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 14, 2024

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 14, 2024, Poseida Therapeutics, Inc. (the "Company") issued a press release announcing its updates and financial results for the first quarter ended March 31, 2024. 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 14, 2024.
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 14, 2024

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

Exhibit 99.1

Poseida Therapeutics Provides Updates and Financial Results for the First Quarter of 2024

Expanded strategic relationship with Astellas with new research collaboration leveraging Poseida's proprietary allogeneic CAR-T platform to develop cell therapies targeting solid tumors

Generated $95 million in milestone and upfront payments to-date in 2024, including $50 million from Astellas collaboration and $45 million from continued execution in the Company's CAR-T partnership with Roche

Presented promising early data at AACR demonstrating clinical responses with P-BCMA-ALLO1 in multiple myeloma patients following progression after prior BCMA-targeted therapy

Presented non-human primate (NHP) data at ASGCT highlighting favorable safety and high-fidelity liver editing for lead non-viral investigational genetic medicine, P-KLKB1-101

SAN DIEGO, May 14, 2024 — Poseida Therapeutics, Inc. (Nasdaq: PSTX), a clinical-stage allogeneic cell therapy and genetic medicines company advancing differentiated non-viral treatments for patients with cancer and rare diseases, today announced updates and financial results for the first quarter ended March 31, 2024.

"We see 2024 as a breakout year for Poseida as we make great strides across our cell therapy and genetic medicine programs and continue to cultivate and expand high value collaborations that highlight Poseida's role as the partner of choice in allogeneic CAR-T," said Kristin Yarema, Ph.D., President and Chief Executive Officer of Poseida Therapeutics. "The promising updates from our BCMA program at AACR 2024 reinforce our belief that P-BCMA-ALLO1 has the potential to treat a broad range of patients with multiple myeloma, including those who are BCMA-therapy naïve and those who have relapsed or are refractory to BCMA-targeted therapies such as autologous CAR-T or T-cell engaging bispecifics. We continue to advance our MUC1-C solid tumor and CD19CD20 B-cell malignancy programs and are on track to provide updates across our wholly owned and Roche-partnered CAR-T programs in the second half of 2024."

"The proprietary and powerful genetic engineering toolkit that we have used ex vivo to deliver our allogeneic CAR-T programs demonstrates compelling potential for the development of in vivo genetic medicines. Moving forward, we are focusing our gene therapy pipeline on fully nonviral approaches, highlighted by our lead gene editing and gene insertion programs, P-KLKB1-101 and P-FVIII-101. New preclinical data supporting the advancement of both programs was recently presented at the ASGCT annual meeting, further confirming their potential to address significant unmet patient need."

Recent Accomplishments

Cell therapy

Announced strategic research collaboration and license agreement with Astellas' wholly owned subsidiary, Xyphos Biosciences, to develop novel cell therapies for solid tumors. The collaboration will utilize Poseida's proprietary allogeneic CAR-T platform with Xyphos' ACCEL™ technology to create one Poseida-developed CAR-T construct to form the basis of two *convertible*CAR® product candidates in areas beyond Poseida's core pipeline focus. Under the research agreement, Poseida is receiving $50 million upfront plus potential development and sales milestones and contingency payments of up to $550 million in total and will be reimbursed for costs incurred as part of the research agreement. Poseida is eligible for up to low double digit tiered royalties as a percentage of net sales. This new collaboration expands the strategic relationship between the companies, which began in 2023 with Astellas' $25 million equity investment in Poseida and concurrent one-time $25 million payment for a right of exclusive negotiation and first refusal to license Poseida's P-MUC1C-ALLO1 program also targeting solid tumors.

Presented new allogeneic CAR-T data at the American Association for Cancer Research (AACR) Annual Meeting from the Company's Phase 1 study of P-BCMA-ALLO1 as well as a comparison of lymphodepletion needs in hematologic vs. solid tumor settings.

- **The P-BCMA-ALLO1 data presented at AACR 2024 builds on the Company's earlier ASH 2023 data, which demonstrated a 100% overall response rate in patients who had not been previously treated with a BCMA-targeted therapy who received adequate lymphodepletion. This new data from a subset of patients in the ongoing Phase 1 study showed that three of five (60%) patients with relapsed/refractory multiple myeloma (RRMM) who had progressed following one or more prior BCMA-targeted therapies achieved clinical responses with P-BCMA-ALLO1. Overall, P-BCMA-ALLO1 was well tolerated, and findings suggest that P-BCMA-ALLO1 could be an appropriate treatment for a broad range of patients with multiple myeloma, including BCMA-naïve patients and those with relapsed/refractory disease whose cancer progressed following prior BCMA-targeted therapy.**
- **Following efforts to optimize its allogeneic CAR-T therapies, Poseida presented new data underscoring the need for higher lymphodepletion chemotherapy doses when treating solid tumors vs. hematologic malignancies. Drawing from these insights, the Company is exploring higher lymphodepletion regimens in its Phase 1 clinical trial of P-MUC1C-ALLO1 for solid tumors.**

P-BCMA-ALLO1 granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of multiple myeloma, highlighting the potential of T_{SCM}-rich allogeneic CAR-T therapies to offer the optimal combination of clinical results, on-demand availability, and high-volume production, while supporting broad access to off-the-shelf allogeneic CAR-T therapies.

Advanced Roche partnership including completion of certain program-related development milestones that resulted in the receipt of a $30 million payment in the first quarter of 2024 and the anticipated receipt of an additional $15 million milestone payment in May 2024. Looking forward, Poseida will continue to have responsibility for the expanded Phase 1 trial of P-BCMA-ALLO1 and the related operational activities, for which Roche will provide reimbursement.

Genetic medicine

Poseida's gene therapy platform technologies, which are based in part on experience developing the Company's allogeneic CAR-T platform, demonstrate significant potential to support the development of in vivo genetic medicines. The Company highlighted these scientific advancements and its pipeline strategy during a virtual Gene Therapy R&D Day, including its fully non-viral approach to genetic medicine employing differentiated gene delivery, gene editing and gene insertion technology.

- **The key advantages of Poseida's fully non-viral approach include low immunogenicity, lower oncogenic risks, integrated and stable expression, personalized titratable dosing, and a favorable cost of goods compared to viral gene therapies.**
- **Poseida is focused on advancing its two fully non-viral lead programs in rare disease with significant unmet patient need: P-KLKB1-101 for Hereditary Angioedema (HAE), which is the Company's first in vivo gene editing program using Cas-CLOVER, and P-FVIII-101, which is the Company's gene insertion program for the treatment of Hemophilia A.**
- **Poseida's hybrid programs remain promising for applications where high levels of editing in liver cells are required and Poseida may opportunistically consider partnering transactions.**

Presented multiple presentations at the American Society of Gene and Cell Therapy 27th Annual Meeting (ASGCT) featuring lead genetic medicine approaches, P-KLKB1-101 and P-FVIII-101.

- **P-KLKB1-101 interim data in a non-human-primate model showed that the Cas-CLOVER nuclease formulation was well tolerated and yielded levels of editing approaching therapeutic efficacy in early read-out doses. Studies in human cells and rodent models show high fidelity and high efficiency KLKB1 editing within a target range for correction of HAE. P-KLKB1-101 demonstrated a highly controlled dose-dependent reduction in kallikrein protein and confirmatory studies revealed minimal off-target editing.**
- **P-FVIII-101 preclinical data support advancing to non-human primate studies based on sustained FVIII expression over 13 months from a single dose, along with data supporting mitigated immunogenicity and ability to fine tune FVIII expression levels via repeat dosing and/or Poseida's proprietary modulator switch.**
- **Additional data describing the Company's advancements in lipid nanoparticle (LNP) technology, intracellular targeting agents and nuclease fidelity.**

Anticipated Milestones

- **P-BCMA-ALLO1 in RRMM: clinical update planned for the second half of 2024 subject to coordination with Roche.**
- **P-MUC1C-ALLO1 in solid tumors: clinical update planned for the second half of 2024.**
- **P-CD19CD20-ALLO1 in B-cell malignancies: interim data update anticipated in the second half of 2024 subject to coordination with Roche.**

Other Operational Updates

Leadership Updates

Poseida appointed Syed Rizvi, M.D., as Chief Medical Officer in April 2024. Dr. Rizvi is a seasoned executive with over 20 years of experience across all stages of drug development, including clinical strategy, execution, and commercialization. He most recently served as Chief Medical Officer of Caribou Biosciences, where he was responsible for overall strategy and execution of all clinical development programs, and also held leadership positions at Chimeric Therapeutics, Legend Biotech, and Celgene.

Financial Results for the First Quarter 2024

Revenues

Revenues were $28.1 million for the first quarter ended March 31, 2024, compared to $10.3 million for the same period in 2023. The increase was primarily due to revenue recognized from the Astellas strategic investment and an increase in Roche-related collaboration activity.

Research and Development Expenses

Research and development expenses were $42.9 million for the first quarter ended March 31, 2024, compared to $38.1 million for the same period in 2023. The increase was primarily due to an increase in allogeneic clinical stage programs, driven mainly by an increase in overall enrollment of our allogeneic programs and the initiation of our third allogeneic clinical trial, P-CD19CD20-ALLO1.

General and Administrative Expenses

General and administrative expenses were $9.8 million for the first quarter ended March 31, 2024, compared to $11.8 million for the same period in 2023. The decrease was primarily due to lower personnel expenses, mainly caused by a decrease in stock-based compensation expense driven by a one-time expense associated with the resignation of our former Executive Chairman in 2023.

Net Loss

Net loss was $24.3 million for the first quarter ended March 31, 2024, compared to net loss of $38.8 million for the same period of 2023.

Cash Position

As of March 31, 2024, the Company's cash, cash equivalents and short-term investments balance was $198.6 million. In addition, the Company will receive $50 million from the recent Astellas research collaboration and $15 million from a recent milestone achievement within the Roche collaboration. The Company expects that its cash, cash equivalents and short-term investments together with these and other remaining near-term milestones and other payments from Roche will be sufficient to fund operations into the second half of 2025. Potential additional payments under the Roche Collaboration Agreement and/or potential additional business development could further extend cash runway.

About Poseida Therapeutics, Inc.

Poseida Therapeutics is a clinical-stage biopharmaceutical company advancing differentiated allogeneic cell therapies and genetic medicines with the capacity to cure certain cancers and rare diseases. The Company's pipeline includes investigational allogeneic CAR-T cell therapies for both solid tumors and hematologic cancers as well as investigational in vivo genetic medicines that address patient populations with high unmet medical need. The Company's approach is based on its proprietary genetic editing platforms, including its non-viral piggyBac® DNA Delivery System, Cas-CLOVER™ Site-Specific Gene Editing System, Booster Molecule and nanoparticle gene delivery

technologies, as well as in-house GMP cell therapy manufacturing. The Company has formed strategic collaborations with Roche and Astellas to unlock the promise of cell therapies for cancer patients. Learn more at www.poseida.com and connect with Poseida on X 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, reimbursements, milestones, royalty payments and other payments that the Company may receive pursuant to its collaboration agreements with Roche and Astellas, including related timing; 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, including the efficacy, safety and tolerability profile of such product candidates; the quote from Dr. Yarema; estimates of the Company's cash balance, cash runway, expenses, capital requirements and any future revenue; the Company's ability to exploit and consummate additional business development opportunities, including with Roche and Astellas, and any anticipated impact on the Company's cash balance and cash runway; 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 associated with conducting clinical trials; whether any of the Company's product candidates will be shown to be safe and effective; the Company's ability to finance continued operations; the Company's reliance on third parties for various aspects of its business; competition in the Company's target markets; the Company's ability to protect its intellectual property; 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 collaborators devote to advancing development programs under their respective collaboration agreements; the fact that the Company may not receive the potential fees, reimbursements and payments under the collaboration agreements; the ability of the Company's collaborators to early terminate the collaborations, such that the Company may not fully realize the benefits of the 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
(In thousands, except share and per share amounts)

STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Revenues:		
Collaboration revenue	$ 28,142	$ 10,343
Total revenue	28,142	10,343
Operating expenses:		
Research and development	42,921	38,052
General and administrative	9,798	11,807
Total operating expenses	52,719	49,859
Loss from operations	(24,577)	(39,516)
Other income (expense):		
Interest expense	(2,253)	(2,028)
Other income, net	2,556	2,697
Net loss	$ (24,274)	$ (38,847)
Net loss per share, basic and diluted	$ (0.25)	$ (0.45)
Weighted-average number of shares outstanding, basic and diluted	96,019,579	86,265,223

SELECTED BALANCE SHEET DATA

	March 31, 2024	December 31, 2023
	(Unaudited)	
Cash, cash equivalents and short-term investments	$ 198,646	$ 212,202
Total assets	262,580	273,885
Total liabilities	177,986	170,184
Total stockholders' equity	84,594	103,701

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