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 15, 2023

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.)**

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 March 15, 2023, Adicet Bio, Inc. announced its financial results for the quarter and year ended December 31, 2022. 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 15, 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: March 15, 2023

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

Adicet Reports Fourth Quarter and Full Year 2022 Financial Results and Highlights Recent Company Progress

- *Announced interim safety and efficacy data for ADI-001 in ongoing Phase 1 study for the potential treatment of relapsed or refractory B-cell non-Hodgkin's lymphoma (NHL); Next data update expected in Q2 2023*
- *Announced preclinical data for differentiated chimeric antigen receptor (CAR) and chimeric adaptor (CAd) programs at The Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting and Adicet's R&D Pipeline Event*

REDWOOD CITY, Calif. and BOSTON – March 15, 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 fourth quarter and year ended December 31, 2022.

"In 2022, Adicet demonstrated strong execution in advancing our gamma delta T cell therapy pipeline and clinical proof of concept for our therapeutic approach that may provide significant benefit for people living with cancer. Following the Phase 1 clinical update in December evaluating ADI-001 for relapsed or refractory non-Hodgkin's lymphoma, we are continuing to track and enroll patients in the study and expect to report additional efficacy, durability, and safety data in the second quarter of 2023. We plan to discuss the design of our first potential pivotal study with the FDA in the second quarter of this year and initiate the pivotal portion of the study in the second half of the year, potentially in the third quarter," said Chen Schor, President and Chief Executive Officer of Adicet Bio. "In addition, we plan to build on the preclinical data presented at ISCT, SITC and our R&D event, to expand our pipeline of first-in-class allogeneic, off-the-shelf gamma delta CAR T-cell product candidates, and in the second half of 2023, expect to submit an IND for ADI-925, our novel CAd gamma delta T cell product candidate."

Fourth Quarter 2022 and Recent Operational Highlights:

- ***Announced Safety & Efficacy Data from Ongoing Phase 1 Study of ADI-001.*** In December 2022, Adicet reported interim safety and efficacy data from its ongoing Phase 1 study of ADI-001, Adicet's investigational therapy targeting CD20 for the potential treatment of relapsed or refractory B-cell NHL. As of a December 5, 2022 data-cut date, treatment with ADI-001 demonstrated a 75% overall response rate (ORR) and a 69% complete response (CR) across all dose levels with a favorable safety and tolerability profile. Additionally, in 5/5 large B-cell lymphoma (LBCL) patients that previously relapsed after prior autologous anti CD-19 CAR T-cell therapy, treatment with ADI-001 demonstrated a 100%

ORR and CR rate. Enrollment in the trial is currently ongoing to provide additional durability data and further support the recommended Phase 2 dose. In the second quarter of 2023, Adicet plans to discuss the design of its first potential pivotal clinical study evaluating ADI-001 in post CAR T LBCL patients with the U.S. Food and Drug Administration (FDA), and initiate the study in the second half of the year, potentially in the third quarter.

- ***Presented Preclinical Data for Four New Pipeline Programs at SITC Annual Meeting.*** In November 2022 at SITC, Adicet presented four posters highlighting preclinical data for four differentiated CAR and CAd gamma delta T cell programs targeting several hematologic and solid malignancies.

- ***Hosted R&D Pipeline Event Highlighting Preclinical Candidates.*** In November 2022, Adicet hosted an R&D event to provide additional detail regarding its emerging pipeline of allogeneic CAR and CAd gamma delta T cell therapy product candidates for a variety of cancer indications, including solid tumors. Adicet expects to submit an Investigational New Drug Application (IND) to the FDA for its lead preclinical candidate, ADI-925, in the second half of 2023.

- ***Appointed Nancy Boman, M.D., Ph.D., as Senior Vice President and Chief Regulatory Officer of Adicet.*** In November 2022, Adicet announced the appointment of Dr. Nancy Boman, M.D., Ph.D., as Senior Vice President and Chief Regulatory Officer. Dr. Boman brings nearly 30 years of industry experience in the biotech and pharmaceutical industry with expertise in regulatory, clinical development, chemistry, manufacturing and quality, leading more than 15 drug marketing applications.

- ***In-House Manufacturing Capacity Established in Redwood City Facility.*** In the fourth quarter of 2022, Adicet's new in-house manufacturing capabilities in its Redwood City facility became operational. The facility is designed to enable drug product and vector manufacturing operations for early clinical development of Adicet's pipeline candidates.

Financial Results for Fourth Quarter and Full Year 2022:

Three months Ended December 31, 2022

- **Research and Development (R&D) Expenses:** R&D expenses were $25.0 million for the three months ended December 31, 2022, compared to $14.7 million during the same period in 2021. The $10.3 million increase is primarily driven by a $3.4 million increase in payroll and personnel expenses, a net increase of $2.8 million for expenses related to contract manufacturing drug organizations (CDMO), contract research organizations (CRO) and consultant costs related to our lead product candidate ADI-001, and a $2.7 million increase

in facility allocation. There was also a $1.0 million increase in lab expenses. Payroll and personnel expenses for the three months ended December 31, 2022, includes $1.9 million of non-cash stock-based compensation expense compared to $1.6 million during the same period in 2021.

- **General and Administrative (G&A) Expenses:** G&A expenses were $6.6 million for the three months ended December 31, 2022, compared to $6.4 million during the same period in 2021. The $0.2 million increase is primarily driven by an increase of $0.5 million of professional fees as well as a $0.2 million increase of payroll and personnel expenses. This increase was partially offset by a decrease of $0.1 million in recruiting fees. Payroll and personnel expenses for the three months ended December 31, 2022, includes $2.4 million of non-cash stock-based compensation expense compared to $2.7 million during the same period in 2021.

- **Net Loss:** Net loss for the three months ended December 31, 2022 was $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, as compared to a net loss of $15.8 million during the same period in 2021, or a net loss of $0.47 per basic and diluted share, including non-cash stock-based compensation expense of $4.3 million.

Twelve Months Ended December 31, 2022

- **Research and Development (R&D) Expenses:** R&D expenses were $71.2 million for the year ended December 31, 2022, as compared to $48.9 million for year ended December 31, 2021. The increase of $22.3 million in R&D expenses year-over-year was primarily due to a $9.9 million increase in payroll and personnel expenses resulting from an increase in overall headcount, a net $4.4 million increase in expenses related to CDMOs, CROs and consultant costs related to our lead product candidate ADI-001, a $4.2 million increase in facility and other expenses and a $2.3 million increase in lab expenses. The increases in facilities and lab expense are primarily due to the move to new facilities in Redwood City and setup activities.

- **General and Administrative (G&A) Expenses:** G&A expenses were $26.3 million for the year ended December 31, 2022, compared to $22.2 million for the year ended December 31, 2021. The increase of $4.1 million was primarily due to a $4.8 million increase in payroll and personnel expenses, which includes an increase in stock-based compensation of $2.1 million, salaries and benefits of $2.0 million and contractor fees of $0.5 million and an increase in professional

fees of $0.4 million. These increases were primarily due to increased headcount for the period. These increases were partially offset by a net $1.2 million decrease in facilities and other related expense.

- **Net Loss:** Net loss for the year ended December 31, 2022 was $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, as compared to a net loss of $62.0 million during the same period in 2021, or a net loss of $2.00 per basic and diluted share, including non-cash stock-based compensation expense of $12.5 million.

- **Cash Position:** Cash and cash equivalents were $257.7 million as of December 31, 2022 as compared to $277.5 million as of December 31, 2021. During fiscal year 2022, the Company received $43.4 million of net proceeds from the sale of common stock through an "at-the-market" offering and $20 million from the exercise of an option by Regeneron related to ADI-002. The Company expects that current cash and cash equivalents securities as of December 31, 2022 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 and Adicet’s preclinical programs; the potential safety, durability, tolerability and therapeutic effects of ADI-001; expected plans, progress and timing for the release of additional clinical data from Adicet’s Phase 1 trial of ADI-001 in relapsed/refractory NHL patients, including ongoing patient

enrollment and the identification of a recommended Phase 2 dose; initiation of a potentially pivotal study in the second half of 2023, potentially in the third quarter; planned discussions with the FDA; the planned timing and submission of regulatory filings, including the potential IND for ADI-925 in the second half of 2023 and other preclinical programs; the utility, benefits and potential of in-house manufacturing capabilities in Adicet's Redwood City facility; and Adicet's growth as a company, the contributions of its 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, 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; regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming, and inherently unpredictable; Adicet's ability to meet production and product release expectations; the effect of COVID-19 on Adicet's business and financial results, including with respect to disruptions to our preclinical and clinical trials, business operations, employee hiring and retention, and ability to raise additional capital. 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 Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Revenue—related party	$ —	$ 5,468	$ 24,990	$ 9,730
Operating expenses:				
Research and development	25,015	14,658	71,246	48,943
General and administrative	6,550	6,352	26,295	22,220
Total operating expenses	31,565	21,010	97,541	71,163
Loss from operations	(31,565)	(15,542)	(72,551)	(61,433)
Interest income	2,179	37	3,760	91
Interest expense	(26)	(25)	(80)	(176)
Other expense, net	(463)	(294)	(919)	(606)
Loss before income tax provision	(29,875)	(15,824)	(69,790)	(62,124)
Income tax provision	—	(11)	—	(125)
Net loss	$ (29,875)	$ (15,813)	$ (69,790)	$ (61,999)
Net loss per share, basic and diluted	$ (0.72)	$ (0.47)	$ (1.70)	$ (2.00)
Weighted-average common shares used in computing net loss per share, basic and diluted	41,651,298	33,912,230	41,080,286	30,952,152

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

	December 31,	
	2022	2021
Cash and cash equivalents	$ 257,656	$ 277,544
Working capital	241,331	266,121
Total assets	330,690	338,938
Contract liabilities – related party, current	—	4,805
Accumulated deficit	(238,114)	(168,324)
Total stockholders' equity	292,338	303,129