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):
May 11, 2021

Poseida Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39376**	**47-2846548**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

9390 Towne Centre Drive, Suite 200, San Diego, California	**92121**
(Address of principal executive offices)	**(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 May 11, 2021, Poseida Therapeutics, Inc. issued a press release announcing its program updates and financial results for the first quarter ended March 31, 2021. 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	Press Release of Poseida Therapeutics, Inc., dated May 11, 2021.

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.

Poseida Therapeutics, Inc.

Date: May 11, 2021

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

Poseida Therapeutics Reports Program Updates and Financial Results for the First Quarter 2021

SAN DIEGO, May 11, 2021 — Poseida Therapeutics, Inc. (Nasdaq: PSTX), a clinical-stage biopharmaceutical company utilizing proprietary genetic engineering platform technologies to create cell and gene therapeutics with the capacity to cure, today announced program updates and financial results for the first quarter ended March 31, 2021.

“We are encouraged by our continued progress in first quarter of 2021, building on the accomplishments from the prior year as we moved multiple programs forward to important inflection points, including our ongoing P-BCMA-101 and P-PSMA-101 CAR-T programs, on which we plan to provide further clinical updates later in the year,” said Eric Ostertag, M.D., Ph.D., Chief Executive Officer of Poseida. “Additionally, we intend to advance two INDs in our allogeneic CAR-T portfolio this year, one for P-BCMA-ALLO1, targeting BCMA in relapsed/refractory multiple myeloma; and the other for P-MUC1C-ALLO1, targeting MUC1-C in a variety of solid tumor indications, including triple negative breast cancer and ovarian cancer. Though still early, initial clinical activity in patients with prostate cancer following treatment with P-PSMA-101 increases our excitement and confidence in the probability of success for this pan-solid tumor program.”

Program Updates

BCMA Program

P-BCMA-101 is an autologous CAR-T product candidate in an ongoing Phase 1 dose expansion trial and Phase 2 trial in development for the treatment of relapsed/refractory multiple myeloma. Phase 1 dose expansion enrollment continues, with an expected update on this program later in 2021.

P-BCMA-ALLO1, the Company’s first allogeneic CAR-T product candidate, is in development for the treatment of relapsed/refractory multiple myeloma and is designed to be fully allogeneic, with genetic edits intended to reduce or eliminate both host-vs-graft and graft-vs-host alloreactivity. The program is proceeding toward an IND filing. Due to a suspected equipment failure at the contract manufacturer for P-BCMA-ALLO1, the IND is now expected in the third quarter of 2021.

PSMA Program

P-PSMA-101 is a solid tumor autologous CAR-T product candidate being developed to treat patients with metastatic castrate resistant prostate cancer (mCRPC) currently in an ongoing Phase 1 dose escalation trial. Following a previously disclosed serious adverse event in cohort 1 (0.75X10E6 cells/kg), the Company elected to de-escalate dosing and treat at least three patients at the protocol preestablished cohort -1 (0.25X10E6 cells/kg) dose. All three patients have been treated, with significant improvements in activity measures seen in the first two patients, one with a >50% decline in prostate-specific antigen (PSA) at about two weeks post CAR-T treatment; and the second with >96% decline in PSA and a 70% reduction in standard uptake value in PSMA PET imaging of target lesions at four weeks post CAR-T treatment. The third patient was only recently treated. One patient demonstrated Grade 1 cytokine release syndrome, or CRS. Assuming no dose limiting toxicities are observed, re-escalation to the cohort 1 dose and beyond is expected. The Company intends to provide an additional update on this program in the second half of 2021.

MUC1-C Program
P-MUC1C-ALLO1 is an allogeneic CAR-T product candidate in preclinical development with the potential to treat a wide range of solid tumors, including breast and ovarian cancers. P-MUC1C-ALLO1 is proceeding as planned, with an anticipated IND filing and initiation of Phase 1 clinical trial by the end of 2021.

Liver-Directed Gene Therapy Programs
P-OTC-101 is the Company's first liver-directed gene therapy program for the in vivo treatment of urea cycle disease caused by congenital mutations in the ornithine transcarbamylase (OTC) gene, a condition characterized by high unmet medical need. The Company expects an IND submission and initiation of a Phase 1 clinical trial in 2022.

Early-Stage Development Programs
For programs in early development, including P-FVIII-101, a liver-directed gene therapy for the in vivo treatment of hemophilia A, preclinical studies are ongoing that will inform the development plans and timelines to IND filings.

For discovery programs, the Company may seek partnerships or collaborations to advance development in the near term.

Other Operational Updates and Upcoming Events
Launch of Immuno-Oncology Scientific Advisory Board (SAB)
In March, the Company announced the appointment of distinguished scientist and pioneer in the field of CAR-T therapy, Carl June, M.D., to chair the newly expanded immuno-oncology scientific advisory board, which will provide advice and counsel on the research and development efforts that drive the Company's innovative cell and gene therapies.

Dr. June has since been joined by Luca Gattinoni, M.D., Chair for Functional Immune Cell Modulation at the Regensburg Center for Interventional Immunology at the University of Regensburg in Germany; Christine Brown, Ph.D., Heritage Provider Network Professor of Immunotherapy at City of Hope Comprehensive Cancer Center; and J. Joseph Melenhorst, Ph.D., Adjunct Associate Professor of Pathology & Laboratory Medicine at the Perelman School of Medicine at the University of Pennsylvania.

The Company is also in the process of establishing a second SAB focused on additional applications for its proprietary gene therapy platform technologies.

American Society of Gene and Cell Therapy 2021 Virtual Annual Meeting
The Company gave multiple oral and poster presentations earlier today, May 11, 2021, at the American Society of Gene and Cell Therapy 2021 Virtual Annual Meeting. The Company's oral presentation highlighted new data demonstrating the potential of its proprietary piggyBac DNA Delivery System for the treatment of genetic liver disorders in children and infants. Two additional presentations highlighted preclinical data supporting Poseida's first allogeneic CAR-T product candidate, P-BCMA-ALLO1 for R/R multiple myeloma, as well as preclinical data supporting the Company's anti-c-kit CAR-T program as a potentially safer preconditioning regimen for hematopoietic stem cell transplantation in patients with AML. The presentation materials can be accessed on the Poseida website.

BofA Securities 2021 Virtual Health Care Conference

The Company is participating in a virtual conference at 2:45pm ET/11:45am PT on Wednesday, May 12, 2021. The audio recording of the presentation, formatted as a fireside chat, will be made available on the Company's website.

BofA Securities 2021 Napa Biopharma Virtual Conference
The Company is participating in a virtual conference at 4:30pm ET/1:30pm PT on Monday, June 14, 2021. The audio recording of the presentation, formatted as a fireside chat, will be made available on the Company's website.

Financial Results for the First Quarter 2021
Research and Development Expenses
Research and development expenses were $29.1 million for the first quarter ended March 31, 2021, compared to $23.4 million for the same period in 2020. The increase was primarily due to increased headcount, external costs related to our preclinical programs and clinical stage programs, including the ongoing enrollment and manufacturing associated with our 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 $8.4 million for the first quarter ended March 31, 2021, compared to $4.9 million for the same period in 2020. The increase was primarily due to increased headcount and professional fees associated with becoming a publicly traded company.

Net Loss
Net loss was $38.3 million for the first quarter ended March 31, 2021 compared to $28.8 million for the first quarter ended March 31, 2020.

Cash Position
As of March 31, 2021, cash, cash equivalents and short-term investments were $270.0 million.

About Poseida Therapeutics, Inc.
Poseida Therapeutics is a clinical-stage biopharmaceutical company dedicated to utilizing our proprietary genetic 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 Delivery 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. To learn more, visit www.poseida.com and connect with us on Twitter and LinkedIn.

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 statement 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 and per share amounts)

STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	$ 29,095	$ 23,414
General and administrative	8,369	4,854
Total operating expenses	37,464	28,268
Loss from operations	(37,464)	(28,268)
Other income (expense):		
Interest expense	(838)	(914)
Other income (expense), net	(12)	398
Net loss before income tax	(38,314)	(28,784)
Income tax expense	—	—
Net loss	$ (38,314)	$ (28,784)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.62)	$ (2.16)
Weighted-average shares of common stock, basic and diluted	61,981,081	13,322,581

SELECTED BALANCE SHEET DATA

	March 31, 2021	December 31, 2020
Cash, cash equivalents and short-term investments	$ 269,960	$ 309,152
Total assets	333,337	371,484
Total liabilities	105,851	109,516
Total stockholders' equity	227,486	261,968

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