

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 9, 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 August 9, 2023, Adicet Bio, Inc. announced its financial results for the quarter ended June 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 August 9, 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: August 9, 2023

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



Adicet Reports Second Quarter 2023 Financial Results and Provides Business Updates

Announced encouraging safety and efficacy data in ongoing Phase 1 study of ADI-001 for the potential treatment of relapsed or refractory B-cell non-Hodgkin's lymphoma (NHL)

On track to report a clinical update for ADI-001 in second half of 2024

Plan to file Investigational New Drug Application (IND) for ADI-925 in H2 2023 and ADI-270 in H1 2024

Strong balance sheet with \$205.5 million in cash and cash equivalents as of June 30, 2023

REDWOOD CITY, Calif. & BOSTON – August 9, 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 second quarter ended June 30, 2023.

“Throughout the first half of 2023, Adicet has achieved several clinical, regulatory and scientific milestones. Specifically, we are encouraged by the clinical results observed in our ongoing Phase 1 study of ADI-001 in patients heavily pretreated with a median of 4 prior lines therapy. The results were particularly meaningful given that 50% of patients enrolled in our study had previously progressed following autologous CAR T therapy,” said Chen Schor, President and Chief Executive Officer at Adicet Bio. “We are initiating an expansion cohort, EXPAND, in post CAR T LBCL patients based on our Phase 1 GLEAN study, and will continue to enroll mantle cell lymphoma patients, as we progress towards initiating our potentially pivotal program in 2024.”

Mr. Schor added, “We declared our third clinical candidate, ADI-270, which serves as our first foray to solid tumors, starting with renal cell carcinoma. ADI-270 leverages our gamma delta1 T cells, which are designed to home to solid tumors as a key differentiated property, with a highly specific targeting moiety for CD70 and an armoring technology of dominant negative TGF beta to address immunosuppressive factors in the tumor microenvironment. We expect to file an IND for ADI-270 in the first half of 2024, following our IND for ADI-925 in the second half of 2023.”

Second Quarter 2023 and Recent Operational Highlights:

- **Announced additional safety and efficacy data from ongoing Phase 1 study of ADI-001.** In June, Adicet reported safety and efficacy data from the Company's ongoing Phase 1 study of ADI-001 for the potential treatment of relapsed or refractory aggressive B-cell NHL. As of the May 4, 2023 data-cut date, ADI-001 demonstrated 71% overall response rate (ORR) and 63% complete response (CR) rate across all dose levels in patients with median 4 prior lines of therapy. ADI-001 was generally well-tolerated in the study and there were no occurrences of dose-limiting toxicities or graft vs host disease.

In May, the Company completed a Type B meeting with the U.S. Food and Drug Administration and plans to transition the ADI-001 program into a potentially pivotal single arm Phase 2 study in post-CAR T LBCL under an accelerated approval pathway in 2024. Adicet is initiating an expansion cohort, EXPAND, in post CAR T LBCL patients based on the Phase 1 study, and will continue to enroll mantle cell lymphoma patients as the Company progresses towards initiating its potentially pivotal program in 2024. Adicet expects to provide a clinical update in the second half of 2024.

- **Continuing to advance broad pipeline of CAR and chimeric antigen adaptor (CAAd) gamma delta T cell product candidates.** The Company continues to advance its pipeline of first-in-class CAR and CAAd gamma delta T cell product candidates targeting hematologic and solid malignancies. Adicet expects to submit an IND for ADI-925 in the second half of 2023.

In May, Adicet presented encouraging preclinical data at the 26th Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT) demonstrating proof-of-concept for ADI-270, an armored CD70-targeted allogeneic gamma delta CAR T cell development candidate. Adicet expects to submit an IND Application for ADI-270 in the first half of 2024.

- **Appointed Katie Peng to Board of Directors.** In July, Adicet announced the appointment of Katie Peng to the Company's Board of Directors. Ms. Peng brings extensive industry and commercial expertise to the Board. She currently serves as Chief Commercial Officer at Denali Therapeutics Inc., where she is leading the global commercialization efforts of Denali's pipeline.

Financial Results for Second Quarter 2023:

- **Research and Development (R&D) Expenses:** R&D expenses were \$28.4 million for the three months ended June 30, 2023, compared to \$16.2 million during the same period in 2022. The \$12.2 million increase is primarily driven by a \$3.7 million increase in payroll and personnel expenses resulting from an increase in overall headcount and a \$3.4 million increase in expenses related to contract drug manufacturing organizations and other externally conducted research and development. There was also a \$2.7 million increase in allocated
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facility expenses and a \$2.1 million increase in laboratory expenses. Payroll and personnel expenses for the three months ended June 30, 2023 includes \$2.4 million of non-cash stock-based compensation expense compared to \$1.9 million during the same period in 2022.

- **General and Administrative (G&A) Expenses:** G&A expenses were \$6.5 million for the three months ended June 30, 2023, compared to \$6.5 million during the same period in 2022. Payroll and personnel expenses for the three months ended June 30, 2023 includes \$2.6 million of non-cash stock-based compensation expense compared to \$2.4 million during the same period in 2022.
- **Net Loss:** Net loss for the three months ended June 30, 2023 was \$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, as compared to a net loss of \$22.5 million during the same period in 2022, or a net loss of \$0.56 per basic and diluted share, including non-cash stock-based compensation expense of \$4.3 million.
- **Cash Position:** Cash and cash equivalents were \$205.5 million as of June 30, 2023, compared to \$257.7 million as of December 31, 2023. The Company expects that current cash and cash equivalents as of June 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) and chimeric antigen adaptors (CADs), 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-925, ADI-270 and Adicet's preclinical programs; 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; the expectations regarding the submission of an IND for ADI-925 in the second half of 2023 and ADI-270

in the first half of 2024; the plan to transition ADI-001 into a potentially pivotal Phase 2 study in 2024; the expected timing of additional data in post-CAR T LBCL patients in the second half of 2024; 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 June 30,</u>		<u>Six Months Ended June 30,</u>	
	2023	2022	2023	2022
Revenue—related party	\$ —	\$ —	\$ —	\$ 24,990
Operating expenses:				
Research and development	28,362	16,178	55,118	29,661
General and administrative	6,528	6,529	13,093	13,330
Total operating expenses	34,890	22,707	68,211	42,991
Loss from operations	(34,890)	(22,707)	(68,211)	(18,001)
Interest income	2,615	325	5,279	357
Interest expense	(4)	(18)	(23)	(36)
Other expense, net	(124)	(138)	(329)	(240)
Loss before income tax provision	(32,403)	(22,538)	(63,284)	(17,920)
Income tax provision	—	—	—	—
Net loss	\$ (32,403)	\$ (22,538)	\$ (63,284)	\$ (17,920)
Net loss per share, basic and diluted	\$ (0.75)	\$ (0.56)	\$ (1.47)	\$ (0.45)
Weighted-average common shares used in computing net loss per share, basic and diluted	42,957,035	40,075,060	42,957,242	39,975,503

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

	<u>June 30,</u>	<u>December 31,</u>
	2023	2022
Cash and cash equivalents	\$ 205,460	\$ 257,656
Working capital	189,817	241,331
Total assets	277,633	330,690
Accumulated deficit	(301,398)	(238,114)
Total stockholders' equity	239,061	292,338

