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 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 March 9, 2023, 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, 2022. 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 March 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: March 9, 2023

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

Poseida Therapeutics Provides Updates and Financial Results for the Fourth Quarter and Full Year 2022

Presented early data from Phase 1 trials of P-MUC1C-ALLO1 and P-BCMA-ALLO1 allogeneic CAR-T cell therapy programs at the European Society for Medical Oncology Immuno-Oncology 2022 Annual Congress (ESMO I-O)

Highlighted preclinical data from P-FVIII-101 gene therapy program at the 64th American Society of Hematology Annual Meeting & Exposition (ASH)

SAN DIEGO, March 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 fourth quarter and full year ended December 31, 2022.

"For Poseida, 2022 was a year of execution, progress and validation for our proprietary technology and programs in both cell and gene therapy. In cell therapy, we advanced two fully allogeneic CAR-T programs into the clinic and presented early clinical data for both programs at ESMO I-O in December 2022. We also established a strategic partnership with Roche, a global leader in oncology, focused on our allogeneic CAR-T platform in hematological indications," said Mark Gergen, Chief Executive Officer of the Company. "In gene therapy, our Takeda-partnered in vivo gene therapy program in Hemophilia A continued to demonstrate promise as a potential functional cure with proof of principle data presented at ASH. Along with the rest of the industry, we continue to manage through headwinds as we deal with macro-economic issues and conditions that can impact multiple aspects of our business. We remain focused on advancing our business and continuing to drive innovation as reflected at our recent R&D Day."

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 ESMO I-O in Geneva, Switzerland. Data highlighted at the meeting showed that P-MUC1C-ALLO1 was well tolerated, with no dose-limiting toxicities (DLTs), cytokine release syndrome (CRS), graft vs host disease (GVHD) or immune effector cell-associated neurotoxicity syndrome (ICANS). In addition, P-MUC1C-ALLO1 showed encouraging clinical activity, including an objective partial response in a breast cancer patient at the lowest dose. The Company expects to present further clinical data 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. P-BCMA-ALLO1 was well tolerated, with no DLTs, CRS, GVHD or ICANS. P-BCMA-ALLO1 demonstrated responses in heavily pre-treated patients with R/R MM at the lowest dose, including in patients who had previously received BCMA-targeted therapy and patients with high-risk disease. In the fourth quarter of 2022, the Company also successfully added the ability to manufacture P-BCMA-ALLO1 at its internal GMP pilot plant in San Diego. The Company expects to present further clinical updates for the program at a medical meeting in 2023, subject to clearance with Roche.

CD19CD20 Program
P-CD19CD20-ALL01 is a preclinical allogeneic CAR-T product being developed to target B-cell malignancies in partnership with Roche. P-CD19CD20-ALL01 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 some of the issues of earlier generation CD19 CAR-T products where antigen escape has been observed. 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 presented preclinical data from this program at the ASH annual meeting in New Orleans in December 2022, which showed that P-FVIII-101 achieved and sustained normalized (>50%) human Factor VIII activity following a single dose and delivered therapeutic Factor VIII activity in mice following single and repeat doses, indicating the potential for dose titration. The data support that, with the Company's piggyBac delivery system, the therapeutic transgene expression cassette can be stably integrated into the genome of liver cells and provide consistent and durable therapeutic activity.

PAH Program
Announced at the Company's R&D Day in February 2023, P-PAH-101 is a liver-directed gene therapy 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 partnered with Takeda and currently in preclinical development.

Expansion of Gene Therapy Scientific Advisory Board

In 2022 the Company announced the formation of its Gene Therapy Scientific Advisory Board (SAB), chaired by George M. Church, Ph.D. In March 2023, the Company announced the appointment of five new members to its Gene Therapy SAB to provide counsel on the Company's gene therapy programs in development.

Financial Results for the Fourth Quarter and Full Year 2022

Revenues

Revenues were $10.1 million and $130.5 million for the fourth quarter and the full year ended December 31, 2022, compared to $31.2 million for both the fourth quarter and the full year ended December 31, 2021. 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, and the Takeda collaboration and license agreement, which became effective in the fourth quarter of 2021.

Research and Development Expenses

Research and development expenses were $33.9 million for the fourth quarter ended December 31, 2022, compared to $39.1 million for the same period in 2021. The decrease was primarily driven by the wind-down of the Company's P-BCMA-101 and P-PSMA-101 autologous programs as the Company transitioned to an allogeneic platform, offset by an increase in personnel expenses as a result of increased headcount, which included an increase in stock-based compensation expense.

For the full year ended December 31, 2022, research and development expenses were $152.9 million, compared to $136.7 million for the same period in 2021. The increase was primarily due to an increase in personnel expenses as a result of increased headcount, which included an increase in stock-based compensation expense, and an increase in overall active clinical programs offset by the wind-down of the Company's P-BCMA-101 autologous program as the Company transitioned to the allogeneic program.

General and Administrative Expenses

General and administrative expenses for the fourth quarter ended December 31, 2022 and 2021, were $9.4 million and $9.6 million, respectively. The decrease was primarily related to a decrease in insurance expense, offset by an increase in personnel expenses due to an increase in headcount. For the full year ended December 31, 2022 and 2021, general and administrative expenses were $37.5 million and $35.9 million, respectively. The increase was primarily related to an increase in personnel expenses due to an increase in headcount, which included an increase in stock-based compensation expense.

Net Income (Loss)

Net loss was $33.3 million for the fourth quarter ended December 31, 2022, compared to a net income of $1.5 million for the same period of 2021. Net loss for the full year ended December 31, 2022 and 2021, were $64.0 million and $125.0 million, respectively.

Cash Position

As of December 31, 2022, the Company's cash, cash equivalents and short-term investments balance was $282.5 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 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; 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
(In thousands, except share and per share amounts)

STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
	(Unaudited)			
Revenues:				
Collaboration revenue	$ 10,051	$ 31,238	$ 130,492	$ 31,238
Total revenue	10,051	31,238	130,492	31,238
Operating expenses:				
Research and development	33,904	39,107	152,899	136,734
General and administrative	9,368	9,609	37,539	35,915
Total operating expenses	43,272	48,716	190,438	172,649
Loss from operations	(33,221)	(17,478)	(59,946)	(141,411)
Other income (expense):				
Interest expense	(1,975)	(840)	(6,370)	(3,358)
Other income, net	2,170	19,787	2,858	19,795
Net income (loss) before income tax	(33,026)	1,469	(63,458)	(124,974)
Income tax expense	(292)	—	(544)	—
Net income (loss)	$ (33,318)	$ 1,469	$ (64,002)	$ (124,974)
Net income (loss) per share, basic and diluted	$ (0.39)	$ 0.02	$ (0.89)	$ (2.01)
Weighted-average number of shares outstanding, basic	85,953,375	62,506,995	71,953,703	62,235,940
Weighted-average number of shares outstanding, diluted	85,953,375	62,980,554	71,953,703	62,235,940

SELECTED BALANCE SHEET DATA

	December 31,	
	2022	2021
Cash, cash equivalents and short-term investments	$ 282,493	$ 206,325
Total assets	351,837	269,309
Total liabilities	164,242	113,098
Total stockholders' equity	187,595	156,211

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