

**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, 2020**

Poseida Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39376
(Commission
File Number)

47-2846548
(I.R.S. Employer
Identification No.)

9390 Towne Centre Drive, Suite 200
San Diego, California
(Address of principal executive offices)

92121
(Zip Code)

Registrant's telephone number, including area code: (858) 779-3100

N/A

(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 | PSTX | Nasdaq Global Select 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 2.02 Results of Operations and Financial Condition.

On November 12, 2020, Poseida Therapeutics, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2020. A copy of this press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02 and the exhibit hereto are being furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall they 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 a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit No. | Description |
|--------------------|--|
| 99.1 | <u>Press Release of Poseida Therapeutics, Inc., dated November 12, 2020.</u> |

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.

Date: November 12, 2020

Poseida Therapeutics, Inc.

By: /s/ Mark J. Gergen
Name: Mark J. Gergen
Title: President, Chief Business Officer

Poseida Therapeutics Reports Operational Update and Financial Results for Third Quarter 2020

SAN DIEGO, November 12, 2020 — Poseida Therapeutics, Inc. (Nasdaq: PSTX), a clinical-stage biopharmaceutical company utilizing proprietary gene engineering platform technologies to create cell and gene therapeutics with the capacity to cure, today announced an operational update and financial results for the quarter ended September 30, 2020.

“During our first quarter as a publicly traded company, we continued to maintain our focus on research innovation and advancement of our clinical programs, while also building new strategic collaborations,” said Eric Ostertag, M.D., Ph.D., Chief Executive Officer of Poseida. “In early September, we released data demonstrating new manufacturing technology that has the potential to create more efficacious cell therapies and have now implemented that technology across our entire CAR-T pipeline. In October, we announced a research collaboration with TScan Therapeutics to evaluate the feasibility of producing a novel cell-based therapeutic for the treatment of COVID-19. This collaboration will expand our platforms to include T cell receptor-engineered T cell (TCR-T) therapies and further expand the indications we can potentially treat beyond oncology.”

Program Updates

P-PSMA-101

P-PSMA-101 is a solid tumor autologous CAR-T product candidate being developed to treat patients with metastatic castrate resistant prostate cancer. The program started enrollment in May 2020. On November 2, 2020, the Company announced that a clinical hold placed on the trial was lifted by the FDA. The trial has now resumed with minor protocol modifications to increase patient compliance and safety. The protocol changes are specific to the P-PSMA-101 program and do not affect the ongoing P-BCMA-101 clinical trial. The Company now expects to provide an initial data update in mid-2021.

P-BCMA-101

P-BCMA-101 is an autologous CAR-T product candidate for the treatment of patients with relapsed/refractory multiple myeloma. The program is currently enrolling in an expanded Phase 1 clinical trial to inform the potentially registrational Phase 2 clinical trial. Phase 1 dose expansion enrollment continues, although at a slower pace than planned due in part to the COVID-19 pandemic. Further, the Company expects to make a Phase 2 dosing decision on P-BCMA-101 by early 2021.

At the CAR-TCR Digital Week meeting on September 16, 2020, the Company presented data related to CAR-T manufacturing optimizations and also illustrated the impact of these optimizations with preliminary clinical analysis of the first patients dosed in the P-BCMA-101 Phase 1 expansion trial.

P-BCMA-ALLO1

The Company’s first allogeneic CAR-T product candidate, P-BCMA-ALLO1, is in development for the treatment of relapsed/refractory multiple myeloma and is designed to be fully allogeneic, with

genetic edits designed to reduce or eliminate both host-vs-graft and graft-vs-host alloreactivity. The program is proceeding toward an IND filing which is expected in the first half 2021.

P-MUC1C-ALLO1

This allogeneic CAR-T product candidate is in preclinical development with the potential to treat a wide range of solid tumors, including breast and ovarian cancers. The program is proceeding with an expected IND filing in 2021.

P-OTC-101 Gene Therapy Program

P-OTC-101 is the Company's first liver-directed gene therapy program for *in vivo* treatment of urea cycle disease caused by congenital mutations in the OTC gene, a condition characterized by high unmet medical need. The Company now expects to submit an IND in 2022 due to pandemic related factors, including longer timelines due to COVID-19 vaccine-related capacity constraints at certain vendors.

Early Stage Development Programs

For programs in early development, including the fully allogeneic Dual CAR programs, P-PSMA-ALLO1 and P-MMUT-101, the Company expects to update specific guidance at a later date, as it gains further clarity on the timelines and any impacts of the COVID-19 pandemic.

Other Operational Updates and Upcoming Events

Collaboration agreement with TScan Therapeutics to explore developing allogeneic T cell receptor therapies for the treatment of COVID-19

In October, the Company and TScan Therapeutics announced a research collaboration and license agreement to explore the use of the Company's fully allogeneic stem cell memory T cell platform in combination with TScan's proprietary TCR platform and findings related to SARS-CoV-2. The collaboration will allow the Company to explore platform and T cell technology utilizing one or more TCRs in allogeneic cell therapy applications.

Piper Sandler 32nd Annual Virtual Healthcare Conference

The Company is participating in a virtual conference that will be made available at 10 am ET on November 23, 2020, ahead of the conference start scheduled for December 1, 2020. The audio recording of the presentation, formatted as a fireside chat, will be available through the conference coordinators and posted on the Company's website.

62nd American Society of Hematology (ASH) Annual Meeting and Exposition

The Company plans to provide an update on the P-BCMA-101 Phase 1 expansion trial in early December with an oral presentation at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition scheduled for Saturday, December 5, 2020.

Financial Results

Research and Development Expenses

Research and development expenses were \$27.0 million for the three months ended September 30, 2020, compared to \$15.7 million for the same period in 2019. For the nine months ended September 30, 2020, research and development expenses were \$75.6 million, compared to \$41.2 million for the same period in 2019. The increase in both periods was primarily due to increased headcount, external costs related to preclinical programs and clinical stage programs, including the

ongoing P-BCMA-101 and P-PSMA-101 clinical trials, and internal costs related to facilities development.

General and Administrative Expenses

General and administrative expenses were \$6.5 million for the three months ended September 30, 2020, compared to \$4.0 million for the same period in 2019. General and administrative expenses were \$15.6 million for the nine months ended September 30, 2020, compared to \$14.4 million for the same period in 2019. The increase in both periods was primarily due to increased headcount and professional fees associated with becoming a publicly traded company.

Net Losses

Net losses were \$34.4 million and \$93.6 million for the three and nine months ended September 30, 2020, respectively, and \$21.0 million and \$62.9 million for the three and nine months ended September 30, 2019, respectively.

Cash Position

As of September 30, 2020, cash, cash equivalents and marketable securities were \$341.5 million. Net proceeds from the Company's initial public offering, which closed in July 2020, were \$205.7 million.

About Poseida Therapeutics, Inc.

Poseida Therapeutics is a clinical-stage biopharmaceutical company dedicated to utilizing our proprietary gene engineering platform technologies to create next generation cell and gene therapeutics with the capacity to cure. We have discovered and are developing a broad portfolio of product candidates in a variety of indications based on our core proprietary platforms, including our non-viral piggyBac® DNA Modification System, Cas-CLOVER™ site-specific gene editing system and nanoparticle- and AAV-based gene delivery technologies. Our core platform technologies have utility, either alone or in combination, across many cell and gene therapeutic modalities and enable us to engineer our wholly-owned portfolio of product candidates that are designed to overcome the primary limitations of current generation cell and gene therapeutics.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the potential benefits of Poseida's technology platforms and product candidates, Poseida's plans and strategy with respect to developing its technologies and product candidates and anticipated timelines and milestones with respect to Poseida's development programs. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon Poseida's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with development and regulatory approval of novel product candidates in the biopharmaceutical industry and the other risks described in Poseida's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Poseida undertakes no

obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

Poseida Therapeutics, Inc.
Selected Financial Data
(Unaudited)
(In thousands, except share amounts)

STATEMENTS OF OPERATIONS

| | <u>Three Months Ended September 30,</u> | | <u>Nine Months Ended September 30,</u> | |
|---|---|--------------------|--|--------------------|
| | 2020 | 2019 | 2020 | 2019 |
| Operating expenses: | | | | |
| Research and development | \$ 27,016 | \$ 15,696 | \$ 75,636 | \$ 41,189 |
| General and administrative | 6,458 | 4,007 | 15,553 | 14,449 |
| Increase in contingent consideration | — | 1,060 | — | 6,683 |
| Total operating expenses | <u>33,474</u> | <u>20,763</u> | <u>91,189</u> | <u>62,321</u> |
| Loss from operations | (33,474) | (20,763) | (91,189) | (62,321) |
| Other income (expense): | | | | |
| Interest expense | (848) | (935) | (2,654) | (2,633) |
| Other income (expense), net | (92) | 744 | 216 | 2,040 |
| Net loss before income tax | (34,414) | (20,954) | (93,627) | (62,914) |
| Income tax benefit | — | — | — | — |
| Net loss | <u>\$ (34,414)</u> | <u>\$ (20,954)</u> | <u>\$ (93,627)</u> | <u>\$ (62,914)</u> |
| Net loss per share attributable to common stockholders, basic and diluted | <u>\$ (0.63)</u> | <u>\$ (1.65)</u> | <u>\$ (3.43)</u> | <u>\$ (5.06)</u> |
| Weighted-average shares of common stock, basic and diluted | <u>54,973,788</u> | <u>12,665,834</u> | <u>27,324,297</u> | <u>12,427,367</u> |

SELECTED BALANCE SHEET DATA

| | <u>September 30,</u> | <u>December 31,</u> |
|---|----------------------|---------------------|
| | 2020 | 2019 |
| Cash, cash equivalents and short-term investments | \$ 341,457 | \$ 125,318 |
| Total assets | 405,171 | 146,996 |
| Total liabilities | 109,335 | 74,334 |
| Convertible preferred stock | - | 222,173 |
| Total stockholders' equity (deficit) | 295,836 | (149,511) |

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Contact:

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