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): March 12, 2018

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.)

200 Technology Square, 4th Floor Cambridge, MA	02139
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code (617) 225-0096

Not Applicable
(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))

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 March 12, 2018, 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.

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: March 12, 2018

PROTEOSTASIS THERAPEUTICS, INC.

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

Exhibit 99.1

Proteostasis Therapeutics Announces FDA Grants Breakthrough Therapy Designation for PTI-428 in Cystic Fibrosis

Designation granted for PTI-428 for the treatment of CF patients based on the results from a recent Phase 2, randomized, placebo controlled study

Cambridge, MA, March 12, 2018 – 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 U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for PTI-428, the Company's cystic fibrosis transmembrane conductance regulator (CFTR) amplifier.

FDA Breakthrough Therapy Designation is intended to expedite the development and review of a drug aimed at treating a serious or life-threatening disease where there is a significant unmet need and preliminary clinical evidence indicates that the drug may offer substantial improvement over existing therapies. Less than half of the drugs submitted for Breakthrough Therapy under the Food and Drug Administration Safety and Innovation Act have been granted the designation since the inception of the program. In the CFTR modulator category, Breakthrough Therapy Designation was granted to Kalydeco® and Orkambi®.

FDA granted the Breakthrough Therapy Designation for PTI-428 for the treatment of CF in homozygous patients for the F508del mutation who are receiving Orkambi® as background therapy. The designation was based on the results from a recent Phase 2, randomized, placebo controlled study of PTI-428, in 24 CF subjects on background treatment with Orkambi® and who were treated with either 50 mg PTI-428 once daily or placebo for 28 consecutive days. The study results showed that treatment with PTI-428 led to mean absolute improvement in percent predicted forced expiratory volume in 1 second ($ppFEV_1$) of 5.2 percentage points from baseline through Day 28 compared to placebo ($p<0.05$). Additionally, consistent with the CFTR amplifier mechanism of action, a positive increase in nasal mucosal CFTR protein was observed in PTI-428 treated subjects and the magnitude of change compared to baseline was consistent with the changes in CFTR protein levels observed in the *in vitro* human bronchial cell model, whereas the placebo subjects had no significant increase in CFTR protein during the treatment period.

“We believe the Breakthrough Therapy Designation for PTI-428 reflects the strength of the recent Phase 2 study results for our amplifier, a novel and proprietary class of CFTR modulators,” said Meenu Chhabra, president and chief executive officer of Proteostasis. “PTI-428 can potentially be added to current and future standards of care, offering the potential for improvement in pulmonary function for patients with cystic fibrosis. We look forward to working closely with the FDA as we advance our clinical programs for PTI-428, including as part of our proprietary triple combination with PTI-801 and PTI-808, our third generation corrector and potentiator, respectively.”

About PTI-428

PTI-428 is an investigational CFTR amplifier in development for the treatment of CF in patients who are homozygous for the F508del mutation in the CFTR gene as an add-on therapy to approved CFTR modulators or as part of PTI’s proprietary triple combination regimen that includes PTI-808, a potentiator, and PTI-801, a corrector. PTI-428 works early during CFTR biogenesis to increase levels of newly synthesized CFTR protein, suggesting potential therapeutic benefits in combination with CFTR correctors and potentiators.

About Proteostasis Therapeutics, Inc.

Proteostasis Therapeutics, Inc. is a clinical stage biopharmaceutical company developing small molecule therapeutics to treat cystic fibrosis (CF) and other diseases caused by dysfunctional protein processing. Headquartered in Cambridge, MA, the Proteostasis Therapeutics team focuses on identifying therapies that restore protein function. In addition to its multiple programs in cystic fibrosis, Proteostasis Therapeutics has formed a collaboration with Astellas Pharma, Inc. to research and identify therapies targeting the Unfolded Protein Response (UPR) pathway.

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 expected benefits of breakthrough therapy designation and possible add-on therapy indications for our drug candidates. 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 we may not achieve expedited clinical development or review as a result of the breakthrough therapy designation, the FDA rescinds such designation if our development program does not continue to meet the criteria for breakthrough therapy designation, 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 FDA 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 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, in endorsement, if any, by therapeutic development arms of CF patient advocacy groups, and those set forth in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2017 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.

Orkambi is a registered trademark of Vertex Pharmaceuticals, Inc.

CONTACTS:

Investors:
David Pitts
Argot Partners
212.600.1902
david@argotpartners.com

Media:
David Rosen
Argot Partners
212.600.1902
david.rosen@argotpartners.com