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 30, 2022

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 7.01 Regulation FD Disclosure.

On November 30, 2022, the European Society for Medical Oncology ("ESMO") published two abstracts from Poseida Therapeutics, Inc. (the "Company"), which present early data from the Company's Phase 1 clinical trials of P-MUC1C-ALLO1 and P-BCMA-ALLO1. The abstracts are attached as Exhibit 99.1 and Exhibit 99.2 to this report. The abstracts will be presented at the ESMO Immuno-Oncology Annual Congress taking place in Geneva, Switzerland and online from December 7-9, 2022.

The information in this Item 7.01 of this report (including Exhibit 99.1 and Exhibit 99.2) is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today's date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Abstract: Development of an Allogeneic CAR-T Targeting MUC1-C (MUC1, Cell Surface Associated, C-Terminal) for Epithelial Derived Tumors.
99.2	Abstract: Phase 1 Study to Assess the Safety and Efficacy of P-BCMA-ALLO1, a Fully Allogeneic CAR-T Therapy, in Patients with Relapsed / Refractory Multiple Myeloma (RRMM).
104	Cover Page Interactive Data File

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: December 1, 2022

By: /s/ Harry J. Leonhardt, Esq.
Name: Harry J. Leonhardt, Esq.
Title: General Counsel, Chief Compliance Officer & Corporate Secretary

Development of an allogeneic CAR-T targeting MUC1-C (MUC1, cell surface associated, C-terminal) for epithelial derived tumors

David Y. Oh, Jason T. Henry, Joaquina Baranda, Ecaterina E. Dumbrava, Ezra Cohen, Jeff D Eskew, Rajesh Belani, Joanne McCaigue, Hamid Namini, Christopher E Martin, Ann Murphy, Eric Ostertag, Julia Coronella, Devon J. Shedlock, Ildefonso Ismael Rodriguez Rivera

Background: Most solid tumors are of epithelial origin and express Mucin 1 (MUC1), a heterodimer of MUC1-N and the oncogenic subunit MUC1-C. Many drugs targeting MUC1 in clinical trials have been primarily directed against MUC1-N. Since MUC1-C is present broadly in tumor due to loss of cell polarity, exposure via hypoglycosylation and MUC1-N shedding, it may represent a more tumor-selective target than MUC1-N. P-MUC1C-ALLO1 is an allogeneic CAR-T targeting MUC1-C and is manufactured using transposon-based integration (piggyBac® DNA Delivery System) and the Cas-CLOVER™ Gene Editing System to knockout the TCR and MHC class I proteins resulting in an enriched T stem cell memory product. Thus, P-MUC1C-ALLO1 addresses multiple common solid tumor indications.

Methods: MUC1-C epitope expression was investigated by IHC using the scFv binder for P-MUC1C-ALLO1 CAR in epithelial tumor and normal frozen tissue arrays. Pre-clinical efficacy of P-MUC1C-ALLO1 was tested in xenograft models for triple-negative breast (TNBC) and ovarian cancers. Clinical safety has been evaluated in three patients in a phase I trial (NCT05239143).

Results: MUC1-C epitope was positive in multiple tumor samples. While tumor expression was relatively nonpolarized, normal tissue expression was restricted to the apical surface. P-MUC1C-ALLO1 demonstrated robust infiltration and activity in TNBC and ovarian cancer xenografts, with >90% of tumor mass comprised of CAR-Ts at day 10, and 100% tumor elimination at 2 weeks. In the phase I trial, 4 pts (esophageal, colorectal, breast, and pancreatic carcinomas) have been infused either at $0.75x10^6$ (pts 1-3) or $2x10^6$ cells/kg (pt 4). No P-MUC1C-ALLO1 related toxicities were observed. Early efficacy was seen at the low dose with one partial response in pt 3 (HR+, Her2- Breast cancer).

Conclusions: MUC1-C epitope is highly expressed across common epithelial cancers and is apically restricted in normal tissues. Potent anti-tumor activity is seen in preclinical models. In early phase I experience, P-MUC1C-ALLO1 is safe and tolerable with an early signal of efficacy at a low starting dose. P-MUC1C-ALLO1 phase I trial enrollment is on-going.

Phase 1 Study to Assess the Safety and Efficacy of P-BCMA-ALLO1, a Fully Allogeneic CAR-T Therapy, in Patients with Relapsed / Refractory Multiple Myeloma (RRMM)

Mehmet Kocoglu, Adam Asch, Aravind Ramakrishnan, Carlos Bachier, Thomas Martin III, Tulio Rodriguez, Katherine McArthur, Joanne McCaigue, Christopher E Martin, Maggie Zhang, Hamid Namini, Eric M. Ostertag, Matthew A. Spear, Ellen Christie, Rajesh Belani, Stacey Cranert, Julia Coronella, Devon J. Shedlock, Caitlin Costello

Introduction

P-BCMA-ALLO1 is an allogeneic Chimeric Antigen Receptor T-cell (CAR-T) targeting B-cell Maturation Antigen (BCMA) being investigated in RRMM. P-BCMA-ALLO1 is manufactured using non-viral transposon-based integration (piggyBac® DNA Delivery System) that introduces a humanized anti-BCMA VH-based CAR producing a highly enriched T stem cell memory product. The Cas-CLOVER™ Site-Specific Gene Editing System eliminates endogenous T cell receptor (TCR) expression via knockout of the *TCR beta chain 1* gene to prevent graft-vs-host disease, and the *beta-2 microglobulin* gene to reduce MHC class I expression to eliminate host-vs-graft responses. P-BCMA-ALLO1 demonstrated compelling activity in MM xenografts, providing rationale for this first-in-human phase I study.

Methods

The primary objective is to assess the safety and maximum tolerated dose based on dose limiting toxicity (DLT) in RRMM patients who have received a proteasome inhibitor, immunomodulatory drug and anti-CD38 monoclonal antibody. Secondary objectives will assess the anti-myeloma effect. The protocol utilizes standard 3+3 dose escalation to treat 40 patients. Patients receive lymphodepleting chemotherapy (LDC) with cyclophosphamide (300 mg/m^2/day) / fludarabine (30 mg/m^2/day) on days -5, -4 and -3 followed by a single dose of P-BCMA-ALLO1 on Day 0.

Results

As of 21SEP2022, 7 patients were treated with P-BCMA-ALLO1. Six patients received the cohort 1 dose of 0.75 X 10^6 CAR-T cells/kg and 1 patient received the cohort 2 dose of 2 X 10^6 cells/kg. To date, 4 cohort 1 patients have completed the DLT evaluation period and are evaluable for response. Most adverse events (AE) were grade 1 and 2. One patient had a significant AE of G3 febrile neutropenia. DLTs, cytokine release syndrome and neurotoxicity have not been observed. To date, 1 patient achieved very good partial response, 2 patients achieved partial response, and 1 patient had stable disease. Responses were seen starting at week 2, and overall response rate is 75%.

Conclusion

Early results demonstrate acceptable toxicity profile and promising efficacy for P-BCMA-ALLO1. Dose escalation is ongoing. Updated safety and efficacy results will be presented.