

**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 12, 2021

Adicet Bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38359
(Commission File Number)

81-3305277
(IRS Employer
Identification No.)

200 Clarendon Street, Floor 6
Boston, MA
(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 (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 7.01 Regulation FD Disclosure

On November 12, 2021, Adicet Bio, Inc. (“Adicet”) issued a press release titled “Adicet Presents Preclinical Data for ADI-002, a GPC3-Targeted Development Candidate for Solid Tumors, at the SITC Annual Meeting,” 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, 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, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events

On November 12th, 2021, Adicet issued a press release announcing the presentation of new preclinical data supporting its Glypican-3 (GPC3)-targeted allogeneic, off-the-shelf gamma delta chimeric antigen receptor (CAR) T cell development candidate for solid tumors at the 36th Society for Immunotherapy of Cancer (SITC) Annual Meeting.

ADI-002 is an investigational allogeneic gamma delta CAR-T cell therapy developed and engineered by Adicet to express a GPC3-targeted CAR and a cell intrinsic soluble form of IL-15 designed to promote additional expansion and activity at the site of tumor engagement. It is the first of Adicet’s product candidates designed specifically to target solid tumors.

Results presented at the SITC Annual Meeting detail findings from in vitro and in vivo preclinical evaluations of ADI-002. ADI-002 demonstrated expansion of gamma delta 1 T cells during manufacture with a predominant naïve-like phenotype. ADI-002 cells also demonstrated high expression of innate activating receptors, including NKG2D and DNAM-1, while maintaining a lower abundance of cells expressing exhaustion markers PD-1, LAG-3, TIGIT, and TIM-3.

In vitro, ADI-002 demonstrated potent and specific cytotoxicity against GPC3-positive cancer cell lines associated with high and low levels of target expression. The demonstrated in vitro killing activity of ADI-002 on cancer cells was associated with release of multiple effector cytokines. ADI-002 further demonstrated enhanced depth, duration and persistence of in vitro killing activity and was associated with increased proliferative potential.

In vivo, ADI-002 was evaluated in mice engrafted with human hepatocellular carcinoma tumors that naturally express GPC3. ADI-002 exhibited potent antitumor activity following a single dose without evident toxicities or graft versus host effects. Tissue-specific homing and proliferation of ADI-002 were compared to that of GPC3-targeted □□ CAR-T cells. ADI-002 cells specifically homed to, and proliferated within the tumors, whereas □□ CAR-T cells demonstrated high levels of off-target proliferation in mouse organ systems. These results demonstrate that, unlike □□ CAR-T cells, ADI-002 and the Company’s gamma delta T cell platform achieved reduced alloreactive potential in these models without the need for manipulation of T cell receptors or incurring additional risks associated with genome editing. Together, Adicet believes these data support initial evaluation of safety and efficacy for ADI-002 in GPC3-positive malignancies.

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 preclinical data resulting from early studies with ADI-002, including future plans or expectations regarding the initiation, design, implementation, timing, and success of future clinical studies of ADI-002 and expectations regarding its other CAR gamma delta T cell therapy development activities; and the therapeutic potential, safety and efficacy of ADI-002 for targeting solid tumors. 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.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit

Number

Description

99.1 [Press release issued by Adicet Bio, Inc. on November 12, 2021, 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 12, 2021

By: /s/ Nick Harvey

Name: *Nick Harvey*

Title: *Chief Financial Officer*

Adicet Presents Preclinical Data for ADI-002, a GPC3-Targeted Development Candidate for Solid Tumors, at the SITC Annual Meeting

Adicet's allogeneic gamma delta CAR-T cell therapy candidate is designed to combine CAR targeting and cell intrinsic IL-15 armoring with the innate and adaptive immune effector functions of the Company's gamma delta T cell platform

Preclinical findings demonstrated potent gamma delta CAR-T cell activation, cytotoxicity, tumor-specific homing, proliferation, and enhanced activity without evidence of graft versus host alloreactivity

Menlo Park, CA and Boston, MA – November 12, 2021 – Adicet Bio, Inc. (Nasdaq: ACET), a biotechnology company discovering and developing first-in-class allogeneic gamma delta T cell therapies for cancer and other diseases, today announced the presentation of new preclinical data supporting its Glypican-3 (GPC3) targeted allogeneic, off-the-shelf gamma delta chimeric antigen receptor (CAR) T cell development candidate for solid tumors at the 36th Society for Immunotherapy of Cancer (SITC) Annual Meeting.

ADI-002 is an investigational allogeneic gamma delta CAR-T cell therapy developed and engineered by Adicet to express a GPC3-targeted CAR and a cell intrinsic soluble form of IL-15 designed to promote additional expansion and activity at the site of tumor engagement. It is the first of Adicet's product candidates designed specifically to target solid tumors.

“We have made meaningful progress advancing IND-enabling studies for ADI-002, which leverages our differentiated gamma delta CAR-T cell platform,” said Blake Aftab, Ph.D., Senior Vice President and Chief Scientific Officer at Adicet Bio. “GPC3 is an antigen associated with a spectrum of solid tumors, including tumors of the liver and lung, and is a promising target when coupled to the natural biology associated with gamma delta T cell homing and residence in these tissues.”

Results presented at the SITC Annual Meeting detail findings from *in vitro* and *in vivo* preclinical evaluations of ADI-002. ADI-002 demonstrated expansion of gamma delta 1 T cells during manufacture with a predominant naïve-like phenotype. ADI-002 cells also demonstrated high expression of innate activating receptors, including NKG2D and DNAM-1, while maintaining a lower abundance of cells expressing exhaustion markers PD-1, LAG-3, TIGIT, and TIM-3.

In vitro, ADI-002 demonstrated potent and specific cytotoxicity against GPC3-positive cancer cell lines associated with high and low levels of target expression. The demonstrated *in vitro* killing activity of ADI-002 on cancer cells was associated with release of multiple effector cytokines. ADI-002 further demonstrated enhanced depth, duration and persistence of *in vitro* killing activity and was associated with increased proliferative potential.

In vivo, ADI-002 was evaluated in mice engrafted with human hepatocellular carcinoma tumors that naturally express GPC3. ADI-002 exhibited potent antitumor activity following a single dose without evident toxicities or graft versus host effects. Tissue-specific homing and proliferation of ADI-002 were compared to that of GPC3-targeted □□ CAR-T cells. ADI-002 cells specifically homed to, and proliferated within the tumors, whereas □□ CAR-T cells demonstrated high levels of off-target proliferation in mouse organ systems. These results demonstrate that, unlike □□ CAR-T cells, ADI-002 and the Company's gamma delta T cell platform achieved reduced alloreactive potential in these models without the need for manipulation of T cell receptors or incurring additional risks associated with genome editing. Together, Adicet believes these data support initial evaluation of safety and efficacy for ADI-002 in GPC3-positive malignancies.

Details of the poster presentation:

Title: ADI-002: an IL-15 armored allogeneic “off-the-shelf” Vδ1 gamma delta CAR-T cell therapy for solid tumors targeting glypican-3 (GPC3)

ePoster Presentation: 7 a.m. EST on Friday, Nov. 12, 2021

Presenting Author: Marissa Herrman, Ph.D. – Adicet Bio, Inc.

About Adicet Bio, Inc.

Adicet Bio, Inc. is a biotechnology company discovering and developing allogeneic gamma delta T cell therapies for cancer and other diseases. Adicet is advancing a pipeline of “off-the-shelf” gamma delta T cells, engineered with chimeric antigen receptors and T cell receptor-like targeting moieties to enhance selective tumor targeting, facilitate innate and adaptive anti-tumor immune response, and improve persistence for durable activity in patients. For more information, please visit our website at <http://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 business and operations of Adicet including, but not limited to, the preclinical data resulting from early studies with ADI-002, including future plans or expectations regarding the initiation, design, implementation, timing, and success of future clinical studies of ADI-002 and expectations regarding its other CAR gamma delta T cell therapy development activities; and the therapeutic potential, safety and efficacy of ADI-002 for targeting solid tumors. 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 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 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.

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