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 09, 2023

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)**	**(IRS 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

(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 9, 2023, Poseida Therapeutics, Inc. (the "Company") issued a press release announcing its updates and financial results for the first quarter ended March 31, 2023. 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 9, 2023.
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.

Poseida Therapeutics, Inc.

Date: May 9, 2023

By: /s/ Johanna M. Mylet
Name: Johanna M. Mylet
Title: Chief Financial Officer

Poseida Therapeutics Provides Updates and Financial Results for the First Quarter of 2023

Highlighted significant research, preclinical advances and platform technology progress at third annual R&D Day

Appointed Kristin Yarema, Ph.D., as President, Cell Therapy, adding extensive oncology and allogeneic T cell immunotherapy experience to the Company's leadership team

SAN DIEGO, May 9, 2023 — Poseida Therapeutics, Inc. (Nasdaq: PSTX), a clinical-stage cell and gene therapy company advancing a new class of treatments for patients with cancer and rare diseases, today announced updates and financial results for the first quarter ended March 31, 2023.

"In the first quarter, we continued to advance our clinical and research stage efforts as well as enhanced our leadership with the recent appointment of Kristin Yarema, Ph.D., as President, Cell Therapy," said Mark Gergen, Chief Executive Officer of the Company. "In our allogeneic CAR-T portfolio, we are actively enrolling patients in the Phase 1 studies for P-MUC1C-ALLO1 and P-BCMA-ALLO1 and remain on track for an IND for P-CD19CD20-ALLO1 mid-year. These initial allogeneic clinical programs are designed to evaluate many aspects of our unique high-T_{SCM} allogeneic platform including dosing strategies, pre-conditioning regimens, potential biomarkers and many other factors. In our gene therapy portfolio, we are in discussions with Takeda about our collaboration following the news that they have made some strategic decisions in their research priorities and will update when appropriate. In the meantime, we remain excited about the strong progress made on all gene therapy programs and look forward to giving six preclinical presentations at the American Society of Gene and Cell Therapy annual meeting next week."

Program Updates

CAR-T Programs

In cell therapy, the Company is focused on three allogeneic CAR-T programs with two programs currently progressing in Phase 1 clinical trials and one expected IND during the year:

MUC1-C Program

P-MUC1C-ALLO1 is an allogeneic CAR-T product candidate targeting solid tumors derived from epithelial cells, including breast and ovarian cancers. The Company is currently evaluating P-MUC1C-ALLO1 in a Phase 1 clinical trial and presented early clinical data in December 2022 at the European Society for Medical Oncology Immuno-Oncology 2022 Annual Congress (ESMO I-O) in Geneva, Switzerland. The Company currently expects to present further clinical updates for the program at a medical meeting in 2023.

BCMA Program

P-BCMA-ALLO1 is an allogeneic CAR-T product candidate being developed to target relapsed/refractory multiple myeloma (R/R MM) in partnership with Roche. The Company is currently evaluating P-BCMA-ALLO1 in a Phase 1 clinical trial and shared early clinical data from the

program at ESMO I-O in December 2022. The Company currently expects to present further clinical updates for the program at a medical meeting in 2023, subject to clearance with Roche.

CD19CD20 Program
P-CD19CD20-ALLO1 is a preclinical allogeneic CAR-T product being developed to target B-cell malignancies in partnership with Roche. P-CD19CD20-ALLO1 is the Company's first dual CAR program and contains two fully functional CAR molecules to target cells that express either CD19 or CD20. The Company believes that by targeting both CD19 and CD20, there is potential to overcome potential antigen escape that has been observed by others. The Company expects to file an IND for P-CD19CD20-ALLO1 in mid-2023.

Gene Therapy Programs
The Company is advancing multiple preclinical gene therapy programs in liver-directed diseases:

OTC Program
P-OTC-101 is an in vivo program for the treatment of urea cycle disease caused by congenital mutations in the ornithine transcarbamylase (OTC) gene. The Company is developing the P-OTC-101 program utilizing a hybrid delivery system and working on an updated timeline for the program. The Company presented data at its R&D Day in February 2023, highlighting continued advancements in preclinical models leading towards a potential functional cure of OTC Deficiency.

FVIII Program
The Company is advancing its P-FVIII-101 preclinical program partnered with Takeda, which is in development for the in vivo treatment of Hemophilia A. P-FVIII-101 utilizes piggyBac gene modification delivered via lipid nanoparticle that has demonstrated stable and sustained Factor VIII expression in animal models. The Company is presenting preclinical data from this program at the upcoming American Society of Gene and Cell Therapy (ASGCT) 26th Annual Meeting being held in Los Angeles on May 16-20, 2023.

PAH Program
Announced at the Company's R&D Day in February 2023, P-PAH-101 is a liver-directed gene therapy partnered with Takeda to treat Phenylketonuria (PKU), an inherited genetic disorder caused by mutations in the phenylalanine hydroxylase (PAH) gene resulting in buildup of phenylalanine in the body. If left untreated, PKU can affect a person's cognitive development. P-PAH-101 utilizes piggyBac technology combined with its hybrid adeno-associated virus (AAV) and nanoparticle delivery system. The Company's preclinical data has demonstrated the potential to resolve phenylalanine to normal levels following a single treatment in juvenile and adult mice. P-PAH-101 is currently in preclinical development.

Leadership Updates

Kristin Yarema, Ph.D., Appointed President, Cell Therapy
In April 2023, the Company announced the appointment of Kristin Yarema, Ph.D., as President, Cell Therapy, to lead the Company's drug development programs in cell therapy, including its collaboration with Roche. She joined the Company after most recently serving as Chief Commercial Officer at Atara Biotherapeutics, where she led the commercialization of EBVALLO™, which became the world's first marketed allogeneic T cell therapy after receiving regulatory approval in Europe for the treatment of a rare lymphoma. Prior to Atara, she held a series of U.S. and global commercial leadership roles at Amgen and Novartis in hematology-oncology among other therapeutic areas.

Rafael G. Amado, M.D., Appointed to Board of Directors
In April 2023, Rafael G. Amado, M.D., was appointed to the Company's Board of Directors. Dr. Amado is currently President, Head of Global Oncology Research and Development at Zai Lab, a public biopharmaceutical company. Prior to Zai Lab, Dr. Amado served as Executive Vice President, Head of Research and Development and Chief Medical Officer from September 2019 to December 2022 at Allogene Therapeutics, Inc. and President of Research and Development from August 2018 to August 2019 and Chief Medical Officer from March 2015 to August 2018 at Adaptimmune, LLC.

Financial Results for the First Quarter 2023

“We continue to be disciplined on spend and evaluate plans and options to help us further manage our cash burn rate,” said Johanna Mylet, Chief Financial Officer at Poseida. “We have been operating at the low end of our guided cash utilization range and our current base plan should allow us to preserve our runway into at least mid-2024, and possibly further depending on other decisions, including business development opportunities.”

Revenues
Revenues were $10.3 million for the first quarter ended March 31, 2023, compared to $1.4 million for the same period in 2022. The increase of revenues was primarily due to revenues earned from the collaboration and license agreement with Roche, which became effective in the third quarter of 2022.

Research and Development Expenses
Research and development expenses were $38.1 million for the first quarter ended March 31, 2023, compared to $48.9 million for the same period in 2022. The decrease was primarily driven by the wind-down of the Company’s clinical development activities associated with our autologous programs and related contract termination expense in the prior year and the transition of manufacturing to the Company’s internal pilot plant for P-BCMA-ALLO1, partially offset by increases in the number of ongoing clinical trials, including enrollment and manufacturing for the P-MUC1C-ALLO1 and P-BCMA-ALLO1 Phase 1 clinical trials, and increases related to the Company’s preclinical stage programs due to an increase in research collaboration activity and personnel and facilities expenses as a result of increased headcount.

General and Administrative Expenses
General and administrative expenses for the first quarter ended March 31, 2023 were $11.8 million compared to $9.5 million for the same period in 2022. The increase was primarily related to an increase in stock-based compensation expense due to a one-time modification associated with the retirement of the Company’s former Executive Chairman.

Net Loss
Net loss was $38.8 million for the first quarter ended March 31, 2023, compared to $58.1 million for the same period of 2022.

Cash Position
As of March 31, 2023, the Company's cash, cash equivalents and short-term investments balance was $247.2 million. The Company expects that its cash, cash equivalents and short-term investments together with the remaining near-term milestones and other payments from Roche will continue to be sufficient to fund operations into at least mid-2024.

About Poseida Therapeutics, Inc.
Poseida Therapeutics is a clinical-stage biopharmaceutical company advancing differentiated cell and gene therapies with the capacity to cure certain cancers and rare diseases. The Company's pipeline includes allogeneic CAR-T cell therapy product candidates for both solid and liquid tumors as well as in vivo gene therapy product candidates that address patient populations with high unmet medical need. The Company's approach to cell and gene therapies is based on its proprietary genetic editing platforms, including its non-viral piggyBac® DNA Delivery System, Cas-CLOVER™ Site-Specific Gene Editing System and nanoparticle and hybrid gene delivery technologies. The Company has formed global strategic collaborations with Roche and Takeda to unlock the promise of cell and gene therapies for patients. Learn more at www.poseida.com and connect with Poseida 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, expected plans with respect to clinical trials, including timing of regulatory submissions and approvals and clinical data updates; potential fees, milestones and other payments that the Company may receive pursuant to its collaboration agreements; anticipated timelines and milestones with respect to the Company's development programs and manufacturing activities and capabilities; the potential capabilities and benefits of the Company's technology platforms and product candidates; estimates of the Company's cash balance, expenses, capital requirements, any future revenue, and need for additional financing; the Company's ability to attract and/or retain new and existing collaborators with relevant expertise and its expectations regarding the potential benefits to be derived from any such collaborations; and the Company's plans and strategy with respect to developing its technologies and product candidates. 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 the Company'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, the Company's reliance on third parties for various aspects of its business; risks and uncertainties associated with development and regulatory approval of novel product candidates in the biopharmaceutical industry; the Company's ability to retain key scientific or management personnel; the fact that the Company will have limited control over the efforts and resources that its strategic partners devote to advancing development programs under their respective collaboration agreements and the Company may not receive the potential fees and payments under the collaboration agreements and the ability of its strategic partners to early terminate the collaborations, such that the Company may not fully realize the benefits of such collaborations; and the other risks described in the Company'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. The Company 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,	
	2023	2022
Revenues:		
Collaboration revenue	$ 10,343	$ 1,435
Total revenue	10,343	1,435
Operating expenses:		
Research and development	38,052	48,850
General and administrative	11,807	9,546
Total operating expenses	49,859	58,396
Loss from operations	(39,516)	(56,961)
Other income (expense):		
Interest expense	(2,028)	(1,077)
Other income (expense), net	2,697	(19)
Net loss	$ (38,847)	$ (58,057)
Net loss per share, basic and diluted	$ (0.45)	$ (0.93)
Weighted-average number of shares outstanding, basic and diluted	86,265,223	62,555,915

SELECTED BALANCE SHEET DATA

	March 31, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	$ 247,201	$ 282,493
Total assets	313,621	351,837
Total liabilities	156,056	164,242
Total stockholders' equity	157,565	187,595

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