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): January 04, 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.)**
200 Berkeley Street, 19th Floor 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 7.01 Regulation FD Disclosure.

On January 4, 2024, Adicet Bio, Inc. (Adicet or the Company) issued a press release titled "Adicet Provides Corporate Update and Highlights Strategic Priorities for 2024," a copy of which is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01, including 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 8.01 Other Events.

On January 4, 2024, the Company provided the following program updates and milestones for 2024:

ADI-001

Autoimmune diseases

- **Investigational New Drug application (IND) cleared for lupus nephritis.** In December 2023, the U.S. Food and Drug Administration (FDA) cleared Adicet's IND application for ADI-001 in lupus nephritis.
- **Initiate Phase 1 clinical trial of ADI-001 for the treatment of lupus nephritis in the second quarter of 2024**. The Company plans to initiate a Phase 1 clinical trial to assess the safety and efficacy of ADI-001 in lupus nephritis and may provide a clinical update from the trial in the second half of 2024. Adicet expects to expand into additional autoimmune indications in the near future.

Hematologic malignancies

- **Focus enrollment on mantle cell lymphoma (MCL) patients in ongoing Phase 1 GLEAN study.** Adicet will focus on the MCL patient population in the ongoing Phase 1 GLEAN study (at dose level 4), which experienced the greatest clinical benefit in the June 2023 update. While these were early data, an 80% CR rate and 60% 6-month CR rate in late line MCL patients were reported in the June 2023 clinical update, Cmax and exposure by area under the curve (AUC) exceeded that of approved autologous CD19 CAR T therapies, and a favorable safety profile was observed with no significant risk of cytokine release syndrome, immune effector cell associated neurotoxicity syndrome or T-cell malignancies. These initial clinical results, coupled with the potential to dose off-the-shelf in a community setting, support ADI-001 as a potentially attractive therapy for MCL patients. The Company is evaluating the option of advancing ADI-001 to a potentially pivotal study in MCL patients under an accelerated approval pathway.
- The Company remains on track to provide an ADI-001 clinical update in the second half of 2024.

ADI-270

Renal cell carcinoma

- **Plan to file IND for ADI-270 in 2Q 2024.** Following positive feedback from a pre-IND meeting with the FDA, the Company remains on track to file an IND application for ADI-270 in the second quarter of 2024.

Financial Outlook

- The Company expects cash and cash equivalents on hand as of December 31, 2023, to enable funding for current and planned operations into the second half of 2025.

Pipeline Chart

- On January 4, 2024, the Company published to its website an updated pipeline chart of its product candidates in development. A copy of the Company's pipeline is filed as Exhibit 99.2 to this Current Report on Form 8-K and incorporated by reference herein.

The disclosure under this Item 8.01 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 and ADI-270 and the potential safety, durability, tolerability and efficacy of these product candidates; the expected progress, timing and success of the Phase 1 clinical trial of ADI-001, including continued enrollment and expectations around a clinical update in the second half of 2024; the Company's plan to initiate a Phase 1 clinical trial to assess the safety and efficacy of ADI-001 in lupus nephritis and potential to provide a clinical update from the trial in the second half of 2024; Adicet plans to expand into additional autoimmune indications in the near future; the Company’s expectations regarding the submission of an IND for ADI-270 in renal cell carcinoma in the second quarter of 2024; and expectations regarding its uses of capital, expenses and financial results, including the expected cash runway.

Any forward-looking statements in this Item 8.01 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 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 titled "Risk Factors" in Adicet’s most recent Annual Report on Form 10-K and subsequent filings with the Securities and Exchange Commission. All disclosure under this Item 8.01 is as of the date of this Current Report on Form 8-K, and Adicet undertakes no duty to update this information unless required by law.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press release issued by Adicet Bio, Inc. on January 4, 2024, furnished herewith.
99.2	Adicet Bio, Inc. pipeline chart as of January 4, 2024.
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: January 4, 2024

By: /s/ Nick Harvey

Name: *Nick Harvey*

Title: *Chief Financial Officer*

Adicet Provides Corporate Update and Highlights Strategic Priorities for 2024

Expanding clinical development of ADI-001 into autoimmune diseases following clearance of Investigational New Drug Application (IND); plan to initiate Phase 1 clinical study in 2Q 2024

Focusing enrollment on mantle cell lymphoma (MCL) in ongoing ADI-001 Phase 1 clinical trial given favorable complete response (CR) rate, durability, and safety

ADI-001 clinical update expected 2H 2024

ADI-270 IND submission in renal cell carcinoma expected in 2Q 2024

Updated cash runway into 2H 2025

REDWOOD CITY, Calif. & BOSTON – January 4, 2024 – Adicet Bio, Inc. (Nasdaq: ACET), a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for cancer and autoimmune diseases, today provided corporate updates and highlighted upcoming priorities for its pipeline programs in 2024.

“In 2024, we aim to make significant strides across our pipeline of differentiated gamma delta T cell therapies through our strategic and disciplined approach,” said Chen Schor, President and Chief Executive Officer at Adicet Bio. “The U.S. FDA’s IND clearance of ADI-001 in lupus nephritis marks an important milestone in maximizing the ADI-001 opportunity in the autoimmune therapeutic category that we believe it is ideally suited to address. Clinical data for ADI-001 have demonstrated B-cell depletion that mirrors the B cell depletion by autologous alpha-beta CAR T in academic clinical studies in systemic lupus erythematosus, systemic sclerosis, and idiopathic inflammatory myopathy patients. Given that gamma delta 1 T cells preferentially traffic to organs and tissues, ADI-001 is designed to target and deplete B cells in the periphery, secondary lymphoid organs, kidneys, and other organs, which is highly desirable in autoimmune diseases. ADI-001’s off-the-shelf availability and the favorable safety profile provide the potential for outpatient administration.”

Mr. Schor continued: “Our internal research and development efforts are focused in areas where we believe we have a high probability of success and opportunity for significant differentiation. In our ongoing Phase 1 clinical trial of ADI-001 in relapsed or refractory NHL, we have decided to focus our current patient enrollment on the MCL population, which demonstrated the greatest clinical benefit in our June 2023 clinical

update. With projected cash runway into the second half of 2025, multiple upcoming milestones, and a disciplined approach, we believe we are well-positioned to advance our pipeline of allogeneic T cell therapy candidates to address substantial unmet needs in oncology and autoimmune diseases."

Program Updates and Expected Milestones for 2024

ADI-001 is an investigational allogeneic gamma delta CAR T cell therapy targeting CD20 for the potential treatment of relapsed or refractory B-cell non-Hodgkin's Lymphoma (NHL) and autoimmune diseases.

Autoimmune diseases

- IND cleared for lupus nephritis. In December 2023, the FDA cleared Adicet's IND application for ADI-001 in lupus nephritis.
- Initiate Phase 1 clinical trial of ADI-001 for the treatment of lupus nephritis in the second quarter of 2024. The Company plans to initiate a Phase 1 clinical trial to assess the safety and efficacy of ADI-001 in lupus nephritis and may provide a clinical update from the trial in the second half of 2024. Adicet expects to expand into additional autoimmune indications in the near future.

Hematologic malignancies

- Focus enrollment on MCL patients in ongoing Phase 1 GLEAN study. Adicet will focus on the MCL patient population in the ongoing Phase 1 GLEAN study (at dose level 4), which experienced the greatest clinical benefit in the June 2023 update. While these were early data, an 80% CR rate and 60% 6-month CR rate in late line MCL patients were reported in the June 2023 clinical update, Cmax and exposure by area under the curve (AUC) exceeded that of approved autologous CD19 CAR T therapies, and a favorable safety profile was observed with no significant risk of cytokine release syndrome, immune effector cell associated neurotoxicity syndrome or T-cell malignancies. These initial clinical results, coupled with the potential to dose off-the-shelf in a community setting, support ADI-001 as a potentially attractive therapy for MCL patients. The Company is evaluating the option of advancing ADI-001 to a potentially pivotal study in MCL patients under an accelerated approval pathway.
- The Company remains on track to provide an ADI-001 clinical update in the second half of 2024.

ADI-270 is an investigational allogeneic gamma delta CAR T cell therapy targeting CD70 via the CD27-ligand for the treatment of renal cell carcinoma with potential in other solid tumor indications. ADI-270 is designed to home to solid tumors, with a highly specific targeting moiety for CD70 and an armoring technology of TGF beta dominant-

negative receptor to address immunosuppressive factors in the tumor microenvironment. Building on gamma delta 1 tissue tropism to solid tumors and three mechanisms of anti-tumor activity (CAR, innate and adaptive), CAR gamma delta 1 T cells may be well positioned to address solid tumors.

Renal cell carcinoma

- Plan to file IND for ADI-270 in 2Q 2024. Following positive feedback from a pre-IND meeting with the FDA, the Company remains on track to file an IND application for ADI-270 in the second quarter of 2024.

Financial Outlook

- The Company expects cash and cash equivalents on hand as of December 31, 2023, to enable funding for current and planned operations into the second half of 2025.

Webcast/ Conference Call Information

The live webcast of the presentation can be accessed by registering under “Presentations & Events” in the investors section of the Company’s website at https://www.adicetbio.com. Upon registration, all participants will receive a confirmation email with a unique passcode to provide access to the webcast event. To participate via telephone, please join by dialing 888-788-0099 (domestic) or 312-626-6799 (international) and referencing the conference ID 918 2940 8885. An archived replay will be available for 30 days following the presentation. The archived webcast will be available on the Company's website beginning approximately two hours after the event.

About Adicet Bio, Inc.
Adicet Bio, Inc. is a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for cancer and autoimmune diseases. 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 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 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 and the potential safety, durability, tolerability and efficacy of these product candidates; the expected progress, timing and success of the Phase 1 clinical trial of ADI-001, including continued enrollment and expectations around a clinical update in the second half of 2024; the Company's plan to initiate a Phase 1 clinical trial of ADI-001 in lupus nephritis and expand into other autoimmune indications in the future; the Company's expectations regarding the submission of an IND for ADI-270 in renal cell carcinoma in the second quarter of 2024; 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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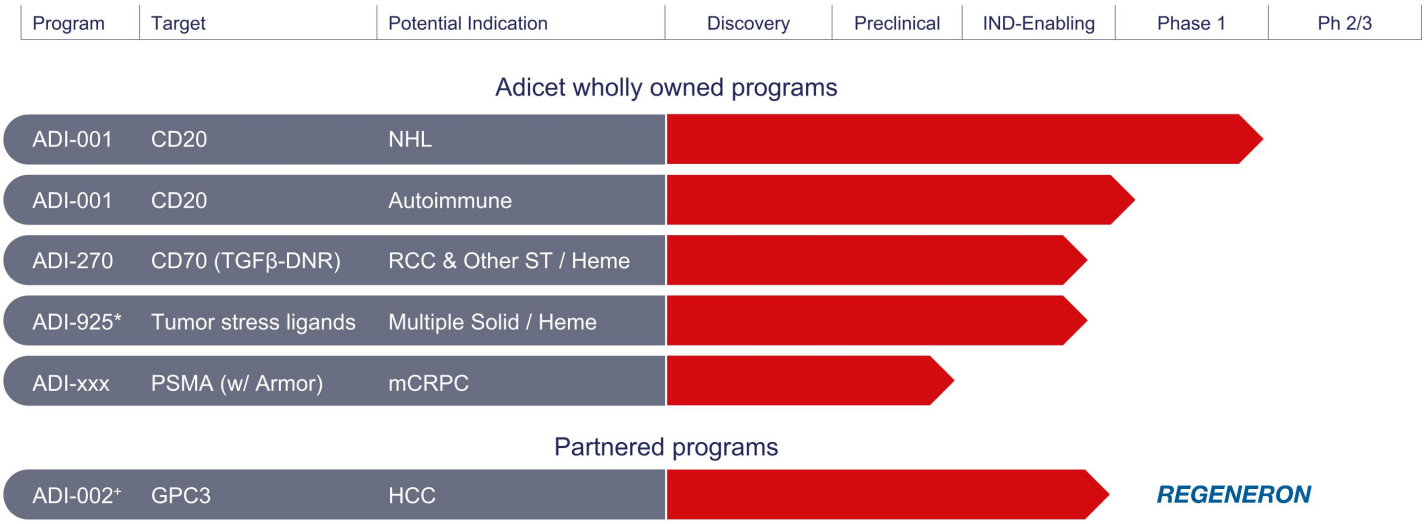
Adicet Bio Pipeline



*ADI-925 is an engineered Chimeric Adapter (CAd) γδ1 T cell product candidate targeting stress ligands, including MICA/MICB & ULBP1-6, expressed on malignant cells. The company has reprioritized its clinical pipeline to focus on ADI-270.