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 9, 2021

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)**	**(I.R.S. Employer Identification No.)**

9390 Towne Centre Drive, Suite 200, San Diego, California	**92121**
(Address of principal executive offices)	**(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	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 9, 2021, Poseida Therapeutics, Inc. issued a press release announcing its program updates and financial results for the third quarter ended September 30, 2021. 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 9, 2021.
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 9, 2021

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

Poseida Therapeutics Provides Program Updates and Financial Results for the Third Quarter of 2021

Clearance of IND by FDA and clinical trial start-up for P-BCMA-ALLO1 begins planned strategic shift to allogeneic BCMA CAR-T program for patients with multiple myeloma; P-BCMA-101 autologous CAR-T program to be wound down

Presented strong data in the quarter on P-PSMA-101 program in prostate cancer demonstrating the potential advantages of high TSCM CAR-T products in solid tumors

Announced research collaboration with Takeda for use of Poseida's platform technologies to develop non-viral liver- and HSC-directed in vivo gene therapies

SAN DIEGO, Nov. 9, 2021 — 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 program updates and financial results for the third quarter ended September 30, 2021.

"The last quarter saw continued progress as Poseida reached multiple key strategic milestones including FDA clearance of our first fully allogeneic CAR-T IND for P-BCMA-ALLO1, the presentation of strong CAR-T data in a solid tumor indication with our P-PSMA-101 program and, shortly after the quarter, the announcement of a strategic collaboration with Takeda focused on non-viral in vivo gene therapy programs utilizing our platform technologies," said Eric Ostertag, M.D., Ph.D., Chief Executive Officer of Poseida.

"The initiation of our P-BCMA-ALLO1 clinical trial represents the beginning of a long-planned strategic transition to what we believe is the 'holy grail' of cell therapy for oncology, a fully allogeneic CAR-T with a fully humanized heavy chain BCMA binder and a high percentage of TSCM cells which we believe are the key to success," continued Ostertag. "While we believe the P-BCMA-101 autologous program has competitive advantages and would be approvable, one long-term strategic benefit of that program has been to inform our highly-differentiated allogeneic approach. With the P-BCMA-ALLO1 clinical program now underway and with very high confidence in our allogeneic platform, we will begin a planned wind down of P-BCMA-101."

Program Updates

BCMA Program

P-BCMA-ALLO1, the Company's first fully allogeneic CAR-T product candidate, is in development for the treatment of relapsed/refractory multiple myeloma. In August of 2021, the U.S. Food and Drug Administration (FDA) cleared the Investigational New Drug (IND) application for P-BCMA-ALLO1. The IND clearance and the start-up of the Phase 1 clinical trial mark the beginning of the Company's strategic shift toward focusing on P-BCMA-ALLO1 rather than the autologous P-BCMA-101 program.

While data in the autologous trial showed meaningful responses and a favorable safety profile, the Company's strategic focus has long been on allogeneic CAR-T therapies, leveraging the learnings of the autologous CAR-T program to provide benefits beyond those of autologous CAR-T, including a more desirable off-the-shelf product profile for future commercialization while maintaining the tolerability advantage of our autologous product candidate. P-BCMA-ALLO1 has the potential to deliver up to hundreds of doses per manufacturing run, thereby dramatically reducing both clinical trial costs and ultimately commercial product cost compared to the autologous P-BCMA-101 program.

PSMA Program
P-PSMA-101 is a solid tumor autologous CAR-T product candidate being developed to treat patients with metastatic castrate-resistant prostate cancer (mCRPC) currently in an ongoing Phase 1 dose escalation trial.

In August of 2021, the Company presented preliminary data at the 6th Annual CAR-TCR Summit virtual meeting that demonstrated meaningful patient responses while maintaining a favorable safety and tolerability profile with modest overall rates of CRS and no neurotoxicity observed at low doses. An additional update on the P-PSMA-101 program is expected in the first half of 2022.

MUC1-C Program
P-MUC1C-ALLO1 is an allogeneic CAR-T product candidate in preclinical development with the potential to treat a wide range of solid tumors, including breast and ovarian cancers. P-MUC1C-ALLO1 is proceeding, with an anticipated IND filing and initiation of a Phase 1 clinical trial by the end of 2021.

Liver-Directed Gene Therapy Program
P-OTC-101 is the Company's first liver-directed gene therapy program for the in vivo treatment of urea cycle disease caused by congenital mutations in the ornithine transcarbamylase (OTC) gene, a condition characterized by high unmet medical need. The Company is currently evaluating whether to modify the P-OTC-101 program to move to the fully non-viral nanoparticle delivery system. The Company will update expected timing on program advancement once that evaluation is complete.

Other Operational Updates and Upcoming Events

Gene Therapy Research Collaboration with Takeda
In October of 2021, the Company entered into a collaboration and license agreement with Takeda Pharmaceuticals USA, Inc. to utilize Poseida's proprietary genetic engineering platforms for the research and development of up to eight gene therapies.
The collaboration will focus on developing non-viral in vivo gene therapy programs, including Poseida's Hemophilia A program. The Company will receive an upfront payment of $45.0 million, of which $5.0 million is for prepaid research. Per the agreement, Takeda will fund all ongoing partnered program research performed by Poseida. The collaboration may utilize all of Poseida's novel genetic engineering platform technologies, including the piggyBac® DNA Modification System for gene addition, the Cas-CLOVER™ Site-specific Gene Editing System for ultra-precise gene editing, biodegradable nanoparticle technologies for gene delivery and other emerging technologies. Poseida will lead research activities up to candidate selection, after which Takeda will assume responsibility for further development and commercialization.

GMP Facility
In the third quarter, the Company completed qualification and commenced GMP activity in its internal pilot manufacturing plant. The pilot plant is designed to support and speed the development of allogeneic product candidates including manufacturing clinical material for early-stage trials. The first product candidate to be produced out of the pilot plant will be P-MUC1C-ALLO1.

Society for Immunotherapy of Cancer (SITC) 36th Annual Meeting
The Company will give two virtual poster presentations at the upcoming SITC Annual Meeting, being held in Washington, D.C., and virtually November 10-14, 2021. The full abstracts were made available on the SITC website earlier today, with presentations taking place on November 12, 2021.

63rd American Society of Hematology (ASH) Annual Meeting and Exposition
The Company will present data from the Company's differentiated P-BCMA-101 autologous CAR-T program including how it has informed the P-BCMA-ALLO1 allogeneic CAR-T program in a poster publication at the ASH Annual Meeting on Monday, December 13, 2021:

Session Name: 704. Cellular Immunotherapies: Clinical: Poster III
Presentation Time: 6:00 PM - 8:00 PM Eastern time
Location: Georgia World Congress Center, Hall B5

Financial Results for the Third Quarter 2021

Research and Development Expenses
Research and development expenses were $32.5 million for the third quarter ended September 30, 2021, compared to $27.0 million for the same period in 2020. For the nine months ended September 30, 2021, research and development expenses were $97.6 million, compared to $75.6 million for the same period in 2020. The increase was primarily due to increased stock-based compensation expense, headcount, external costs related to our preclinical programs and clinical stage programs, including the ongoing enrollment and manufacturing associated with our P-BCMA-101, P-BCMA-ALLO1 and P-PSMA-101 clinical trials, and internal costs related to facilities development.

General and Administrative Expenses
General and administrative expenses were $9.1 million for the third quarter ended September 30, 2021, compared to $6.5 million for the same period in 2020. General and administrative expenses were $26.3 million for the nine months ended September 30, 2021, compared to $15.6 million for the same period in 2020. The increase was primarily due to increased stock-based compensation expense, headcount, insurance costs and professional fees.

Net Loss
Net loss was $42.4 million and $126.4 million for the three and nine months ended September 30, 2021, respectively, and $34.4 million and $93.6 million for the three and nine months ended September 30, 2020, respectively.

Cash Position
As of September 30, 2021, our cash and cash equivalents balance was $197.8 million.

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, the potential benefits of Poseida's technology platforms and product candidates, Poseida's plans and strategy with respect to developing its technologies and product candidates, and anticipated timelines and milestones with respect to Poseida’s development programs and manufacturing activities. 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, risks and uncertainties associated with development and regulatory approval of novel product candidates in the biopharmaceutical industry and the other risks described in Poseida's filings with the Securities and Exchange Commission. All forward-looking statement 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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 32,524	$ 27,016	$ 97,627	$ 75,636
General and administrative	9,066	6,458	26,306	15,553
Total operating expenses	41,590	33,474	123,933	91,189
Loss from operations	(41,590)	(33,474)	(123,933)	(91,189)
Other income (expense):				
Interest expense	(837)	(848)	(2,518)	(2,654)
Other income (expense), net	3	(92)	8	216
Net loss before income tax	(42,424)	(34,414)	(126,443)	(93,627)
Income tax expense	—	—	—	—
Net loss	$ (42,424)	$ (34,414)	$ (126,443)	$ (93,627)
Net loss per share, basic and diluted	$ (0.68)	$ (0.63)	$ (2.03)	$ (3.43)
Weighted-average shares of common stock, basic and diluted	62,298,243	54,973,788	62,144,595	27,324,297

SELECTED BALANCE SHEET DATA

	September 30, 2021	December 31, 2020
Cash, cash equivalents and short-term investments	$ 197,811	$ 309,152
Total assets	261,937	371,484
Total liabilities	111,780	109,516
Total stockholders' equity	150,157	261,968

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