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 07, 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 November 7, 2024, Poseida Therapeutics, Inc. (the "Company") issued a press release announcing its updates and financial results for the third quarter ended September 30, 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 November 7, 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: November 7, 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 Third Quarter of 2024

Strong collaboration momentum with Roche expansion of CAR-T partnership and Astellas nomination of second solid tumor research program target

Cash flow positive for the first nine months of 2024; $130 million generated in milestone and upfront payments to-date

Presented positive interim Phase 1 results for RMAT-designated P-BCMA-ALLO1 with 91% overall response rate and differentiated safety profile in heavily pretreated relapsed/refractory BCMA-exposed and BCMA-naïve multiple myeloma patients

Introduced P-BCMACD19-ALLO1 as wholly-owned program with compelling biologic rationale for autoimmune disease and hematological malignancies

On track to deliver further updates across allogeneic CAR-T pipeline before year-end 2024, including presentations at the 66th American Society of Hematology Annual Meeting in December

SAN DIEGO, November 7, 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, autoimmune and rare diseases, today announced updates and financial results for the third quarter ended September 30, 2024.

"Poseida continues to make excellent progress across all of our key initiatives, highlighted by compelling data presentations from our pipeline of innovative, non-viral allogeneic cell therapy and genetic medicine programs, the expansion and advancement of our collaborations with Roche and Astellas, and our science-backed strategy to apply our platform to the large and growing opportunity for CAR-T in autoimmune diseases," said Kristin Yarema, Ph.D., President and Chief Executive Officer of Poseida Therapeutics. "As a result, we have generated $130 million in non-dilutive, partnership related milestones and payments so far this year, along with $49 million earned through R&D expense reimbursements. This has resulted in Poseida being cash flow positive for the first nine months of the year and extended our cash runway, with additional upside potential from continued execution, clinical progress and business development. We look forward to sharing updates on our CAR-T programs at our upcoming Cell Therapy R&D Day and future medical meetings."

Recent Accomplishments

Cell Therapy

Expanded strategic global collaboration with Roche, including ongoing pipeline progress and the nomination of a new dual CAR-T development candidate.

- **The new candidate is an allogeneic, dual CAR-T therapy targeting known antigens expressed in hematologic malignancies, including multiple myeloma. Poseida and Roche now have three programs under their collaboration, including P-BCMA-ALLO1, an allogeneic**

CAR-T therapy in Phase 1/1b development for multiple myeloma, and P-CD19CD20-ALLO1, an allogeneic dual CAR-T candidate in Phase 1 development for B-cell malignancies. Roche has the option to nominate additional development candidates in the future.

- **P-BCMA-ALLO1 continues to be positioned as a leading clinical-stage allogeneic CAR-T therapy with a compelling and differentiated profile: interim Phase 1 data presented at the International Myeloma Society (IMS) annual meeting in September showed a 91% overall response rate (ORR) in an optimized lymphodepletion arm, including a 100% ORR in B-cell maturation antigen (BCMA)-naïve patients, and an 86% ORR in those who had received at least one prior BCMA- and/or G protein-coupled receptor class C group 5 member D (GPRC5D)-targeting treatment modality, along with differentiated safety results with no dose-limiting toxicities, low rates of cytokine release syndrome (CRS) and immune effector cell neurotoxicity syndrome (ICANS) all Grade 2 or less and no graft vs. host disease or Parkinsonism. No anti-myeloma bridging therapy or prophylaxis with steroids or tocilizumab, no invasive apheresis or manufacturing wait with average time from treatment decision to clinical response of only 3.5 weeks[1] (median time to response of 16 days post initial P-BCMA-ALLO1 therapy). The patients in this study had more advanced disease than the myeloma patients studied in clinical trials of approved autologous CAR-T therapies[2], and in the intent-to-treat population, 100% of patients were infused with P-BCMA-ALLO1.**
- **Poseida's conference call to discuss IMS data featured a fireside chat with leading myeloma experts that highlighted key aspects of the data and provided context on current treatment approaches. The experts highlighted that off-the-shelf availability allows patients to start therapy fast, without need for bridging therapy commonly required by autologous CAR-T, and in some cases, offers a solution for patients who are ineligible for autologous treatments; rapid clinical responses; attractive safety profile; ability to treat patients on an outpatient basis; and ability to treat BCMA-exposed patients as key benefits observed in the trial.**
- **P-BCMA-ALLO1 development continues, with ongoing patient enrollment in the recently initiated Phase 1/1b trial that is using the same lymphodepletion regimen as the optimized lymphodepletion arm described above, including two different cell doses. During the third quarter, P-BCMA-ALLO1 was granted Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA) to treat relapsed/refractory multiple myeloma after three or more prior lines of therapies including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 antibody.**
- **Poseida has secured $80 million from Roche collaboration milestones to-date in 2024, including a milestone payment received in the third quarter related to the initiation of the P-BCMA-ALLO1 Phase 1b clinical trial, and an additional payment for the nomination of the new development candidate in October.**

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[1] Based on interim data from Phase 1 P-BCMA-ALLO1 clinical trial announced in September 2024, Arms A and B.

[2] No head-to-head trial has been conducted evaluating P-BCMA-ALLO1 against other products included herein. Cross-trial data interpretation should be considered with caution as it is limited by differences in study population, study design, and other factors.

Progressed the strategic research collaboration and license agreement with Astellas' wholly owned subsidiary Xyphos Biosciences with the formal nomination of the second high potential program target. Both program targets nominated under the collaboration are well-known and validated solid tumor targets.

Accelerating highly differentiated dual targeting allogeneic CAR-T for autoimmune disease with P-BCMACD19-ALLO1 as first pipeline candidate to address this significant market opportunity. P-BCMACD19-ALLO1 is an allogeneic dual CAR-T candidate currently in IND-enabling studies. We believe targeting BCMA and CD19 could provide the potential to enable more complete immune cell depletion than CAR-Ts targeting only one of the antigens, and that targeting BCMA specifically could provide the potential to deplete autoantibodies from plasma cells, which are believed to be a key driver in many autoimmune diseases and not addressed by targeting CD19 alone. Emerging data from an autologous dual CAR-T targeting BCMA and CD19 has thus far substantiated this dual targeting approach. P-BCMACD19-ALLO1 is also positioned to provide the access benefits of an allogeneic product and a potentially attractive safety profile derived from Poseida's non-viral T_{SCM} approach and other features unique to the Company's CAR-T platform, such as its proprietary safety switch.

Strengthened Poseida's innovation profile and emerging leadership in allogeneic CAR-T with new data at the Society of Hematologic Oncology (SOHO) Twelfth Annual Meeting in September and the Society for Immunotherapy of Cancer (SITC) 39th Annual Meeting & Pre-Conference Programs in November.

- **A new case study demonstrating the reactivation of an autologous Poseida CAR-T therapy with a T-cell engager in a patient with relapsed multiple myeloma was presented at SOHO. The patient attained and remains in stringent complete response over 10 months after CAR-T reactivation. This case highlights the potential of Poseida's T_{SCM}-based CAR-T therapies to deliver a strong anti-myeloma response with long-term remission and CAR-T cell persistence. The Company believes this is the first time that a T-cell engager has been seen to reactivate a CAR-T therapy.**
- **New preclinical data highlighting the potential of Poseida's platform to design and manufacture CAR-TCR-T cells that are rich in stem cell memory T cell (T_{SCM}) and central memory T cells (T_{CM}) for potential use in solid tumors will be presented at SITC on November 9. In solid tumors, multi-antigens are believed to be necessary for efficacy, and CAR+TCR-T cells can recognize and kill single and double antigen target cells and show the potential to synergize with T-cell engagers. Key highlights from the SITC presentation include:**
  - **CAR+TCR-T cells were shown to control single and double antigen-positive tumor growth in vivo, with sustained persistence.**
  - **T-cell engager was used to re-activate and re-direct engrafted CAR+TCR-T cells to control a secondary tumor challenge expressing different antigens echoing the patient case study presented at SOHO and suggesting an approach to address heterogeneous tumors and/or tumors whose composition evolves over time.**

Continued to enroll patients in the Phase 1 clinical trial of P-CD19CD20-ALLO1. In light of the competitive environment for therapies targeting CD19 and CD20, Poseida and Roche anticipate providing initial clinical data from the trial in 2025 once a more complete dataset of the program is available.

Genetic Medicines

Demonstrated ongoing leadership in development of non-viral approaches to genetic medicines, supported by data presentation at the American College of Allergy, Asthma & Immunology (ACAAI) 2024 Scientific Meeting featuring P-KLKB1-101, a non-viral, liver-directed genetic medicine that uses the Company's Cas-CLOVER™ Site-Specific Gene Editing System. The data showed high-fidelity gene editing at KLKB1 for the targeted correction of hereditary angioedema (HAE), the ability for controlled dose response, favorable tolerability and liver editing approaching the desired therapeutic range. The data reinforce the potential of Cas-CLOVER to be a unique and attractive gene editing tool for a variety of diseases, starting with HAE and KLKB1 editing.

In addition, Poseida had a successful INTERACT meeting with the U.S. FDA for P-FVIII-101 in September 2024. The meeting provided Poseida with early engagement and communication with FDA on the program, in order to support efficient development designed to be aligned with FDA standards. INTERACT meetings focus on innovative and emerging technologies covered by the FDA's Center for Biologics Evaluation and Research (CBER).

Other Operational Updates and Upcoming Events

Manufacturing Updates
The Company continues to advance its platform process and analytical capabilities for allogeneic cell therapy manufacturing. Recent analytical enhancements have enabled more precise evaluation of prospective donors as well as providing improved characterization of drug product attributes.

Cell Therapy R&D Day
Poseida will host a cell therapy-focused R&D Day on November 14, 2024, to highlight progress and further opportunities across its clinical-stage and earlier-stage pipeline of differentiated allogeneic CAR-T therapies in oncology and autoimmune disease.

The virtual event and access to the live webcast will be available through the following registration link: https://wsw.com/webcast/cc/pstx7/1467684. Registration for this virtual event and access to a replay of the live webcast will also be available on the Investors & Media section of www.poseida.com. A replay of the webcast will be available for approximately 90 days following the presentation.

Financial Results for the Third Quarter 2024

Revenues
Revenues were $71.7 million for the three months ended September 30, 2024, and $125.9 million for the nine months ended September 30, 2024, compared to $9.4 million and $39.7 million for the same periods in 2023, respectively. The increases were primarily due to milestone recognition and an increase in reimbursed research and development expenses under the Roche Collaboration Agreement, and revenue recognized from the Astellas Strategic Agreements and Astellas Collaboration Agreement.

Research and Development Expenses
Research and development expenses were $41.9 million for the three months ended September 30, 2024, compared to $37.5 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

the Company's allogeneic programs, and by an increase in preclinical stage programs and other unallocated expenses.

Research and development expenses were $130.4 million for the nine months ended September 30, 2024, compared to $114.7 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 the Company's allogeneic programs and the initiation of its third allogeneic clinical trial, P-CD19CD20-ALLO1, and by an increase in preclinical stage programs and other unallocated expenses.

General and Administrative Expenses
General and administrative expenses were $10.1 million for the three months ended September 30, 2024, and $32.1 million for the nine months ended September 30, 2024, compared to $8.1 million and $28.6 million for the same periods in 2023, respectively. The increases were primarily due to increased legal and professional fees as a result of higher patent-related and other consulting costs, and higher personnel expenses.

Net Income (Loss)
Net income was $20.2 million for the three months ended September 30, 2024, and net loss was $35.4 million for the nine months ended September 30, 2024, compared to net loss of $31.8 million and $98.1 million for the three and nine months ended September 30, 2023, respectively.

Cash Position
As of September 30, 2024, the Company's cash, cash equivalents and short-term investments balance was $230.9 million. This includes $115 million in milestone and upfront payments generated in the first nine months of 2024, consisting of a $50 million upfront payment from the Astellas collaboration and $65 million from continued execution in the Company's CAR-T partnership with Roche. 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 early 2026. Potential additional anticipated progress and payments under the Roche Collaboration Agreement and/or potential additional business development could further extend the 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. The Company's pipeline includes investigational allogeneic CAR-T cell therapies for hematologic cancers, autoimmune diseases, and solid tumors, 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 transposon-based 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 meetings and 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, benefits and opportunities of the Company's technology platforms and product candidates, including the efficacy, safety and tolerability profile of such product candidates or any ability to deliver therapeutic approaches in autoimmune disease; 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 upside potential and 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; 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues:				
Collaboration revenue	$ 71,748	$ 9,352	$ 125,863	$ 39,708
Total revenue	71,748	9,352	125,863	39,708
Operating expenses:				
Research and development	41,914	37,482	130,382	114,727
General and administrative	10,092	8,092	32,072	28,576
Total operating expenses	52,006	45,574	162,454	143,303
Income (loss) from operations	19,742	(36,222)	(36,591)	(103,595)
Other income (expense):				
Interest expense	(2,295)	(2,236)	(6,807)	(6,404)
Other income, net	2,831	6,787	8,031	12,025
Net income (loss) before income tax	20,278	(31,671)	(35,367)	(97,974)
Income tax expense	(43)	(107)	(43)	(107)
Net income (loss)	$ 20,235	$ (31,778)	$ (35,410)	$ (98,081)
Net income (loss) per share, basic and diluted	$ 0.21	$ (0.35)	$ (0.37)	$ (1.11)
Weighted-average number of shares outstanding, basic	97,160,467	91,898,347	96,716,649	88,321,943
Weighted-average number of shares outstanding, diluted	98,219,947	91,898,347	96,716,649	88,321,943

SELECTED BALANCE SHEET DATA

	September 30, 2024	December 31, 2023
	(Unaudited)	
Cash, cash equivalents and short-term investments	$ 230,852	$ 212,202
Total assets	293,577	273,885
Total liabilities	206,366	170,184
Total stockholders' equity	87,211	103,701

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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