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): September 10, 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.)**
131 Dartmouth Street, Floor 3 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 8.01 Other Events.

On September 10, 2024, Adicet Bio, Inc. (the Company or Adicet) announced a strategic prioritization to focus ADI-001 development resources on autoimmune indications. The Company is focusing on advancing the clinical development of ADI-001 in four autoimmune indications, which include lupus nephritis, systemic lupus erythematosus, systemic sclerosis and anti-neutrophil cytoplasmic autoantibody associated vasculitis, and expects to further expand ADI-001 clinical development into additional autoimmune indications in the near term. Due to this prioritization, patient enrollment in the Phase 1 clinical study of ADI-001 in mantle cell lymphoma (MCL) has been closed, and topline results are reported below.

Across all doses, 10 evaluable patients with MCL that were treated with ADI-001 demonstrated an overall response rate (ORR) of 80% (8/10), a complete response (CR) rate of 60% (6/10), with a median duration of complete response of 17.5 months as of August 22, 2024. Patients were heavily pretreated with a median of 3 prior lines of therapy and 30% of patients had progressed on prior CAR T. In the Phase 1 study, ADI-001 demonstrated a favorable safety and tolerability profile, with no occurrences of graft-versus-host disease and low incidence of grade ≥3 cytokine release syndrome and neurotoxicity that compared favorably to data reported for autologous CD19 CAR T in MCL. Additional translational data from patients enrolled in the Phase 1 clinical study in relapsed/refractory B-cell non-Hodgkin's Lymphoma, which further support the significant potential of ADI-001 in autoimmune indications, will be presented during the 9th Annual CAR-TCR Summit on September 19, 2024 in Boston, MA.

Forward-Looking Statements

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 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 reprioritization of the Company's pipeline and expectations for future clinical development activities; the clinical development of ADI-001 in lupus nephritis, systemic lupus erythematosus, systemic sclerosis and anti-neutrophil cytoplasmic autoantibody associated vasculitis and the Company's expectation to further expand ADI-001 clinical development into additional autoimmune indications in the near term; and the potential safety, tolerability and efficacy of ADI-001 multiple indications.

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 crises on the Company's business and financial results, including with respect to disruptions to its 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; that 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 U.S. Food and Drug Administration 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 titled "Risk Factors" in Adicet's most recent Quarterly Report on Form 10-Q and subsequent filings with the U.S. Securities and Exchange Commission (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 thereunto duly authorized.

ADICET BIO, INC.

Date:	September 10, 2024	By:	/s/ Nick Harvey
		Name:	*Nick Harvey*
		Title:	*Chief Financial Officer*