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 17, 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 August 17, 2020, Poseida Therapeutics, Inc. (the "Company") announced that following notification to the U.S. Food and Drug Administration (FDA) of a pause in enrollment pursuant to the protocol to investigate a patient death, it has received communication from the FDA that the Company's Phase 1 clinical trial for P-PSMA-101 in metastatic castrate resistant prostate cancer has been placed on clinical hold.

The patient in question had metastatic castrate-resistant prostate cancer, had failed treatment with multiple anti-cancer agents and was treated with P-PSMA-101 in late July. Through the first 7 days post-treatment, the patient had normal lab results and no clinical symptoms indicating an adverse event. The patient missed both his Day 10 and Day 14 follow up visits, but during this time developed symptoms that subsequently lead to hospitalization and he died of hepatic failure at Day 19 post-treatment. Although the direct cause of the hepatic failure has not yet been confirmed, the patient developed symptoms consistent with macrophage activation syndrome (MAS). MAS is a serious and potentially fatal overactivation of the immune system which has been associated with CAR-T therapies, but can have other causes such as infection and autoimmune disease. The patient also developed blurred vision which was diagnosed as uveitis. The clinical investigator has assessed the SAE as possibly related to P-PSMA-101 pending further investigation. To date, there have been no other serious adverse events of decreased vision, uveitis, MAS, or hepatic failure reported in study P-PSMA-101-001. There has also been no cytokine release syndrome or neurotoxicity reported to date.

The Company's assessment of the event and evaluation of next steps is ongoing, including assessment of protocol changes, if any, as indicated by the findings. The Company is awaiting a formal response from the FDA and is preparing recommendations designed to allow resumption of the clinical trial. Once the FDA's questions are answered and a plan submitted, the FDA then has 30 days to notify the Company if the clinical study of P-PSMA-101 may be resumed.

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, among other things, our plans and strategy with respect to developing our technologies and product candidates, including with respect to potential timing and plans of our on-going clinical trial of P-PSMA-101. These forward-looking statements are based upon our 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 clinical development of and regulatory decisions with respect to P-PSMA-101 and our other product candidates, as well as the other risks described in our 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. We undertake 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.

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 17, 2020

By: /s/ Mark J. Gergen
Mark J. Gergen
President and Chief Business Officer