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): June 4, 2019

Proteostasis Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-37695**	**20-8436652**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

80 Guest Street, Suite 500 **Boston, MA**	**02135**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code (617) 225-0096
(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	Name of exchange on which registered
Common stock, $0.001	**PTI**	**Nasdaq**

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 June 4, 2019, the Company issued the press release attached hereto as Exhibit 99.1.

The furnishing of the attached press release is not an admission as to the materiality of any information therein. The information contained in the press release is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the U.S. Securities and Exchange Commission, or the SEC, and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures. For important information about forward looking statements, see the "Safe Harbor" section of the press release in Exhibit 99.1 attached hereto.

The information in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01 and in the press release attached as Exhibit 99.1 to this Current Report shall not be incorporated by reference into any filing with the SEC made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, furnished herewith.

EXHIBIT INDEX

Exhibit No.	Exhibit Name
99.1	Press release, furnished herewith.

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.

Date: June 4, 2019

PROTEOSTASIS THERAPEUTICS, INC.

By: /s/ Meenu Chhabra
Meenu Chhabra
President and Chief Executive Officer

Exhibit 99.1

Proteostasis Therapeutics Receives Orphan Drug Designation in the EU for PTI-428 for the Treatment of Cystic Fibrosis

BOSTON, Mass. – June 4, 2019 – Proteostasis Therapeutics, Inc. (NASDAQ:PTI), a clinical stage biopharmaceutical company dedicated to the discovery and development of groundbreaking therapies to treat cystic fibrosis (CF) and other diseases caused by dysfunctional protein processing, today announced that the European Commission (EC) has granted orphan drug designation (ODD) to PTI-428 for the treatment of cystic fibrosis. PTI-428 is the Company's proprietary cystic fibrosis transmembrane conductance regulator (CFTR) amplifier that is currently in clinical development. In addition to ODD from the EC, PTI-428 has ODD, Breakthrough Therapy Designation and Fast Track Designation from the U.S. Food and Drug Administration.

ODD in the European Union (EU) is based upon a positive opinion from the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products (COMP) and provides regulatory and financial incentives for companies to develop and market therapies to treat serious disorders affecting no more than five in 10,000 persons in the EU. Companies that obtain ODD benefit from a number of incentives, including ten-year marketing exclusivity in the EU upon approval, as well as eligibility for protocol assistance, reduced fees and access to the EU's centralized marketing authorization procedure. Currently, over half of the global CF population lives in Europe with limited access to approved CFTR modulator therapies.

"This designation by the EC is further validation of both PTI-428's potential and PTI's mission to offer additional disease modifying treatment options for CF," said Meenu Chhabra, President and Chief Executive Officer of Proteostasis Therapeutics. "Orphan drug status is granted to development-stage drugs that make a major contribution to patients' care, either by demonstrating a significant clinical benefit over existing therapies or by providing a treatment for patients for whom existing therapies do not work. We look forward to advancing PTI-428 in the clinic later this year, as part of the planned 28-day Phase 2 studies of our proprietary combination CFTR modulator treatments."

About PTI-428

PTI-428 is an investigational CFTR amplifier in development for the treatment of CF in patients with at least one F508del mutation in the CFTR gene, as part of PTI's proprietary triple combination regimen that includes PTI-808, a novel potentiator, and PTI-801, a third-generation corrector. PTI-428 has been shown to work early during CFTR biogenesis to increase levels of newly synthesized CFTR protein, suggesting potential therapeutic benefits in combination with CFTR correctors and potentiators.

In March, PTI announced results from the Company's 14-day clinical studies of its proprietary combination CFTR modulators in CF subjects. Later this year, the Company is planning to initiate Phase 2, placebo-controlled, 28-day studies in CF subjects with at least one *F508del* mutation.

About Proteostasis Therapeutics, Inc.

Proteostasis Therapeutics, Inc. is a clinical stage biopharmaceutical company developing small molecule therapeutics to treat cystic fibrosis and other diseases caused by dysfunctional protein processing. Headquartered in Boston, MA, the Proteostasis Therapeutics team focuses on identifying therapies that restore protein function. For more information, visit www.proteostasis.com.

Safe Harbor

To the extent that statements in this release are not historical facts, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Words such as "aim," "may," "will," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Examples of forward-looking statements made in this release include, without limitation, statements regarding the potential of our proprietary combination therapies for the treatment of CF, the potential benefit to patients of our proprietary combination therapies, expected presentations and expected timing of the initiation of, patient enrollment in, data from, the completion of, our clinical studies and cohorts for our clinical programs, including our planned Phase 2 program, and the potential benefits associated with orphan drug designation. Forward-looking statements made in this release involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements, and we, therefore cannot assure you that our plans, intentions, expectations or strategies will be attained or achieved. Such risks and uncertainties include, without limitation, the possibility final or future results from our drug candidate trials (including, without limitation, longer duration studies) do not achieve positive results or are materially and negatively different from or not indicative of the preliminary results reported by the Company (noting that these results are based on a small number of patients and small data set), uncertainties inherent in the execution and completion of clinical trials (including, without limitation, the possibility that FDA or other regulatory agency comments delay, change or do not permit trial commencement, or intended label, or the FDA or other regulatory agency requires us to run cohorts sequentially or conduct additional cohorts or pre-clinical or clinical studies), in the enrollment of CF patients in our clinical trials in a competitive clinical environment, in the timing of availability of trial data, in the results of the clinical trials, in possible adverse events from our trials, in the actions of regulatory agencies, including maintaining orphan drug designation, in the endorsement, if any, by therapeutic development arms of CF patient advocacy groups (and the maintenance thereof), and those set forth in our Annual Report on Form 10-K for the year ended December 31, 2018, our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 and our other SEC filings. We assume no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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