

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): March 05, 2024

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  
(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 March 7, 2024, Poseida Therapeutics, Inc. (the “Company”) issued a press release announcing its updates and financial results for the fourth quarter and full year ended December 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On March 5, 2024, Brent Warner informed the Company of his intent to resign from his position as the Company’s President, Gene Therapy, effective April 1, 2024, to pursue an external career opportunity.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release of Poseida Therapeutics, Inc., dated March 7, 2024.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: March 7, 2024

By: /s/ Johanna M. Mylet

Name: Johanna M. Mylet

Title: Chief Financial Officer

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## Poseida Therapeutics Provides Updates and Financial Results for the Fourth Quarter and Full Year 2023

*Lead asset P-BCMA-ALLO1 Phase 1 clinical trial data presented at ASH 2023 demonstrated 82% ORR and favorable emerging safety and reliability profile*

*Initiated clinical trial of Phase 1 P-CD19CD20-ALLO1, the Company's first allogeneic dual CAR-T program*

*Allogeneic CAR-T data to be presented at AACR in April 2024 describing activity of P-BCMA-ALLO1 in BCMA-experienced patients and comparison of lymphodepletion needs in heme vs. solid tumor settings*

*P-FVIII-101 gene therapy data presented at ASH and Company to host Gene Therapy R&D Day April 17, 2024*

**SAN DIEGO, March 7, 2024 — 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 business updates and financial results for the fourth quarter and full year ended December 31, 2023.**

**"2024 looks to be a breakout year for Poseida as we build on the recent allogeneic BCMA clinical data presented at ASH, which demonstrated the potential of our high-T<sub>SCM</sub> allogeneic CAR-T therapies to offer effective, safe, and reliable treatment addressing unmet needs in multiple myeloma. We are able to achieve high levels of CAR-T<sub>SCM</sub> in our products because of our proprietary, nonviral technologies," said Kristin Yarema, Ph.D., President and Chief Executive Officer. "Over the coming months we are planning data readouts for each of our three clinical-stage CAR-T programs, all of which are manufactured at our own GMP facility and will discuss the latest progress of our gene therapy programs at our R&D Day in April."**

### Recent 2023 Accomplishments

#### *Cell therapy*

- Presented positive data from the Phase 1 study of P-BCMA-ALLO1 in relapsed/refractory multiple myeloma (RRMM) at ASH: In December 2023, the Company presented data from its Phase 1 study of P-BCMA-ALLO1 at the 65<sup>th</sup> American Society of Hematology (ASH) Annual Meeting and Exposition. These early data support the Company's belief that T<sub>SCM</sub>-rich allogeneic CAR-Ts have the potential to offer promising product response rates, safety profiles, and rapid patient access which if confirmed could provide differentiation from currently available therapies, including autologous CAR-T therapies. The study used product from 6 different CAR-T lots produced from 6 different donors with data demonstrating:

- 82% ORR in deep clinical responses, including sCRs and MRD-negative patients from off-the-shelf, allogeneic BCMA-targeted CAR-T in heavily pretreated patients receiving adequate lymphodepletion.
- 100% ORR in those patients who were not previously treated with a BCMA-targeted bispecific T-cell engaging antibody.
- Favorable emerging safety and reliability profile, with all (100%) intent-to-treat patients receiving therapy with no use of bridging chemotherapy or other anti-myeloma bridging therapies and low incidences of CRS and neurotoxicity observed (all  $\leq$  Grade 2).
- Preliminary data suggest that allogeneic TSCM-rich CAR-T cells traffic to bone marrow, differentiate to cell-killing effector T cells and persist at least 6 weeks, supporting the hypothesis of cell persistence at tumor-relevant sites.
- 8 of 9 responding patients still in response at data cut off.
- **Continued enrollment of P-MUC1C-ALLO1:** The Company continued enrollment in the Phase 1 clinical trial of P-MUC1C-ALLO1 for solid tumors. Drawing from insights gained in allogeneic BCMA CAR-T, it is exploring various dosing approaches, including higher lymphodepletion, cell dose, and scheduling in the MUC1C program. Data from the allogeneic BCMA CAR-T program, presented at ASH, underscored the important role of cyclophosphamide conditioning dose in CAR-T cell expansion and persistence. Patients in arms receiving higher doses (500 mg/m<sup>2</sup> and 1,000 mg/m<sup>2</sup>) demonstrated significantly elevated P-BCMA-ALLO1 levels compared to those in the 300 mg/m<sup>2</sup> cohort. Consequently, the Company is assessing lymphodepleting conditioning regimens with doses exceeding 300 mg/m<sup>2</sup> in the MUC1C program.
- **Advanced programs within hematologic malignancies at all stages, in partnership with Roche, throughout 2023:**
  - Previously announced the expected acceleration of achieving milestones, resulting in the receipt of a \$30 million payment in the first quarter of 2024.
  - Expanded the protocol and continued to enroll patients in the Phase 1 study of P-BCMA-ALLO1, incorporating lymphodepletion learnings from ASH 2023.
  - Continued site activation activities and initiation of enrollment for P-CD19CD20-ALLO1, the Company's first dual, allogeneic CAR-T for B-cell malignancies.
  - Advanced research programs optioned to Roche (P-BCMACD19-ALLO1 for multiple myeloma and P-CD70-ALLO1 for AML).
  - Developed and deployed manufacturing platform improvements to all programs that delivered higher and more consistent levels of cell expansion.

#### *Gene therapy*

- **Presented proof-of-principle data supporting P-FVIII-101 as a potential treatment option for Hemophilia A at ASH:** New preclinical data presented at ASH demonstrated the capabilities of the Company's non-viral approach in providing stable Factor VIII (FVIII) transgene expression through genomic integration. Additionally, the data highlighted re-dosing, or titrating to efficacy, along with favorable tolerability data for this approach, including 52-week durability data in an adult Hemophilia A mouse model supporting sustained and robust expression.
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## Anticipated Milestones

- **P-BCMA-ALLO1:** The Company plans to present data at the American Association for Cancer Research (AACR) Annual Meeting in San Diego. At AACR, the Company will present data on a subset of recently enrolled patients refractory to initial BCMA targeting therapy. The poster presentation, titled “Clinical Activity of P-BCMA-ALLO1, a B-cell Maturation Antigen (BCMA) Targeted Allogeneic Chimeric Antigen Receptor T-cell (CAR-T) Therapy, in Relapsed Refractory Multiple Myeloma (RRMM) Patients (pts) Following Progression on Prior BCMA Targeting Therapy,” is anticipated to take place on April 8, 2024, 9:00 AM to 12:30 PM PT. Subject to coordination with Roche, the Company plans to provide an additional clinical update on this program at a scientific meeting in the second half of 2024.
- **P-MUC1C-ALLO1:** The Company plans to review initial clinical findings from the Phase 1 clinical trial in solid tumors at AACR related to cell expansion and lymphodepletion regimens. The poster presentation, titled “Solid Tumor Patients Require Higher Cyclophosphamide Dose than Multiple Myeloma Patients to Achieve Adequate Lymphodepletion (LD) Necessary to Enable Allogeneic CAR-T Expansion,” is anticipated to take place on April 8, 2024, 9:00 AM to 12:30 PM PT. In addition to the AACR presentation, the Company plans to present a more fulsome clinical update at an appropriate forum in the second half of 2024.
- **P-CD19CD20-ALLO1:** Following the initiation of the Phase 1 trial targeting B-cell malignancies in late 2023, the Company expects to provide an interim data update in the second half of 2024, subject to coordination with Roche.
- **P-PSMA-ALLO1:** In January 2024, Poseida announced that it expects to advance its next allogeneic solid tumor program, P-PSMA-ALLO1 in prostate cancer, into IND-enabling studies incorporating the progress and learnings of its previous autologous study and recent advancements in its allogeneic platform in 2024.

The Company believes its T<sub>SCM</sub>-rich CAR-T platform and associated proprietary technologies have strong potential to deliver new therapeutic approaches in autoimmune disease. The Company is actively developing a strategy in inflammation and autoimmune disease and will provide an update at an appropriate time.

## Other Operational Updates and Upcoming Events

### *Poseida R&D Days*

The Company plans to host two R&D Days in 2024 focusing on gene therapy and cell therapy respectively.

The Company plans to host its gene therapy specific R&D Day on April 17, 2024, which will feature presentations from gene therapy management as well as key opinion leaders. The event will highlight the Company’s progress across its proprietary non-viral gene insertion and editing technologies, an update following a strategic review of its portfolio and new preclinical data across in vivo gene therapy programs.

The Company plans to host an R&D Day focusing on cell therapy in the second half of 2024.

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### *Evaluating Opportunities in CAR-T Beyond Oncology*

The Company believes its TSCM-rich CAR-T platform and associated proprietary technologies have strong potential to deliver new therapeutic approaches in autoimmune disease. The Company is developing a strategy in inflammation and autoimmune disease and will provide an update at an appropriate time.

### *Leadership Updates*

Alexander Chapman joined Poseida on February 26, 2024, as Senior Vice President, Investor Relations & Corporate Communications. He has over 20 years' experience spanning a broad range of strategic roles across the biotech sector. Prior to Poseida, he was the Head of Corporate Communications & Investor Relations at Atara Biotherapeutics, the first company in the world to receive regulatory approval for an allogeneic T-cell immunotherapy. Previously, Mr. Chapman held a series of global and U.S. leadership roles at Amgen, including Corporate Affairs, Value, Access & Pricing, and U.S. Business Operations.

Loren Wagner was promoted to the role of Chief Operations Officer in February 2024. Mr. Wagner joined the Company in March 2021 and most recently served as Senior Vice President, Global Operations. He has more than 30 years of industry experience across a variety of manufacturing, quality, and engineering roles. Prior to the Company, Mr. Wagner was the Head of CAR-T Operations at Bristol Myers Squibb/Celgene. Prior to Celgene, he worked for 12 years at Allergan, where he was responsible for the production and distribution of investigational supplies globally.

Brent Warner, who has served as the Company's President, Gene Therapy, will depart Poseida to pursue an external career opportunity effective April 1, 2024.

### **Financial Results for the Fourth Quarter and Full Year 2023**

#### *Revenues*

Revenues were \$25.0 million for the fourth quarter ended December 31, 2023, compared to \$10.1 million for the same period in 2022. The increase was primarily due to revenue earned as a result of a milestone achieved in the fourth quarter under the amendment to the collaboration and license agreement with Roche and increased activity under the collaboration, offset by a decrease in revenue related to Takeda due to the termination of its collaboration agreement in the third quarter of 2023.

For the full year ended December 31, 2023, revenues were \$64.7 million, compared to \$130.5 million for the same period in 2022. The decrease was primarily due to initial license revenue recognized from the collaboration and license agreement with Roche, which became effective in the third quarter of 2022, offset by the revenue recognized related to the research services performed under the collaboration and license agreements with Roche and Takeda, including \$8.9 million of previously deferred revenue recognized as a result of the termination of its collaboration agreement with Takeda in the third quarter of 2023.

#### *Research and Development Expenses*

Research and development expenses were \$42.0 million for the fourth quarter ended December 31, 2023, compared to \$33.9 million for the same period in 2022. The increase was primarily due to an increase in preclinical stage programs and other unallocated expenses due to an increase in research collaboration activity, an increase in personnel expenses as a result of increased headcount, and an increase in clinical stage allogeneic programs, partially offset by a decrease in clinical stage autologous programs driven by the wind-down of the Company's clinical development activities for such programs.

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For the full year ended December 31, 2023, research and development expenses were \$156.8 million, compared to \$152.9 million for the same period in 2022. The increase was primarily due to an increase in preclinical stage programs and other unallocated expenses due to an increase in research collaboration activity, an increase in personnel expenses as a result of increased headcount, an increase in clinical stage allogeneic programs, and an increase in internal costs related to facilities and other expenses, offset by a decrease in clinical stage autologous programs driven by the wind-down of the Company's clinical development activities for such programs.

#### *General and Administrative Expenses*

General and administrative expenses were \$8.9 million for the fourth quarter ended December 31, 2023, compared to \$9.4 million for the same period in 2022. The decrease was primarily due to lower insurance costs.

For the full year ended December 31, 2023, general and administrative expenses were \$37.4 million, compared to \$37.5 million for the same period in 2022. The decrease was primarily due to lower insurance costs, offset by an increase in personnel costs due to an accelerated stock-based compensation expense in the first quarter of 2023 related to a one-time expense associated with the retirement of the Company's former Executive Chairman.

#### *Net Loss*

Net loss was \$25.3 million and \$123.4 million for the fourth quarter and full year ended December 31, 2023, respectively, compared to net loss of \$33.3 million and \$64.0 million for the fourth quarter and full year ended December 31, 2022, respectively.

#### *Cash Position*

As of December 31, 2023, the Company's cash, cash equivalents and short-term investments balance was \$212.2 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 be sufficient to fund operations into the second half of 2025. Potential additional payments under the amended Roche collaboration and license 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 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<sup>®</sup> DNA Delivery System, Cas-CLOVER<sup>™</sup> Site-Specific Gene Editing System, Booster Molecule, and nanoparticle and hybrid gene delivery technologies as well as in-house GMP cell therapy manufacturing. The Company has formed a global strategic collaboration with Roche to unlock the promise of cell therapies for patients with hematological malignancies. Learn more at [www.poseida.com](http://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

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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 agreement with Roche, 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 and safety profile of such product candidates; the quote from Dr. Yarema; estimates of the Company's cash balance, expenses, capital requirements and any future revenue; the Company's ability to exploit and consummate additional business development opportunities, including with Roche, 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 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 Roche devotes to advancing development programs under its collaboration agreement and the Company may not receive the potential fees and payments under the collaboration agreement and the ability of Roche to early terminate the collaboration, such that the Company may not fully realize the benefits of the collaboration; 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.

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**Poseida Therapeutics, Inc.**  
**Selected Financial Data**  
(In thousands, except share and per share amounts)

**STATEMENTS OF OPERATIONS**

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
	(Unaudited)			
<b>Revenues:</b>				
Collaboration revenue	\$ 24,995	\$ 10,051	\$ 64,703	\$ 130,492
Total revenue	<u>24,995</u>	<u>10,051</u>	<u>64,703</u>	<u>130,492</u>
<b>Operating expenses:</b>				
Research and development	42,045	33,904	156,772	152,899
General and administrative	8,859	9,368	37,435	37,539
Total operating expenses	<u>50,904</u>	<u>43,272</u>	<u>194,207</u>	<u>190,438</u>
Loss from operations	(25,909)	(33,221)	(129,504)	(59,946)
<b>Other income (expense):</b>				
Interest expense	(2,267)	(1,975)	(8,671)	(6,370)
Other income, net	2,827	2,170	14,852	2,858
Net loss before income tax	<u>(25,349)</u>	<u>(33,026)</u>	<u>(123,323)</u>	<u>(63,458)</u>
Income tax expense	—	(292)	(107)	(544)
Net loss	<u>\$ (25,349)</u>	<u>\$ (33,318)</u>	<u>\$ (123,430)</u>	<u>\$ (64,002)</u>
Net loss per share, basic and diluted	<u>\$ (0.27)</u>	<u>\$ (0.39)</u>	<u>\$ (1.37)</u>	<u>\$ (0.89)</u>
Weighted-average number of shares outstanding, basic and diluted	<u>95,623,219</u>	<u>85,953,375</u>	<u>90,185,096</u>	<u>71,953,703</u>

**SELECTED BALANCE SHEET DATA**

	December 31,	
	2023	2022
Cash, cash equivalents and short-term investments	\$ 212,202	\$ 282,493
Total assets	273,885	351,837
Total liabilities	170,184	164,242
Total stockholders' equity	103,701	187,595

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**Poseida Investor and Media Relations:**  
**Alex Chapman**  
Senior Vice President, IR & Corporate Communications  
IR@poseida.com

**Sarah Thailing**  
Senior Director, IR & Corporate Communications  
PR@poseida.com

