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): December 5, 2020

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** **(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	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 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 8.01 Other Events.

On December 5, 2020, Poseida Therapeutics, Inc. (the "Company") issued a press release reporting updated results of an ongoing Phase 1 clinical trial of P-BCMA-101, an autologous chimeric antigen receptor T-cell (CAR-T) product candidate in relapsed/refractory multiple myeloma. The results were presented at the 2020 American Society of Hematology (ASH) Annual Meeting and showed that patients treated with equivalent doses of product manufactured with a modified nanoplasmid process in the expanded Phase 1 trial achieved deeper responses while maintaining a similar safety profile compared to product manufactured with the Company's legacy plasmid.

Based on the results, the Company announced that it is moving forward with this optimized manufacturing method in all of its CAR-T programs and is currently moving into higher dosing cohorts with the nanoplasmid manufactured P-BCMA-101 product candidate. The Company expects to finalize its Phase 2 dose in the first quarter of 2021.

The Phase 1 dose escalation trial initially included five cohorts with a product candidate created using a standard plasmid process. The trial was expanded in 2020 to include cohorts utilizing a new nanoplasmid manufacturing process. The nanoplasmid technology allows for a reduction in the plasmid backbone size, enhancing the transposition efficiency during manufacturing and improving the final CAR-T product performance. The expansion part of the trial is also evaluating several novel dosing strategies with 19 patients treated as of the data cutoff with a variety of dosing regimens, including single administration, cyclic dosing, combination with rituximab, and combination with lenalidomide.

Using the new manufacturing process, a dose of 0.75 x 10^6 cells/kg was administered to eight patients in the initial P-BCMA-101 nanoplasmid expansion cohorts. Patients treated in this cohort and evaluable by International Myeloma Working Group (IMWG) criteria (n=6) showed a higher response rate, with an ORR of 67 percent as compared to an ORR of 50 percent for the same dosing cohort using the standard P-BCMA-101 plasmid (n=2). Additionally, as of the cutoff date, three patients achieved deeper responses of either very good partial response (VGPR) or complete response (CR) in the nanoplasmid expansion cohort as compared to no patients reaching a VGPR or CR in the standard plasmid group at the Cohort 1 dose. As of the data cutoff date, two of the three nanoplasmid patients who reached VGPR or CR remained in durable responses at approximately 6 months.

At the 0.75 x 10^6 cells/kg dose, cytokine release syndrome (CRS) was seen in just one, or 12.5%, of evaluable Phase 1 nanoplasmid patients (n=8) and neurotoxicity was not seen in any patients, demonstrating the preservation of the product safety profile within the expansion cohort. The Company believes this highly favorable safety profile can be attributed to the gradual expansion of stem cell memory T (Tscm) cells when compared with published data from competitor products comprised of a higher percentage of T effector and other differentiated T cells (2-3 weeks to peak versus 3-7 days for most CAR-T cells). There have been no patient deaths, dose limiting toxicities or unexpected/off-target toxicities related to P-BCMA-101. The most common adverse events were cytopenias and infections generally attributable to lymphodepleting chemotherapy regimens. Based on the safety results, the protocol was amended to allow fully outpatient CAR-T cell administration.

The median patient age was 60, with a median time since diagnosis of approximately five years. Patients were heavily pre-treated, with a median of eight prior lines of therapy (2-18). All patients had received a protease inhibitor or at least one IMid, and nearly all patients had been previously treated with a CD38 monoclonal antibody. Sixty percent of the patients were refractory to all three drug classes, and four patients had previously received an anti-BCMA targeted therapy.

This open label, multicenter Phase 1 study is designed to assess the safety of P-BCMA-101 in subjects with relapsed and/or refractory multiple myeloma and includes multiple exploratory cohorts to evaluate the administration of P-BCMA-101 CAR-T within the framework of moving from the standard plasmid CAR-T product to the nanoplasmid product. The primary objective of this study is to determine the safety and maximum-tolerated dose of P-BCMA-101. Secondary objectives include anti-myeloma effect of P-BCMA-101.

A copy of the press release is attached hereto as Exhibit 99.1.

Forward-Looking Statements

Statements contained in this report 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 the clinical data presented, the potential 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, risks and uncertainties associated with development and regulatory approval of novel product candidates in the biopharmaceutical industry, the fact that future clinical results could be inconsistent with results observed to date and the other risks described in the Company's filings with the Securities and Exchange Commission. All forward-looking statements contained in this report 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Poseida Therapeutics, Inc., dated December 5, 2020.

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 7, 2020

By: /s/ Harry J. Leonhardt
Harry J. Leonhardt
General Counsel and Chief Compliance Officer

Poseida Therapeutics Provides Update on Phase 1 Trial of P-BCMA-101 at the 2020 American Society of Hematology Annual Meeting

Data from ongoing Phase 1 expansion trial using nanoplasmid demonstrated an improvement in efficacy over standard plasmid and a potentially best-in-class safety profile

SAN DIEGO – Dec. 5, 2020 – Poseida Therapeutics, Inc. (NASDAQ:PSTX), a clinical-stage biopharmaceutical company utilizing proprietary gene engineering platform technologies to create cell and gene therapeutics with the capacity to cure, today reported results of an ongoing Phase 1 clinical trial of P-BCMA-101, an autologous chimeric antigen receptor T-cell (CAR-T) product candidate in relapsed/refractory multiple myeloma, during an oral presentation at the 2020 American Society of Hematology (ASH) Annual Meeting. The results show that patients treated with equivalent doses of product manufactured with a modified nanoplasmid process in the expanded Phase 1 trial achieved deeper responses while maintaining a similar safety profile compared to product manufactured with the Company's legacy plasmid.

"Based on the dual benefits of improved efficacy and consistent safety demonstrated with the new nanoplasmid, we are moving forward with this optimized manufacturing method in all of our CAR-T programs," said Eric Ostertag, M.D., Ph.D., chief executive officer of Poseida Therapeutics. "Furthermore, using our first-generation plasmid, we saw higher response rates as we escalated to higher dose cohorts not yet reached with the nanoplasmid product. We are currently moving into higher dosing cohorts with the nanoplasmid manufactured P-BCMA-101 product candidate and are optimistic further increases in effectiveness and durability are possible at these higher doses. We expect to finalize our Phase 2 dose in the first quarter of 2021."

The Phase 1 dose escalation trial initially included five cohorts with a product candidate created using a standard plasmid process. The trial was expanded in 2020 to include cohorts utilizing a new nanoplasmid manufacturing process. The nanoplasmid technology allows for a reduction in the plasmid backbone size, enhancing the transposition efficiency during manufacturing and improving the final CAR-T product performance. The expansion part of the trial is also evaluating several novel dosing strategies with 19 patients treated as of the data cutoff with a variety of dosing regimens, including single administration, cyclic dosing, combination with rituximab, and combination with lenalidomide.

Using the new manufacturing process, a dose of 0.75 x 10^6 cells/kg was administered to eight patients in the initial P-BCMA-101 nanoplasmid expansion cohorts. Patients treated in this cohort and evaluable by International Myeloma Working Group (IMWG) criteria (n=6) showed a higher response rate, with an ORR of 67 percent as compared to an ORR of 50 percent for the same dosing cohort using the standard P-BCMA-101 plasmid (n=2). Additionally, as of the cutoff date, three patients achieved deeper responses of either very good partial response (VGPR) or complete response (CR) in the nanoplasmid expansion cohort as compared to no patients reaching a VGPR or CR in the standard plasmid group at the Cohort 1 dose. As of the data cutoff date, two of the three nanoplasmid patients who reached VGPR or CR remained in durable responses at approximately 6 months.

"We observed an excellent efficacy and safety profile with a single dose escalation. There were very low rates of CRS with no ICU admissions for CRS, resulting in a safety profile suggesting this therapy

could be delivered to a greater number of patients in a community hospital or outpatient setting," said Caitlin Costello, MD, Associate Clinical Professor of Medicine and member of the Division of Blood and Marrow Transplantation at University of California, San Diego. Dr. Costello is the principal investigator in the study, who presented the data during the ASH meeting.

At the 0.75 x 10^6 cells/kg dose, cytokine release syndrome (CRS) was seen in just one, or 12.5%, of evaluable Phase 1 nanoplasmid patients (n=8) and neurotoxicity was not seen in any patients, demonstrating the preservation of the product safety profile within the expansion cohort. The Company believes this highly favorable safety profile can be attributed to the gradual expansion of stem cell memory T (Tscm) cells when compared with published data from competitor products comprised of a higher percentage of T effector and other differentiated T cells (2-3 weeks to peak versus 3-7 days for most CAR-T cells). There have been no patient deaths, dose limiting toxicities or unexpected/off-target toxicities related to P-BCMA-101. The most common adverse events were cytopenias and infections generally attributable to lymphodepleting chemotherapy regimens. Based on the safety results, the protocol was amended to allow fully outpatient CAR-T cell administration.

The median patient age was 60, with a median time since diagnosis of approximately five years. Patients were heavily pre-treated, with a median of eight prior lines of therapy (2-18). All patients had received a protease inhibitor or at least one IMid, and nearly all patients had been previously treated with a CD38 monoclonal antibody. Sixty percent of the patients were refractory to all three drug classes, and four patients had previously received an anti-BCMA targeted therapy.

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About P-BCMA-101

P-BCMA-101 is an autologous CAR-T therapy which is currently being evaluated in an expanded Phase 1 clinical trial for the treatment of patients with relapsed/refractory multiple myeloma to inform the potentially registrational Phase 2 clinical trial. P-BCMA-101 targets cells that express B cell maturation antigen, or BCMA, which is expressed on essentially all multiple myeloma cells. P-BCMA-101 is engineered with Poseida's non-viral piggyBac® DNA Modification System, resulting in a high percentage of T stem cell memory cells. P-BCMA-101 is composed primarily of Tscm, a very young subset of T cells that are long-lived, self-renewing and multipotent, with the capacity to reconstitute the entire spectrum of T cell subsets, including T effector cells. They also survive for decades, and potentially for entire lifespans, with non-CAR-Tscm cells normally providing lifelong T cell immunity against some infectious agents. P-BCMA-101 received regenerative medicine advanced therapy (RMAT) status and orphan drug designation from the FDA. Preliminary results from the Company's ongoing Phase 1 clinical trial suggest that P-BCMA-101 may have improved response rates with a favorable safety profile compared to published results from clinical trials of other CAR-T therapies at similar doses. The Phase 1 study is funded in part by the California Institute for Regenerative Medicine.

About Poseida Therapeutics, Inc.

Poseida Therapeutics is a clinical-stage biopharmaceutical company dedicated to utilizing our proprietary gene 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 Modification 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 wholly-owned portfolio of product candidates that are designed to overcome the primary limitations of current generation cell and gene therapeutics.

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 the clinical data presented, the potential benefits of Poseida's technology platforms and product candidates and Poseida'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 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, the fact that future clinical results could be inconsistent with results observed to date 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.

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