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): December 6, 2021

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 Clarendon Street, Floor 6 Boston, MA		**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 (see General Instructions A.2. below):

☐ 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 8.01 Other Events

On December 6, 2021, Adicet Bio, Inc. (Adicet) issued a press release announcing positive interim data from its dose escalation Phase 1 study evaluating the safety and tolerability of ADI-001, Adicet's investigational therapy targeting CD20 for the potential treatment of B Cell Non-Hodgkin's Lymphoma.

As of the November 22, 2021 data cutoff, six patients had been enrolled and received ADI-001. The first two patients enrolled in the lowest dose level tested did not reach the day 28 assessment and were not evaluable for efficacy per protocol. Three of the four evaluable patients achieved responses, including two complete responses (CR) and one partial response (PR) that investigators characterized as near complete response. Patients were heavily pre-treated, with a median of five lines of prior systemic therapy, including a patient who had received prior autologous CD19 CAR T, and achieved complete response following a single infusion of ADI-001 administered at the lowest dose level.

Of the four efficacy evaluable patients, three received ADI-001 at dose level one (30 million CAR+ cells) and one received ADI-001 at dose level two (100 million CAR+ cells). In dose level one, one patient achieved a CR, one patient achieved a PR that was characterized as near CR and one patient had progressive disease (PD). In dose level two, the first patient achieved a CR.

All evaluable patients had been heavily pre-treated with a median of five lines of prior systemic therapies. Of the three patients who achieved PR or better under Lugano 2014 criteria (ORR=75%, CR=50%), one had follicular lymphoma transformed into a large B-cell tumor with four prior lines of therapy, one had diffuse large B-cell lymphoma (DLBCL) with five prior lines of therapy including two cycles of anti-CD19 CAR T cell therapy, and the third had mantle cell lymphoma with five prior lines of therapy. These patients achieved two CRs and a near CR.

Overall, ADI-001 infusions were generally well-tolerated. No dose-limiting toxicities, graft vs host disease (GvHD), Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), Grade 3 or higher Cytokine Release Syndrome (CRS) have been reported to-date, suggesting a potentially wide therapeutic window for ADI-001.

A significant increase in circulating IL-15 was observed during the 28-day window following lymphodepletion, potentially providing cytokine support for the proliferation of ADI-001. Emergence of circulating ADI-001 in the blood was observed by quantitative polymerase chain reaction and by flow cytometry, demonstrating expansion of ADI-001 in patients. Elevations in additional circulating cytokines, primarily IL-2 and IL-8 were observed during the first 14 days from dosing, consistent with the activation profile of ADI-001 and similar to the observed time-to-peak for cytokines previously reported in association with autologous alpha-beta CAR T cells. Importantly, no meaningful increases in IL-6 were seen in association with ADI-001, except for one patient who experienced COVID-19 infection, suggesting reduced likelihood for ICANS and high-grade CRS.

Table 1: Summary of ADI-001 interim data from two dosing cohorts*:

Dose Level	Age/Sex	B-cell lymphoma subtypes	# Prior lines of therapies	Prior CAR T?	Best Response (BOR) by Lugano Criteria (2014)
30 million CAR+ cells	62/F	Transformed DLBCL (from chronic lymphocytic leukemia)	5 prior lines	No	PD
	66/F	Transformed high grade B cell tumor (from follicular lymphoma)	4 prior lines	No	PR (Near CR)
	75/M	DLBCL	5 prior lines	Yes (liso-cel)	CR
100 million CAR+ cells	62/M	Mantle cell lymphoma	5 prior lines	No	CR

*Efficacy evaluable patients as of November 22, 2021 database entry. Data are subject to further review and verification.

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 including, but not limited to the interim clinical data resulting from its Phase 1 study of ADI-001, including the expected potential therapeutic effects, safety and tolerability profile, design, implementation, timing, and success of ADI-001; and expectations regarding the potential of its other CAR gamma delta T cell therapy development activities. 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, including with respect to disruptions to preclinical and clinical trials, business operations, and

ability to raise additional capital; Adicet's ability to execute on its strategy; that positive results from a preclinical study may not necessarily be predictive of the results of future or ongoing preclinical and clinical studies; future studies may fail to demonstrate adequate safety and efficacy of our product candidates, which would prevent, delay, or limit the scope of regulatory approval and commercialization; and regulatory approval processes of the U.S. Food and Drug Administration (FDA) and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable; and regulatory developments in the United States and foreign countries. 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 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.

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: December 6, 2021

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