

**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):
August 11, 2022**

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
(I.R.S. 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

N/A

(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
Common Stock, par value \$0.0001 per share

Trading Symbol(s)
PSTX

Name of each exchange on which registered
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 August 11, 2022, Poseida Therapeutics, Inc. (the “Company”) issued a press release announcing its updates and financial results for the second quarter ended June 30, 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 August 11, 2022.
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: August 11, 2022

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



Poseida Therapeutics Provides Updates and Financial Results for the Second Quarter of 2022

Announced strategic collaboration with Roche, with a \$110 million upfront payment, to focus on the research and development of allogeneic CAR-T cell therapies directed to hematologic malignancies

Completed an underwritten public offering adding multiple quality institutional shareholders with gross proceeds of \$80.5 million

Well capitalized with cash runway into at least mid-2024

SAN DIEGO, August 11, 2022 — Poseida Therapeutics, Inc. (Nasdaq: PSTX), a clinical-stage biopharmaceutical company utilizing proprietary genetic engineering platform technologies to create cell and gene therapeutics with the capacity to cure, today announced business updates and financial results for the second quarter ended June 30, 2022.

“We continue to advance our pipeline in both cell and gene therapy, powered by strategic collaborations that validate our unique genetic engineering platform technologies while giving us access to resources and non-dilutive capital,” said Mark Gergen, Chief Executive Officer of Poseida. “In cell therapy, we recently announced a broad partnership with Roche focused on developing allogeneic CAR-T cell therapies in hematologic malignancies, including P-BCMA-ALLO1 in multiple myeloma, while preserving a large opportunity for Poseida within the solid tumor space. We look forward to delivering on future milestones with Roche in cell therapy, with our partner Takeda in liver- and HSC-directed in vivo gene therapy, as well as our internal programs in both cell and gene therapy as we continue to execute on future opportunities for growth.”

Business Development Update

Cell Therapy Collaboration with Roche

In August, the Company announced it had entered into a strategic collaboration and license agreement with Roche focused on the research and development of allogeneic CAR-T cell therapies directed to hematologic malignancies utilizing Poseida's proprietary genetic engineering platforms.

Under the agreement, Roche will receive from Poseida either exclusive rights or options to develop and commercialize a number of allogeneic CAR-T programs in Poseida's portfolio that are directed to hematologic malignancies, including P-BCMA-ALLO1, an allogeneic CAR-T for the treatment of relapsed/refractory multiple myeloma, or R/R MM, and for which a Phase 1 study is underway, and P-CD19CD20-ALLO1, an allogeneic dual CAR-T for the treatment of B cell malignancies. The Company anticipates an IND filing and initiation of a Phase 1 clinical trial for P-CD19CD20-ALLO1 in the first half of 2023.

Poseida will receive \$110.0 million upfront from Roche and could receive up to \$110.0 million in near-term fees and milestone and other payments. In addition, subject to Roche exercising its options and contingent on achievement of specified development, regulatory, and net sales milestone events, Poseida is eligible to receive payments potentially up to \$6.0 billion in aggregate value, as well as tiered net sales royalties into the low double digits, across the multiple programs.

For a subset of both the Poseida portfolio programs licensed or optioned to Roche and the parties' future collaboration programs, Poseida will conduct the Phase 1 studies and manufacture clinical materials before transitioning the programs to Roche for further development and commercialization. Roche will be solely responsible for the late-stage clinical development and global commercialization of all products that are subject to the collaboration. The effectiveness of the agreement is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act, or HSR Act.

Program Updates

The Company currently has three ongoing CAR-T programs in the clinic, including two allogeneic CAR-T programs progressing in Phase 1 clinical trials:

BCMA Program

P-BCMA-ALLO1 is an allogeneic CAR-T program targeting R/R MM. The Company is currently evaluating P-BCMA-ALLO1 in a Phase 1 clinical trial and this program is now partnered with Roche. Poseida expects initial clinical data from its Phase 1 clinical trial in the second half of 2022 subject to coordination with its partner, Roche.

MUC1C Program

P-MUC1C-ALLO1 is an allogeneic CAR-T product candidate targeting solid tumors derived from epithelial cells, including breast and ovarian cancers. Poseida is currently evaluating P-MUC1C-ALLO1 in a Phase 1 clinical trial, with an initial clinical data update on the program expected in the second half of 2022.

PSMA Program

P-PSMA-101 is a solid tumor autologous CAR-T product candidate targeting prostate-specific membrane antigen, or PSMA, being developed to treat patients with metastatic castrate-resistant prostate cancer, or mCRPC, and the Company has recently added salivary gland carcinoma to its clinical protocol. Poseida is currently evaluating P-PSMA-101 in a Phase 1 clinical trial and presented encouraging preliminary results from its Phase 1 clinical trial of P-PSMA-101 in its first solid tumor indication on February 2022 at ASCO-GU. The Company may provide a further clinical update at a scientific meeting or forum, likely in 2023. Poseida also has a second-generation program, P-PSMA-ALLO1, which is an allogeneic program, targeting PSMA utilizing a VH binder, in preclinical development.

Liver-Directed Gene Therapy Programs

Poseida is advancing multiple gene therapy programs in liver-directed diseases, including its wholly-owned P-OTC-101 program for the in vivo treatment of the urea cycle disease caused by congenital mutations in the ornithine transcarbamylase (OTC) gene. The Company has made the decision to develop the P-OTC-101 program utilizing a hybrid delivery system and is working on an updated timeline for the program.

Poseida is also advancing its P-FVIII-101 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.

Other Business and Board Leadership Updates

Underwritten Public Offering

On August 8, 2022, the Company completed the sale of an aggregate of 23,000,000 shares of its common stock in an underwritten public offering, at a price of \$3.50 per share, including 3,000,000 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares. The net proceeds to Poseida from the offering were approximately \$75.3 million after deducting underwriting discounts and commissions and estimated offering expenses.

George M. Church, Ph.D., to Chair Poseida's Gene Therapy Scientific Advisory Board

In July 2022, the Company announced that renowned geneticist George M. Church, Ph.D., will serve as chair of the Company's newly formed Gene Therapy Scientific Advisory Board. In this role, Dr. Church will provide advice and counsel on the research and development efforts that drive the Company's innovative gene therapies.

Charles M. Baum, M.D., Ph.D., Appointed to Board of Directors

In May 2022, Charles M. Baum, M.D., Ph.D., was appointed to the Company's Board of Directors. Dr. Baum is currently President, Head of Research and Development, and a member of the Board of Directors at Mirati Therapeutics Inc., a company he founded and where he served as CEO from 2012 to 2021.

Financial Results for the Second Quarter 2022

Revenues

Revenues were \$2.7 million for the second quarter ended June 30, 2022, and \$4.1 million for the six months ended June 30, 2022, consisting of revenue earned from the collaboration and license agreement with Takeda that the Company entered into in the fourth quarter of 2021, compared to no revenue for the same periods in 2021.

Research and Development Expenses

Research and development expenses were \$35.0 million for the three months ended June 30, 2022, compared to \$36.0 million for the same period in 2021. The decrease was primarily due to the wind-down of the Company's P-BCMA-101 autologous program as the Company transitions to the allogeneic program, offset by an increase in active clinical programs and personnel costs to support those efforts.

For the six months ended June 30, 2022, research and development expenses were \$83.9 million, compared to \$65.1 million for the same period in 2021. The increase was primarily due to the contract termination to reduce the Company's autologous manufacturing footprint, costs related to its clinical stage programs from an increase in the number of ongoing clinical trials, and personnel expenses to support these efforts, offset by the wind-down of the Company's P-BCMA-101 autologous program.

General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2022 and 2021, were \$9.2 million and \$8.9 million, respectively. For the six months ended June 30, 2022 and 2021, general and administrative expenses were \$18.8 million and \$17.2 million, respectively. The increases were primarily related to an increase in personnel expenses due to an increase in headcount, which included an increase in stock-based compensation expense.

Net Loss

Net loss was \$43.0 million and \$101.1 million for the three and six months ended June 30, 2022, respectively, compared to net loss of \$45.7 million and \$84.0 million for the three and six months ended June 30, 2021, respectively.

Cash Position

As of June 30, 2022, the Company's cash, cash equivalents and short-term investments balance was \$142.6 million, excluding approximately \$75.3 million of the net proceeds from the underwritten public offering that Poseida received in August 2022 and \$110.0 million of the upfront payment from Roche that the Company, subject to HSR Act clearance, expects to receive in 2022. Poseida expects that its cash, cash equivalents and short-term investments together with expected upfront and near-term fees and milestones other payments from Roche and proceeds from its recent public offering will be sufficient to fund operations into at least mid-2024.

About Poseida Therapeutics, Inc.

Poseida Therapeutics is a clinical-stage biopharmaceutical company dedicated to utilizing our proprietary genetic engineering platform technologies to create next generation cell and gene therapeutics with the capacity to cure. We have discovered and are developing a broad portfolio of product candidates in a variety of indications based on our core proprietary platforms, including our non-viral piggyBac® DNA Delivery System, Cas-CLOVER™ Site-specific Gene Editing System and nanoparticle- and AAV-based gene delivery technologies. Our core platform technologies have utility, either alone or in combination, across many cell and gene therapeutic modalities and enable us to engineer our portfolio of product candidates that are designed to overcome the primary limitations of current generation cell and gene therapeutics. To learn more, visit www.poseida.com and connect with us 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 timing and plans with respect to development milestones, clinical trials, manufacturing and regulatory activities; statements regarding the upfront payment from Roche and other potential fees, milestone and royalty payments Poseida may receive pursuant to its collaboration agreements; the potential benefits of Poseida's technology platforms and product candidates; the clearance of the Roche collaboration agreement under the HSR Act; Poseida's plans and strategy with respect to developing its technologies and product candidates; and Poseida's ability to prioritize and utilize its resources efficiently and expected benefits from any such prioritization. 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 Poseida'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 fact that Poseida's collaboration agreements may not become effective or may be terminated early; the fact that Poseida will have limited control over the efforts and resources its collaborators devote to advancing development programs under their respective collaboration agreements; Poseida'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; Poseida's ability to retain key scientific or management personnel; and the other risks described in Poseida'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. Poseida 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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Revenues:				
Collaboration revenue	\$ 2,700	\$ —	\$ 4,135	\$ —
Total revenue	<u>2,700</u>	<u>—</u>	<u>4,135</u>	<u>—</u>
Operating expenses:				
Research and development	35,008	36,008	83,858	65,103
General and administrative	9,237	8,871	18,782	17,240
Total operating expenses	<u>44,245</u>	<u>44,879</u>	<u>102,640</u>	<u>82,343</u>
Loss from operations	(41,545)	(44,879)	(98,505)	(82,343)
Other income (expense):				
Interest expense	(1,543)	(843)	(2,620)	(1,681)
Other income, net	52	17	32	5
Net loss before income tax	(43,036)	(45,705)	(101,093)	(84,019)
Income tax expense	—	—	—	—
Net loss	<u>\$ (43,036)</u>	<u>\$ (45,705)</u>	<u>\$ (101,093)</u>	<u>\$ (84,019)</u>
Net loss per share, basic and diluted	<u>\$ (0.69)</u>	<u>\$ (0.74)</u>	<u>\$ (1.61)</u>	<u>\$ (1.35)</u>
Weighted-average shares of common stock, basic and diluted	<u>62,713,363</u>	<u>62,150,961</u>	<u>62,635,074</u>	<u>62,066,498</u>

SELECTED BALANCE SHEET DATA

	<u>June 30,</u>	<u>December 31,</u>
	<u>2022</u>	<u>2021</u>
Cash, cash equivalents and short-term investments	\$ 142,557	\$ 206,325
Total assets	205,455	269,309
Total liabilities	139,655	113,098
Total stockholders' equity	65,800	156,211

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