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):
February 17, 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 8.01 Other Events.

On February 17, 2022, Poseida Therapeutics, Inc. (the "Company") issued a press release reporting interim results from its Phase 1 clinical trial of P-PSMA-101, the Company's solid tumor autologous CAR-T product candidate to treat patients with metastatic castrate-resistant prostate cancer ("mCRPC"). These data are also being presented at the 2022 American Society of Clinical Oncology Genitourinary Cancers Symposium ("ASCO GU").

Efficacy:

Of the 17 patients treated thus far, 14 were treated and evaluable at the cutoff date of December 31, 2021. Six patients were treated in the 0.25X106 cells/kg cohort (an average of about 22M cells), seven patients were treated in the 0.75X106 cells/kg cohort (an average of about 61M cells), and one patient was treated in the 2.0X106 cells/kg cohort (112M cells). All patients received a lymphodepletion regimen consisting of 30 mg/m2 fludarabine + 300 mg/m2 cyclophosphamide, prior to a single infusion of P-PSMA-101. Patients were heavily pre-treated, having received an average of seven prior lines of therapy with a median time since diagnosis of 6.4 years.

Key findings included:

- 10/14 (71%) patients demonstrated measurable declines in PSA levels.
- 5/14 (36%) patients showed a decline in PSA levels of 50% or more.
- One patient demonstrated evidence of complete tumor elimination and remains in a durable response of greater than ten months at the time of the presentation.
- Clinical evidence confirmed by biopsy in several patients that the T_{SCM} nature of the product resulted in trafficking of CAR-T cells to the bone, important in a bone-avid disease like prostate cancer.

Safety and Tolerability:

As of December 31, 2021, the data cutoff date, P-PSMA-101 had an acceptable safety and tolerability profile and most treatment-emergent adverse events in the trial were managed with early treatment. Six patients experienced grade 1/2 cytokine release syndrome (CRS), with two patients experiencing grade 3 or higher, including the previously reported case of Macrophage Activation Syndrome (MAS) exacerbated by patient non-compliance. Immune effector cell-associated neurotoxicity syndrome (ICANS) was experienced in two patients, both of which were manageable when treated rapidly with anti-cytokine agents and/or steroids. Common reported adverse events included headache, fatigue, chills and blurred vision but were overall well-tolerated.

The Phase 1 trial is an open label, multi-center, 3+3 dose-escalating study designed to assess the safety of P-PSMA-101 in up to 60 adult subjects with mCRPC. The primary objectives of this study are to determine the safety, efficacy, and maximum tolerated dose of P-PSMA-101.

A copy of the press release and the slides presented by the Company at the 2022 ASCO GU are attached hereto as Exhibits 99.1 and 99.2, respectively.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Poseida Therapeutics, Inc., dated February 17, 2022.
99.2	Presentation of Poseida Therapeutics, Inc., dated February 17, 2022.
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: February 17, 2022

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

Poseida Therapeutics to Present Interim Results from Phase 1 Trial of P-PSMA-101 at ASCO Genitourinary Cancers Symposium

P-PSMA-101 demonstrated strong anti-tumor activity and induced durable responses at low doses in heavily pretreated patients with mCRPC

10/14 (71%) evaluable patients demonstrated prostate-specific antigen (PSA) declines, with 5/14 (36%) achieving PSA declines of 50% or more

SAN DIEGO, Feb. 17, 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 interim results from its Phase 1 clinical trial of P-PSMA-101, the Company's solid tumor autologous CAR-T product candidate to treat patients with metastatic castrate-resistant prostate cancer (mCRPC). These data are being presented today at the 2022 American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) in a poster presentation entitled, "Phase 1 Study of P-PSMA-101 CAR-T Cells in Patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC)." The presentation (Abstract 98/Poster E9) will be available on demand through the Symposium's virtual platform and during Poster Session A: Prostate Cancer today at 2:30 pm ET at ASCO GU, which is taking place in San Francisco and virtually February 17-19, 2022.

"The results being presented at ASCO GU continue to reinforce the potential for a CAR-T product to effectively treat solid tumor indications like prostate cancer," said Mark Gergen, Chief Executive Officer of Poseida Therapeutics. "We are excited by the initial responses seen even at the lowest doses and will continue to evaluate additional dosing regimens as we treat patients. We are also encouraged by the durable responses observed to date and look forward providing additional updates on this program as the trial progresses."

Of the 17 patients treated thus far, 14 were treated and evaluable at the cutoff date of December 31, 2021. Six patients were treated in the 0.25X106 cells/kg cohort (an average of about 22M cells), seven patients were treated in the 0.75X106 cells/kg cohort (an average of about 61M cells), and one patient was treated in the 2.0X106 cells/kg cohort (112M cells). All patients received a lymphodepletion regimen consisting of 30 mg/m2 fludarabine + 300 mg/m2 cyclophosphamide, prior to a single infusion of P-PSMA-101. Patients were heavily pre-treated, having received an average of seven prior lines of therapy with a median time since diagnosis of 6.4 years.

"The responses we have seen in this trial are impressive and speak to the innovative nature and potential of Poseida's CAR-T cell therapy platform," said Susan F. Slovin, M.D., Ph.D., with Memorial Sloan Kettering Cancer Center, an investigator who is presenting at the Symposium. "This interim update on the P-PSMA-101 trial shows the exceptional efficacy of this novel anti-PSMA CAR-T cell product. Thus far, at very low doses P-PSMA-101 has shown to produce a robust and durable anti-tumor response in heavily pretreated patients with mCRPC, including one pathologic complete response."

Efficacy

Standard responses were measured as per Prostate Cancer Working Group 3 (PCWG3) criteria including PSA, bone scans/CT, and exploratory biomarkers and novel tumor-targeted PET imaging (PSMA-PET, FDG). PET imaging was dependent on institutional availability.

Key findings included:

- 10/14 (71%) patients demonstrated measurable declines in PSA levels
- 5/14 (36%) patients showed a decline in PSA levels of 50% or more
- One patient demonstrated evidence of complete tumor elimination and remains in a durable response of greater than ten months at the time of this presentation
- Clinical evidence confirmed by biopsy in several patients that the T_{SCM} nature of the product resulted in trafficking of CAR-T cells to the bone, important in a bone-avid disease like prostate cancer

Safety and Tolerability

P-PSMA-101 demonstrated an acceptable safety and tolerability profile and most treatment-emergent adverse events in the trial were managed with early treatment. Six patients experienced grade 1/2 cytokine release syndrome (CRS), with two patients experiencing grade 3 or higher, including the previously reported case of Macrophage Activation Syndrome (MAS) exacerbated by patient non-compliance. Immune effector cell-associated neurotoxicity syndrome (ICANS) was experienced in two patients, both of which were manageable when treated rapidly with anti-cytokine agents and/or steroids. Common reported adverse events included headache, fatigue, chills and blurred vision but were overall well-tolerated.

The Phase 1 trial is an open label, multi-center, 3+3 dose-escalating study designed to assess the safety of P-PSMA-101 in up to 60 adult subjects with mCRPC. The primary objectives of this study are to determine the safety, efficacy, and maximum tolerated dose of P-PSMA-101. Additional information about the study is available at www.clinicaltrials.gov using identifier: NCT04249947.

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 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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ASCO Genitourinary Cancers Symposium

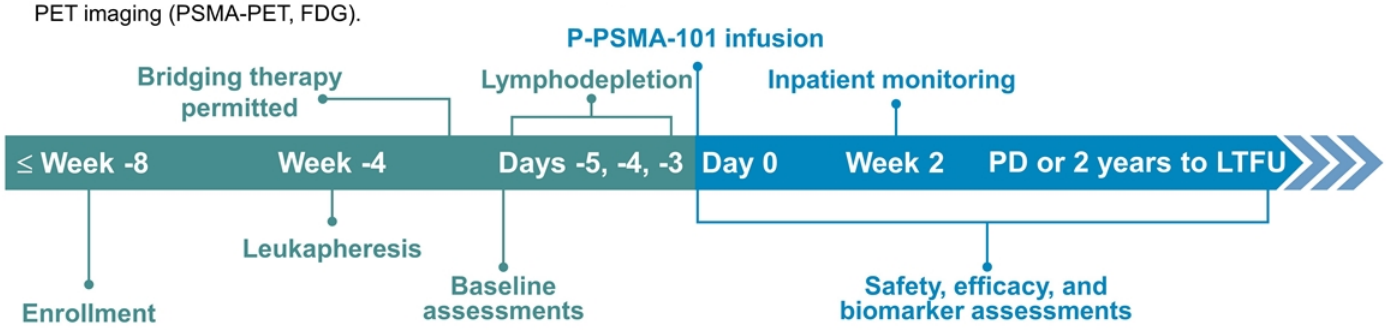
Phase 1 Study of P-PSMA-101 CAR-T Cells in Patients With Metastatic Castration-Resistant Prostate Cancer (mCRPC)

Susan Slovin, MD, PhD, Memorial Sloan Kettering Cancer Center, New York, NY

PRESENTED BY: Susan Slovin, MD, PhD, Memorial Sloan Kettering Cancer Center, New York, NY

Phase 1 mCRPC Clinical Trial: P-PSMA-101-001

- P-PSMA-101 is an autologous CAR-T therapy targeting PSMA and is made using a unique non-viral transposon system (piggyBac®) that results in a CAR-T product composed of a high percentage of stem cell memory T cells (T_{SCM}).
- Open label, 3+3 design, dose escalation + recommended Phase 2 dose expansion, 60 patients.
- Standard 3-day lymphodepletion regimen: fludarabine 30 mg/m^2 and cyclophosphamide 300 mg/m^2.
- Standard response criteria as per PCWG3: PSA, bone scans/CT, and exploratory biomarkers and novel tumor-targeted PET imaging (PSMA-PET, FDG).
- PET imaging was dependent on institutional availability.
- Key inclusion criteria: mCRPC, measurable disease, received a CYP17 inhibitor or second-generation anti-androgen therapy and a taxane, and adequate organ function.
- Key exclusion criteria: second malignancy, active infection, or significant autoimmune, central nervous system, cardiac, ocular, or liver disease.
- 17 patients have been treated, with 14 by the Dec 31, 2021 data cutoff for this presentation



CAR = chimeric antigen receptor; CT = computed tomography; FDG = fluorodeoxyglucose; LTFU = long-term follow-up; mCRPC = metastatic castration-resistant prostate cancer; PCWG3 = Prostate Cancer Working Group 3; PD = progressive disease; PET = positron emission tomography; PSA = prostate-specific antigen; PSMA = prostate membrane-specific antigen.

PRESENTED BY: Susan Slovin, MD, PhD, Memorial Sloan Kettering Cancer Center, New York, NY

Treatment-Emergent Adverse Events

TEAEs (n=14)

TEAE, n (%)	Overall	Grade ≥3
Dose-limiting toxicity (at dose 0.75 x 10^6 cells/kg)	1 (7)	1 (7)
CRS[a]	8 (57)	2 (14)
ICANS	2 (14)	1 (7)
Neutropenia/neutrophil count decreased[b]	5 (36)	5 (36)
Thrombocytopenia/platelet count decreased[b]	5 (36)	4 (27)
Anemia	5 (36)	5 (36)
Infection		
Overall	2 (14)	1 (7)
First month	2 (14)	1 (7)

TRAEs (n=14)

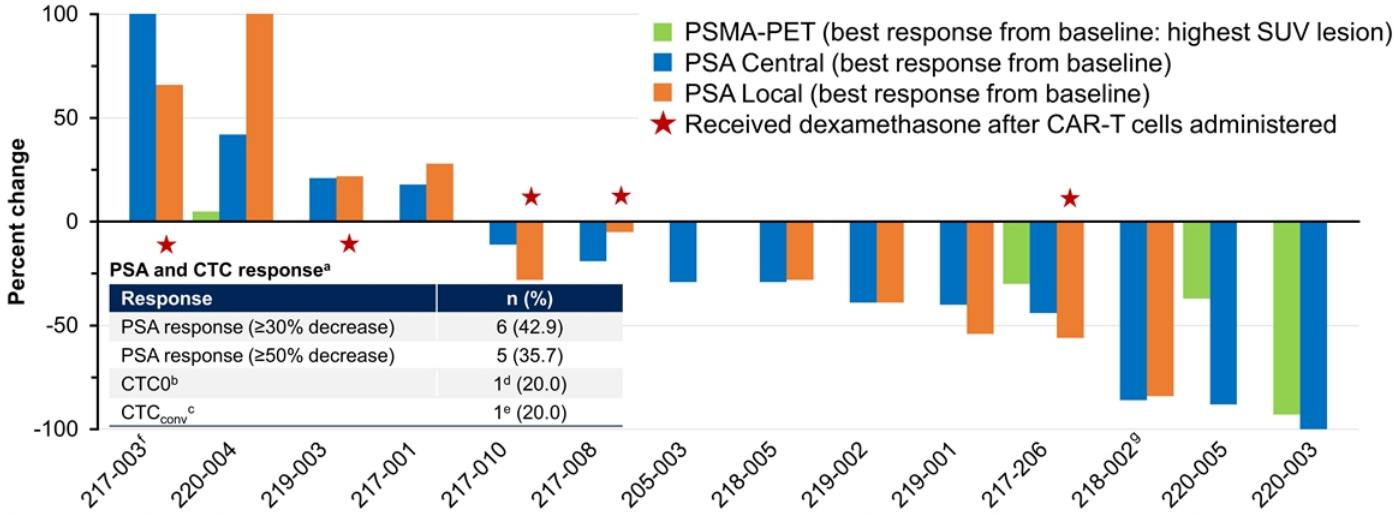
TRAE, n (%)	With >20% incidence	Grade ≥3
CRS	7 (50)	2 (14)
Headache	7 (50)	0 (0)
Fatigue	6 (43)	1 (7)
Chills	5 (36)	0 (0)
AST increased	5 (36)	3 (21)
Vision blurred	4 (29)	0 (0)
ALT increased	4 (29)	1 (7)
Pyrexia	3 (21)	0 (0)
aPTT prolonged	3 (21)	0 (0)

[a] Grade ≥3 events were 2 cases of macrophage activation syndrome/CRS, one fatal after non-compliance in follow-up. CRS was frequently associated with transaminitis and intermittently with ocular symptoms/inflammation.
[b] Patient counted once for either term.
ALT = alanine aminotransferase; aPTT = activated partial thromboplastin time; AST = aspartate aminotransferase; CRS = cytokine release syndrome; ICANS = immune effector cell–associated neurotoxicity; TEAE = treatment-emergent adverse event; TRAE = treatment-related adverse event.

PRESENTED BY: Susan Slovin, MD, PhD, Memorial Sloan Kettering Cancer Center, New York, NY

Efficacy: Exceptional Antitumor Responses at the Lowest Dose Levels

Marked decreases in PSA and PSMA-PET SUVs



PSA and CTC response[a]

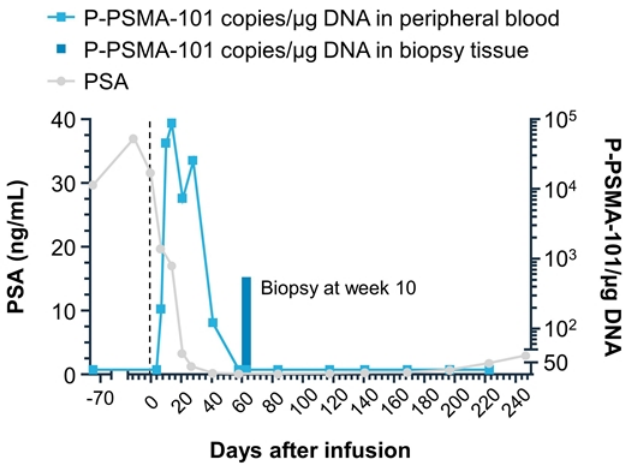
Response	n (%)
PSA response (≥30% decrease)	6 (42.9)
PSA response (≥50% decrease)	5 (35.7)
CTC0[b]	1[d] (20.0)
CTC_{conv}[c]	1[e] (20.0)

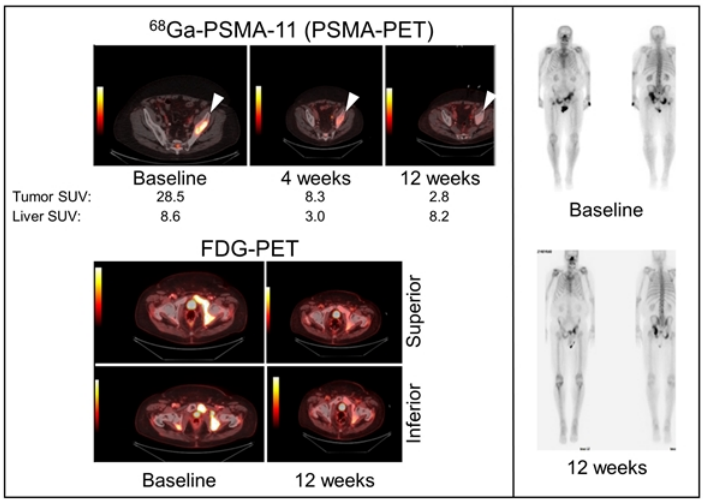
[a] Central or local results. [b] CTC0 (n=5) defined as patients with CTCs >0 at enrollment and CTC = 0 at a post-infusion CTC assessment (12–13-week follow-up). [c] CTC_{conv} (n=5) defined as patients with CTCs ≥5 at enrollment, then CTCs ≤4 measured at a post-infusion assessment. [d] Patient 219-001. [e] Patient 217-206. [f] Only 1 PSA timepoint obtained from patient. [g] Patient 218-002 received dexamethasone 2 mg BID starting at month 3 post–P-PSMA-101 infusion due to bone pain; steroid was tapered to 0.5 mg QD and is currently ongoing. BID = twice daily; CAR = chimeric antigen receptor; CTC = circulating tumor cells; PET = positron emission tomography; PSA = prostate-specific antigen; PSMA = prostate membrane-specific antigen; QD = every day; SUV = standardized uptake value.

PRESENTED BY: Susan Slovin, MD, PhD, Memorial Sloan Kettering Cancer Center, New York, NY

Patient 220-003: Evidence of Near-Complete Tumor Elimination

PK, PSA, PSMA-PET, FDG-PET, bone scan, and pathology correlate in response





Biopsy at week 10 of prior bone metastasis showed CAR-T cells, bone remodeling, and bone marrow but no tumor cells.

CAR = chimeric antigen receptor; FDG = fluorodeoxyglucose; PET = positron emission tomography; PK = pharmacokinetics; PSA = prostate-specific antigen; PSMA = prostate membrane-specific antigen; SUV = standardized uptake value.

PRESENTED BY: Susan Slovin, MD, PhD, Memorial Sloan Kettering Cancer Center, New York, NY

Conclusions

- This interim update shows the exceptional efficacy of novel anti-PSMA CAR-T-cell product.
- P-PSMA-101 at very low doses induced durable biochemical, radiographic, and functional radiographic responses in heavily pretreated patients with mCRPC, including a pathologic complete response, with notable PFS and OS, and significant CAR-T-cell expansion to the 10^4 to 10^5 copies/µg DNA range.
- 10 of 14 patients (71%) demonstrated PSA declines, with 5 of 14 patients (36%) showing PSA declines of ≥50%.
- T_{SCM} had elevated bone and inflammation homing markers and demonstrated trafficking to bone tumor biopsies, highly relevant in bone-avid disease like prostate cancer.
- CRS rate was 57% and ICANS rate was 14%, which was manageable when treated rapidly with anticytokine agents (29% treated with tocilizumab) and/or steroids.

CAR = chimeric antigen receptor; CRES = CAR-T–related encephalopathy syndrome; CRS = cytokine release syndrome; ICANS = immune effector cell–associated neurotoxicity; mCRPC = metastatic castration-resistant prostate cancer; OS = overall survival; PFS = progression-free survival; PSMA = prostate membrane-specific antigen; T_{SCM} = stem cell memory T cells.

PRESENTED BY: Susan Slovin, MD, PhD, Memorial Sloan Kettering Cancer Center, New York, NY