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): July 08, 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 7.01 Regulation FD Disclosure.

On July 8, 2024, Adicet Bio, Inc. issued a press release titled "Adicet Bio Receives FDA Fast Track Designation for ADI-270 in Metastatic/Advanced Clear Cell Renal Cell Carcinoma," 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 9.01 Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press release issued by Adicet Bio, Inc. on July 8, 2024, 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:	July 8, 2024	By:	/s/ Nick Harvey
		Name:	*Nick Harvey*
		Title:	*Chief Financial Officer*

Adicet Bio Receives FDA Fast Track Designation for ADI-270 in Metastatic/Advanced Clear Cell Renal Cell Carcinoma

Redwood City, Calif. and BOSTON, July 8, 2024 – Adicet Bio, Inc. (Nasdaq: ACET), a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for autoimmune diseases and cancer, today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to ADI-270 for the potential treatment of patients with metastatic/advanced clear cell renal cell carcinoma (ccRCC) who have been treated with an immune checkpoint inhibitor and a vascular endothelial growth factor inhibitor.

“We are pleased that ADI-270, our first ever gamma delta 1 CAR T cell therapy candidate to enter clinical trials for solid tumors, has been granted Fast Track Designation by the FDA,” said Chen Schor, President and Chief Executive Officer of Adicet Bio. “ccRCC is the most common type of kidney cancer, and this significant milestone underscores our commitment to advancing innovative treatments to these patients as quickly as possible.”

Fast Track Designation is a process designed to facilitate development and expedite the review of drugs intended to treat serious conditions and fill an unmet medical need.

About ADI-270

ADI-270 is an armored allogeneic “off-the-shelf” gamma delta CAR T cell therapy candidate targeting CD70-positive cancers. CD70 is a compelling target due to its high expression in both solid and hematological malignancies. ADI-270 is engineered with a third-generation CAR designed to target CD70 using its natural receptor, CD27, as the binding moiety and is further armored with a dominant negative form of the transforming growth factor-β receptor II (dnTGFβRII) to provide functional resilience to the immunosuppressive tumor microenvironment. ADI-270 is also designed to increase exposure and persistence by reducing susceptibility to host vs. graft elimination. These properties of ADI-270 combined with the potent tumor infiltration demonstrated with gamma delta 1 T cells aim to improve clinical responses of RCC patients and other patients with CD70+ tumors.

About Adicet Bio, Inc.

Adicet Bio, Inc. is a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for autoimmune diseases and cancer. Adicet is advancing a pipeline of “off-the-shelf” gamma delta T cells, engineered with chimeric antigen receptors (CARs), to facilitate 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: clinical development of Adicet’s product candidates, including future plans or expectations for ADI-270; the potential safety, durability, tolerability and activity of ADI-270; and the potential of ADI-270 to become a treatment for patients with metastatic/advanced ccRCC.

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 geopolitical conflicts and economic conditions on Adicet’s business and financial results, including with respect to disruptions to Adicet’s 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, timeconsuming, 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 periodic and current reports on Form 10-Q and Form 8-K filed 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 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
Precision AQ
212-362-1200