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 03, 2022

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 7.01 Regulation FD Disclosure.

On November 3, 2022, Adicet Bio, Inc. ("Adicet" or the "Company") issued a press release titled "Adicet Bio Reports ASH Abstract Data from Ongoing ADI-001 Phase 1 Trial in 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 November 3, 2022, the Company issued a press release and reported interim data from the Company's Phase 1 study of ADI-001 for the potential treatment of relapsed or refractory B-cell Non-Hodgkin's lymphoma (NHL). Data highlights as of the July 15, 2022 data-cut date are as follows:

- Of the nine evaluable patients, three patients were treated at each of the three dose levels: dose level 1 (DL1; 30 million CAR+ cells), dose level 2 (DL2; 100 million CAR+ cells), and dose level 3 (DL3; 300 million CAR+ cells). Two patients at DL3 were re-dosed with a second course of ADI-001, per protocol. Six of nine were male (67%) and the median age was 62 years (range 45-75). There were eight patients with large B-cell lymphoma (LBCL) and one with mantle cell lymphoma. Of the eight patients with LBCL, five had diffuse-large B-cell lymphoma (DLBCL), two had high-grade B-cell lymphoma (HGBCL) with double/triple hit, and one had HGBCL not otherwise specified. Indolent lymphomas, such as follicular lymphoma, are currently excluded from the study.
- Overall, the patients were heavily pretreated with a median number of prior therapies of four (range 2-5), and had a poor prognostic outlook as indicated by the median International Prognostic Index (IPI) score of four (range 2-4); the median tumor burden was 2,974 (150-7,919) mm^2, and 89% (8/9) had stage III/IV disease.
- The best overall response rate (ORR) and complete response rate (CR) was 78% (7/9). For the four patients who had prior autologous CD19 CAR T therapies, the ORR and CR rate was 100% (4/4). As of the data-cut date, of the seven patients who had achieved CR, two patients progressed, one died of unrelated causes while in complete remission and four were still in CR and in active follow up, with a range of follow-up time between 1.2 and 8.8 months.
- CAR+ gamma delta T cell kinetics in the peripheral blood increased in a dose-dependent manner with peak cell expansion occurring between Days seven and 10 at DL3 based on flow cytometry.
- Of the nine patients, there were no ≥ Grade 3 Cytokine Release Syndrome (CRS) or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) events. Two patients developed CRS: one Grade 1 and one Grade 2. At the time of the ASH abstract submission, there were three reported related serious adverse events: Grade 2 CRS, Grade 1 ICANS and Grade 3 adenoviraemia. There was no reported graft versus host disease or protocol-defined dose-limiting toxicity events.
- Response data were evaluated per Lugano 2014 criteria by independent radiographic review.

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. These forward-looking statements include, but are not limited to, express or implied statements regarding: the potential safety, durability, tolerability and therapeutic effects of ADI-001; plans and timing for the release of additional clinical data from Adicet's Phase 1 trial of ADI-001 in relapsed or refractory NHL patients; and future progress of the Phase 1 study.

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 clinical trials, 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 interim results, from a clinical study may not necessarily be predictive of the results of future or ongoing clinical 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 entitled "Risk Factors" in Adicet's most recent Annual Report on Form 10-K for the year ended December 31, 2021 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 of Adicet Bio, Inc. on November 3, 2022, 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 3, 2022

By: /s/ Chen Schor
Name: Chen Schor
Title: President and Chief Executive Officer

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

As of the July 15, 2022 ASH abstract data-cut date, ADI-001 demonstrated a 78% overall and complete response rate and sustained durability in patients, including those previously exposed to CAR T therapy

100% ORR and CR rate in four anti-CD19 CAR T relapsed patients

ADI-001 continued to demonstrate a favorable safety and tolerability profile

Clinical data will be presented during poster presentation at ASH Annual Meeting on Saturday, December 10, 2022, from 5:30 – 7:30 p.m. CT

Adicet to host ADI-001 webcast to discuss more recent data-cut date from Phase 1 study on Sunday, December 11, 2022, at 8:00 a.m. CT / 9:00 a.m. ET

Redwood City, CA and Boston, MA – November 3, 2022 – Adicet Bio, Inc. (Nasdaq: ACET), a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for cancer, today announced that an abstract detailing updated safety and efficacy data from the Company's Phase 1 study of ADI-001 for the potential treatment of relapsed or refractory B-cell Non-Hodgkin's lymphoma (NHL) was made available as part of the 64th American Society of Hematology (ASH) Annual Meeting, which is being held December 10-13, 2022 in New Orleans, Louisiana. The abstract outlines a summary of clinical data as of a July 15, 2022 data-cut date. Clinical data will be provided during a poster presentation by Sattva Neelapu, M.D., from the MD Anderson Cancer Center at the ASH Annual Meeting on Saturday, December 10, 2022.

"The latest data-cut from our ongoing study of ADI-001 is extremely encouraging, as we continue to see complete responses and preliminary durability coupled with a benign safety profile in heavily pre-treated patients with aggressive NHL. We look forward to providing additional clinical data from a later data-cut date during the ASH Annual Meeting," said Francesco Galimi, M.D., Ph.D., Chief Medical Officer of Adicet Bio. "With the data generated to date coupled with the pace of enrollment in dose level 4, we remain on track to initiate a potentially pivotal program for ADI-001 in the first half of 2023."

Data highlights as of the July 15, 2022 data-cut date included in the ASH abstract were as follows:

- Of the nine evaluable patients, three patients were treated at each of the three dose levels: dose level 1 (DL1; 30 million CAR+ cells), dose level 2 (DL2; 100 million CAR+ cells), and dose level 3 (DL3; 300 million CAR+ cells). Two patients at DL3 were re-dosed with a second

course of ADI-001, per protocol. Six of nine were male (67%) and the median age was 62 years (range 45-75). There were eight patients with large B-cell lymphoma (LBCL) and one with mantle cell lymphoma. Of the eight patients with LBCL, five had diffuse-large B-cell lymphoma (DLBCL), two had high-grade B-cell lymphoma (HGBCL) with double/triple hit, and one had HGBCL not otherwise specified. Indolent lymphomas, such as follicular lymphoma, are currently excluded from the study.

- Overall, the patients were heavily pretreated with a median number of prior therapies of four (range 2-5), and had a poor prognostic outlook as indicated by the median International Prognostic Index (IPI) score of four (range 2-4); the median tumor burden was 2,974 (150-7,919) mm^2, and 89% (8/9) had stage III/IV disease.
- The best overall response rate (ORR) and complete response rate (CR) was 78% (7/9). For the four patients who had prior autologous CD19 CAR T therapies, the ORR and CR rate was 100% (4/4). As of the data-cut date, of the seven patients who had achieved CR, two patients progressed, one died of unrelated causes while in complete remission and four were still in CR and in active follow up, with a range of follow-up time between 1.2 and 8.8 months.
- CAR+ gamma delta T cell kinetics in the peripheral blood increased in a dose-dependent manner with peak cell expansion occurring between Days seven and 10 at DL3 based on flow cytometry.
- Of the nine patients, there were no ≥ Grade 3 Cytokine Release Syndrome (CRS) or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) events. Two patients developed CRS: one Grade 1 and one Grade 2. At the time of the ASH abstract submission, there were three reported related serious adverse events: Grade 2 CRS, Grade 1 ICANS and Grade 3 adenoviraemia. There was no reported graft versus host disease or protocol-defined dose-limiting toxicity events.
- Response data were evaluated per Lugano 2014 criteria by independent radiographic review.

The full abstract is available online on the ASH website.

Clinical data will be presented during a poster presentation by Sattva Neelapu, M.D. at the ASH Annual Meeting on Saturday, December 10, 2022 from 5:30 -7:30 p.m. CT. Adicet will provide data from a more recent data-cut date from the Phase 1 study in a press release and company webcast on Sunday, December 11, 2022 at 8:00 a.m. CT/ 9:00 a.m. ET.

Details of the poster presentation are as follows:

Session Title: 704. Cellular Immunotherapies: Early Phase and Investigational Therapies: Poster I
Title: A Phase 1 Study of ADI-001: Anti-CD20 CAR-Engineered Allogeneic Gamma Delta1 (γδ) T Cells in Adults with B-Cell Malignancies
Presenting Author: Sattva Neelapu, M.D., MD Anderson Cancer Center
Date/Time: Saturday, December 10, 2022 from 5:30 - 7:30 p.m. CT.

Adicet ADI-001 Webcast Information
The Company will host a webcast event on Sunday, December 11, 2022, at 8:00 a.m. CT/ 9:00 a.m. ET to discuss recent data from its ongoing Phase 1 clinical study of ADI-001 in relapsed or refractory aggressive B-cell NHL.

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 antitumor activity in preclinical models, leading to long-term control of tumor growth. In April 2022, ADI-001 was granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the potential treatment of relapsed or refractory B-cell NHL.

About the GLEAN Study
This 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. The study is expected to enroll approximately 75 patients. 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 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. These forward-looking statements include, but are not limited to, express or implied statements regarding the potential safety, durability, tolerability and therapeutic effects of ADI-001; plans and timing for the release of additional clinical data from Adicet’s Phase 1 trial of ADI-001 in NHL patients; future progress of the Phase 1

trial, including ongoing patient enrollment in the dose level 4 cohort; and expectations around the initiation of a potentially pivotal program in the first half of 2023.

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 clinical trials, 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 interim results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical 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 entitled "Risk Factors" in Adicet's most recent Annual Report on Form 10-K for the year ended December 31, 2021 and subsequent filings with the Securities and Exchange Commission. 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