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): June 26, 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		**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 June 26, 2023, Adicet Bio, Inc. (Adicet or the Company) issued a press release titled "Adicet Bio Reports Positive Data from Ongoing ADI-001 Phase 1 Trial in Patients with Relapsed or Refractory Aggressive B-Cell Non-Hodgkin's Lymphoma (NHL)," 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 June 26, 2023, the Company issued a press release and presented on 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 non-Hodgkin's lymphoma (NHL). Data highlights as of the May 4, 2023 data-cut date were as follows:

- Of the 24 efficacy-evaluable patients, 3 received ADI-001 at dose level 1 (DL1) (30 million CAR+ cells), 3 received ADI-001 at dose level 2 (DL2) (100 million CAR+ cells), 6 received ADI-001 at dose level 3 (DL3) (300 million CAR+ cells), 4 received two infusions of ADI-001 at DL3 (two doses of 300 million CAR+ cells, one on day 1 and the second dose on day 7 following a single lymphodepletion), and 8 received ADI-001 at dose level 4 (DL4) (1 billion CAR+ cells).

- Patients were heavily pretreated with a median of 4 prior lines of therapy (range 2-9), had relatively high tumor burden, and had a poor prognostic outlook based on their median International Prognostic Index (IPI) score. 50% of patients enrolled in the study had progressed on prior CAR T.

- ADI-001 treatment demonstrated a 71% ORR and 63% CR rate in the study across all dose levels.

- ADI-001 demonstrated an 83% ORR and 67% CR rate in heavily pre-treated patients (4 median prior lines of therapy) who had progressed on prior CAR T.

- ADI-001 demonstrated a 6-month CR rate consistent with autologous CAR T when factoring number of prior lines of therapy and percent of patients enrolled in the study who progressed on prior CAR T.

- Adicet selected the recommended Phase 2 dose (RP2D) as 1 billion CAR positive cells (DL4).

- At the RP2D (DL4) (with 4 median prior lines of therapy, 38% post-CAR T) the 6-month CR rate was 25%. At this dose level, in patients who had progressed on prior CAR T, the CR rate was 67% and the 6-month CR rate was 33%.

- The expansion and persistence of ADI-001 at the RP2D exceed values reported for approved autologous CD19 CAR T cell therapy. DL4 demonstrated a mean Cmax of 483 cells/ul with a mean time-to-peak at approximately day 9 and demonstrated persistence through day 28 with a mean concentration of 21 cells/ul.

- ADI-001 was generally well-tolerated in the study and there were no occurrences of dose-limiting toxicities or graft vs host disease (GvHD). Of the 24 patients evaluable for safety, there was 1 report of Grade 3 or higher CRS and 1 report of Grade 3 or higher ICANS.

- In May, the Company completed a Type B meeting with the FDA and expects to transition the ADI-001 program into a potentially pivotal Phase 2 study in post- CAR T LBCL in the first half of 2024.

Table 1 – Summary of Phase 1 ADI-001 Preliminary Efficacy Data as of the May 4, 2023 data-cut date:

	Median No. of Prior Lines	Post-CAR T Patients	ORR (%)	CR Rate (%)	3-month CR Rate (%)	6-month CR Rate (%)
DL4 (RP2D)	4	3/8 (37.5%)	6/8 (75.0%)	5/8 (62.5%)	4/8 (50.0%)	2/8 (25.0%)
DL4 (RP2D) Post CAR T	4	3/3 (100.0%)	3/3 (100.0%)	2/3 (67.7%)	1/3 (33.3%)	1/3 (33.3%)
All Doses	4	12/24 (50%)	17/24 (70.8%)	15/24 (62.5%)	9/24 (37.5%)	4/24 (16.7%)
Post CAR T All Doses	4	12/12 (100.0%)	10/12 (83.3%)	8/12 (66.7%)	4/12 (33.3%)	2/12 (16.7%)

Table 2 – Summary of Phase 1 ADI-001 Safety Data in Efficacy Evaluable Patients as of the May 4, 2023 data-cut date*:

	DL1(N=3)		DL2(N=3)		DL3(N=6)		DL3 X2(N=4)		DL4(N=8)		Total (N=24)	
	Any Grade	Gr>=3	Any Grade	Gr>=3	Any Grade	Gr>=3	Any Grade	Gr>=3	Any Grade	Gr>=3	Any Grade	Gr>=3
CRS	2 (66.7%)	0	0	0	1 (16.7%)	1 (16.7%)	4 (100.0%)	0	4 (50.0%)	0	11 (45.8%)	1 (4.2%)
ICANS	0	0	1 (33.3%)	0	0	0	1 (25.0%)	1 (25.0%)	1 (12.5%)	0	3 (12.5%)	1 (4.2%)
GvHD	0	0	0	0	0	0	0	0	0	0	0	0
DLT	0	0	0	0	0	0	0	0	0	0	0	0
Infection	1 (33.3%)	1 (33.3%)	2 (66.7%)	0	3 (50.0%)	2 (33.3%)	2 (50.0%)	1 (25.0%)	3 (37.5%)	2 (25.0%)	11 (45.8%)	6 (25.0%)
SAE-TEAE	1 (33.3%)	1 (33.3%)	2 (66.7%)	2 (66.7%)	4 (66.7%)	3 (50.0%)	2 (50.0%)	2 (50.0%)	3 (37.5%)	2 (25.0%)	12 (50.0%)	10 (41.7%)

Related SAE-TEAE	1 (33.3%)	0	1 (33.3%)	1 (33.3%)	3 (50.0%)	2 (33.3%)	2 (50.0%)	2 (50.0%)	3 (37.5%)	2 (25.0%)	10 (41.7%)	7 (29.2%)

*Safety assessment was performed using the Common Terminology Criteria for Adverse Events (v5) and the American Society for Transplantation and Cellular Therapy criteria.

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 the potential safety, durability, tolerability and efficacy of ADI-001; the expected progress, timing and success of the Phase 1 study of ADI-001 in relapsed/refractory NHL patients, including the identification of a recommended Phase 2 dose and the expected performance compared to approved CD19 autologous CAR T therapy; the plan to transition ADI-001 into a potentially pivotal Phase 2 study in the first half of 2024; and expected timing of additional data in post-CAR T LBCL patients in the second half of 2024.

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 COVID-19 on Adicet's business and financial results, including with respect to disruptions to Adicet's preclinical or clinical studies, business operations 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 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. 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 for the year ended December 31, 2022 and subsequent filings with the Securities and Exchange Commission. All disclosure under this Item 8.01 is as of the date of this 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 June 26, 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 thereunto duly authorized.

ADICET BIO, INC.

Date: June 26, 2023

By: /s/ Nick Harvey

Name: *Nick Harvey*

Title: *Chief Financial Officer*

ACTIVE/123834403

Adicet Bio Reports Positive Data from Ongoing ADI-001 Phase 1 Trial in Patients with Relapsed or Refractory Aggressive B-Cell Non-Hodgkin's Lymphoma (NHL)

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; 50% of patients enrolled had previously progressed on anti-CD19 chimeric antigen receptor T cell (CAR T) therapy

83% ORR and 67% CR rate observed in heavily pre-treated patients who had progressed on prior CAR T

Six-month CR rate consistent with autologous CAR T cell therapy

Favorable safety with no significant incidence of CRS (cytokine release syndrome) or ICANS (immune effector cell associated neurotoxicity syndrome)

Robust pharmacokinetic profile in dose level 4 (DL4) with Cmax and Day 28 persistence exceeding approved CD19 autologous CAR T therapy

Plan to transition ADI-001 program into potentially pivotal Phase 2 study in post-CAR T large B-cell lymphoma (LBCL) patients in first half of 2024

Clinical update from additional post-CAR T LBCL patients expected in second half of 2024

Company to host investor webcast on Monday, June 26 at 4:30pm ET

REDWOOD CITY, Calif. & BOSTON – June 26, 2023 – Adicet Bio, Inc. (Nasdaq: ACET), a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for cancer, today announced positive 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 non-Hodgkin's lymphoma (NHL).

"These data are exciting and beyond what one might expect to see given that patients enrolled in the study were heavily pre-treated," said Francesco Galimi, M.D., Ph.D., Senior Vice President and Chief Medical Officer of Adicet Bio. "Autologous CD19 CAR T therapies were studied on CAR T naïve patients with a median of 3 prior lines of therapy. In contrast, the ADI-001 Phase 1 trial enrolled patients with a median of 4 lines of prior therapy and, importantly, 50% had previously progressed on autologous CAR T therapy. Despite the advanced nature of the patients at baseline in the ADI-001 Phase

1 study, at our recommended Phase 2 dose (DL4) ADI-001 demonstrated an overall CR rate of 63%, a 6-month CR rate of 25%, and in patients that had progressed following autologous CD19 CAR T therapy, the CR rate of ADI-001 was 67% with a 6-month CR rate of 33%."

Added Galimi, "We plan to transition the ADI-001 program into a potential pivotal Phase 2 study in post-CAR T LBCL in the first half of 2024. In addition, we expect to provide a clinical update which will include efficacy, 6-month CR rate, and safety data, from additional post-CAR T LBCL patients in the second half of 2024."

"The autologous CD19 CAR T market is estimated to have an annual run rate in excess of $2.2 billion and is growing given recent approvals in the second line setting. Unfortunately, approximately 60-70% of these patients progress, which represents a significant unmet medical need," said Chen Schor, President and Chief Executive Officer of Adicet Bio. "In May we met with the FDA and discussed the design of our first potentially pivotal Phase 2 study with an accelerated approval pathway. We are very encouraged by these data and look forward to advancing ADI-001 into the next stage of clinical development and progressing our pipeline of novel gamma delta T cell product candidates in both hematologic malignancies and solid tumors."

Data highlights as of the May 4, 2023 data-cut date were as follows:

- Of the 24 efficacy-evaluable patients, 3 received ADI-001 at dose level 1 (DL1) (30 million CAR+ cells), 3 received ADI-001 at dose level 2 (DL2) (100 million CAR+ cells), 6 received ADI-001 at dose level 3 (DL3) (300 million CAR+ cells), 4 received two infusions of ADI-001 at DL3 (two doses of 300 million CAR+ cells, one on day 1 and the second dose on day 7 following a single lymphodepletion), and 8 received ADI-001 at dose level 4 (DL4) (1 billion CAR+ cells).
- Patients were heavily pretreated with a median of 4 prior lines of therapy (range 2-9), had relatively high tumor burden, and had a poor prognostic outlook based on their median International Prognostic Index (IPI) score. 50% of patients enrolled in the study had progressed on prior CAR T.
- ADI-001 treatment demonstrated a 71% ORR and 63% CR rate in the study across all dose levels.
- ADI-001 demonstrated an 83% ORR and 67% CR rate in heavily pre-treated patients (4 median prior lines of therapy) who had progressed on prior CAR T.
- ADI-001 demonstrated a 6-month CR rate consistent with autologous CAR T when factoring number of prior lines of therapy and percent of patients enrolled in the study who progressed on prior CAR T.
- Adicet selected the recommended Phase 2 dose (RP2D) as 1 billion CAR positive cells (DL4).
- At the RP2D (DL4) (with 4 median prior lines of therapy, 38% post-CAR T) the 6-month CR rate was 25%. At this dose level, in patients who had progressed on prior CAR T, the CR rate was 67% and the 6-month CR rate was 33%.
- The expansion and persistence of ADI-001 at the RP2D exceed values reported for approved autologous CD19 CAR T cell therapy. DL4 demonstrated a mean

Cmax of 483 cells/ul with a mean time-to-peak at approximately day 9 and demonstrated persistence through day 28 with a mean concentration of 21 cells/ul.

- ADI-001 was generally well-tolerated in the study and there were no occurrences of dose-limiting toxicities or graft vs host disease (GvHD). Of the 24 patients evaluable for safety, there was 1 report of Grade 3 or higher CRS and 1 report of Grade 3 or higher ICANS.
- In May, the Company completed a Type B meeting with the FDA and expects to transition the ADI-001 program into a potentially pivotal Phase 2 study in post- CAR T LBCL in the first half of 2024.

Table 1 – Summary of Phase 1 ADI-001 Preliminary Efficacy Data as of the May 4, 2023 data-cut date:

	Median No. of Prior Lines	**Post-CAR T Patients**	**ORR (%)**	**CR Rate (%)**	**3-month CR Rate (%)**	**6-month CR Rate (%)**
DL4 (RP2D)	**4**	**3/8 (37.5%)**	**6/8 (75.0%)**	**5/8 (62.5%)**	**4/8 (50.0%)**	**2/8 (25.0%)**
DL4 (RP2D) Post CAR T	**4**	**3/3 (100.0%)**	**3/3 (100.0%)**	**2/3 (67.7%)**	**1/3 (33.3%)**	**1/3 (33.3%)**
All Doses	4	12/24 (50%)	17/24 (70.8%)	15/24 (62.5%)	9/24 (37.5%)	4/24 (16.7%)
Post CAR T All Doses	4	12/12 (100.0%)	10/12 (83.3%)	8/12 (66.7%)	4/12 (33.3%)	2/12 (16.7%)

Table 2 – Summary of Phase 1 ADI-001 Safety Data in Efficacy Evaluable Patients as of the May 4, 2023 data-cut date*:

	DL1(N=3)		DL2(N=3)		DL3(N=6)		DL3 X2(N=4)		DL4(N=8)		Total (N=24)	
	Any Grade	Gr>=3	Any Grade	Gr>=3	Any Grade	Gr>=3	Any Grade	Gr>=3	Any Grade	Gr>=3	Any Grade	Gr>=3
CRS	2 (66.7%)	0	0	0	1 (16.7%)	1 (16.7%)	4 (100.0%)	0	4 (50.0%)	0	11 (45.8%)	1 (4.2%)
ICANS	0	0	1 (33.3%)	0	0	0	1 (25.0%)	1 (25.0%)	1 (12.5%)	0	3 (12.5%)	1 (4.2%)
GvHD	0	0	0	0	0	0	0	0	0	0	0	0
DLT	0	0	0	0	0	0	0	0	0	0	0	0
Infection	1 (33.3%)	1 (33.3%)	2 (66.7%)	0	3 (50.0%)	2 (33.3%)	2 (50.0%)	1 (25.0%)	3 (37.5%)	2 (25.0%)	11 (45.8%)	6 (25.0%)
SAE-TEAE	1 (33.3%)	1 (33.3%)	2 (66.7%)	2 (66.7%)	4 (66.7%)	3 (50.0%)	2 (50.0%)	2 (50.0%)	3 (37.5%)	2 (25.0%)	12 (50.0%)	10 (41.7%)
Related SAE-TEAE	1 (33.3%)	0	1 (33.3%)	1 (33.3%)	3 (50.0%)	2 (33.3%)	2 (50.0%)	2 (50.0%)	3 (37.5%)	2 (25.0%)	10 (41.7%)	7 (29.2%)

*Safety assessment was performed using the Common Terminology Criteria for Adverse Events (v5) and the American Society for Transplantation and Cellular Therapy criteria.

Webcast/ Conference Call Information
Adicet will host a webcast presentation on Monday, June 26 at 4:30pm ET to discuss the most recent data-cut from its ongoing Phase 1 study evaluating the safety and tolerability of ADI-001 for the potential treatment of relapsed or refractory B-cell NHL.

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 972-9349-2674 (domestic) or 1-646-876-9923 (international) and referencing the conference ID 97293492674. 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 ADI-001
ADI-001 is an investigational allogeneic gamma delta CAR T cell therapy being developed as a potential treatment for relapsed or refractory B-cell NHL. ADI-001 targets malignant B-cells via an anti-CD20 CAR and via the gamma delta innate and T cell endogenous cytotoxicity receptors. Gamma delta T cells engineered with an anti-CD20 CAR have demonstrated potent anti-tumor activity in preclinical models, leading to long-term control of tumor growth. In April 2022, ADI-001 was granted Fast Track Designation by the FDA for the potential treatment of relapsed or refractory B-cell NHL.

About the GLEAN Study
The Phase 1 study is an open-label, multi-center study of ADI-001 enrolling adults diagnosed with B-cell malignancies who have either relapsed, or are refractory to, at least two prior regimens. The primary objectives of the study are to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of ADI-001, and to determine optimal dosing as a monotherapy. For more information about the clinical study design, please visit www.clinicaltrials.gov (NCT04735471).

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.

Available Information
Adicet announces material information to the public about the Company, its product candidates and clinical trials, and other matters through a variety of means, including filings with the U.S. Securities and Exchange Commission (SEC), press releases, public conference calls, webcasts, the investor relations section of the Company website at investor.adicetbio.com and the Company’s Twitter account (@AdicetBio), in order to achieve broad, non-exclusionary distribution of information to the public and for complying with its disclosure obligations under Regulation FD.

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 the potential safety, durability, tolerability and efficacy of ADI-001; the expected progress, timing and success of the Phase 1 study of ADI-001 in relapsed/refractory NHL patients, including the identification of a recommended Phase 2

dose and the expected performance compared to approved CD19 autologous CAR T therapy; the plan to transition ADI-001 into a potentially pivotal Phase 2 study in the first half of 2024; and expected timing of additional data in post-CAR T LBCL patients in the second half of 2024. 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 COVID-19 on Adicet's business and financial results, including with respect to disruptions to Adicet's preclinical or clinical studies, business operations 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 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. 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 for the year ended December 31, 2022 and subsequent 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.

Adicet Bio., Inc.
Investor and Media Contacts

Anne Bowdidge
abowdidge@adicetbio.com

Janhavi Mohite
Stern Investor Relations, Inc.
212-362-1200
janhavi.mohite@sternir.com