>
Weighted-average common shares used in computing net loss per share, basic and diluted	<u>42,980,641</u>	<u>41,642,815</u>	<u>43,001,901</u>	<u>40,547,792</u>

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

	<u>September 30,</u>	<u>December 31,</u>
	2023	2022
Cash and cash equivalents	\$ 183,257	\$ 257,656
Working capital	166,115	241,331
Total assets	233,257	330,690
Accumulated deficit	(351,283)	(238,114)
Total stockholders' equity	194,677	292,338

