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): July 31, 2017

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 July 31, 2017, 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.

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 dated July 31, 2017 regarding business update

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: July 31, 2017

PROTEOSTASIS THERAPEUTICS, INC.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated July 31, 2017 regarding business update

Exhibit 99.1

Proteostasis Therapeutics Announces Progression of PTI-428 and PTI-801 to Longer Duration Studies in CF Subjects

PTI-801 Moving to 14 Day Proof of Concept Study in CF Subjects on Orkambi®
PTI-428 Continues to Enroll 28 Day Proof of Concept Study in CF Subjects on Orkambi®
PTI-808 Investigational New Drug Application Now Active; Phase 1 Study in Healthy Volunteers Initiated

CAMBRIDGE, Mass. – July 31, 2017 – Proteostasis Therapeutics, Inc. (NASDAQ: PTI), a biopharmaceutical company developing small molecule therapeutics to treat diseases caused by dysfunctional protein processing such as cystic fibrosis (CF), announced updates across the Company's later stage development programs in CF, including PTI-428, a cystic fibrosis transmembrane conductance regulator (CFTR) amplifier, PTI-801, a new generation CFTR corrector, and PTI-808, a CFTR potentiator.

Proteostasis announced that it has completed dosing of 19 patients as part of the ongoing Phase 1/2 study designed to evaluate the safety and pharmacokinetics of PTI-428, the Company's CFTR amplifier. PTI-428 was administered together with background Orkambi® (lumacaftor/ivacaftor) or as the only CFTR modulator therapy in CF subjects over a 14-day period (7-day dosing followed by 7-day follow-up period). The trial met its primary safety and pharmacokinetic endpoints, confirming PTI-428's safety, tolerability and lack of clinically meaningful drug-drug interaction with ivacaftor and lumacaftor.

"Preliminary data suggests that PTI-428 continues to demonstrate a favorable safety and pharmacokinetic profile, which has enabled the initiation of Phase 2, enrolling CF subjects on background Orkambi® taking PTI-428 or placebo for 28 days," said Meenu Chhabra, President and CEO of Proteostasis Therapeutics. "We continue to make meaningful progress with all three components of our proprietary triple combination: with the support of US and EU patient advocacy groups for the PTI-801 protocol, we are eligible to begin screening and enrolling CF subjects on background Orkambi® and 40 clinical sites in the US, Canada and EU have been identified or are in process of activation; enrollment continues in our 28-day study of PTI-428 across 14 active clinical sites in the US, with activation of another 23 sites in both the US and EU in process; and we have initiated a Phase 1 study of PTI-808 in healthy volunteers."

In the Phase 1 portion of the PTI-428 study, 11 subjects in the Orkambi® cohort and eight in the PTI-428 monotherapy cohort were enrolled, with each group enrolling 2 placebo subjects. All adverse events (AEs) were mild or moderate and none occurred in more than one subject. There were no hematology-related adverse events and no serious adverse events (SAEs) reported. Safety endpoints evaluated included lung function as measured by forced expiratory volume in one second (FEV1), although the study was not designed to show a statistically significant difference. In the subjects who received PTI-428 in addition to their background Orkambi, there was no significant improvement of FEV1 compared to placebo, although there was a numerical increase in FEV1 at day 7. Measurements of sweat chloride and mRNA in nasal mucosa were used as exploratory biomarkers but the changes were not significant nor correlated with lung function changes.

Ms. Chhabra added, “While confirming the safety of PTI-428, the phase 1 portion of this study was not expected to demonstrate efficacy over a 7-day dosing period, as PTI-428, as a CFTR amplifier, is designed to deliver substrate to correctors and was investigated in combination with Orkambi®, whose signal of efficacy required a 28-day study. As a result, we look forward to generating data in our 28-day proof-of-concept study to begin understanding the activity profile of PTI-428.” Proteostasis is enrolling patients in the Phase 2 safety and efficacy portion of the study, which explores PTI-428 dosed over a 28-day period, and preliminary data is expected in Q4 2017.

Po-Shun Lee, M.D., Executive Vice President, Chief Medical Officer, added: “This is a very exciting time for the CF community, with the potential of next generation CFTR modulator therapies and combinations just beginning to emerge inclusive of doublets, triplets and quadruplets. We believe that PTI-428, PTI-801 and PTI-808 have the potential to play a pivotal role in emerging next generation therapies as proprietary combinations and as add-ons to the evolving standard of care. In fact, recent clinical data published with triple combinations of CFTR modulators confirms that in vitro assays have high translational value correlating with improvements in lung function beyond what had been observed to date. This continues to reinforce the correlation between *in vitro* chloride transport and FEV1 and further suggests a ceiling on lung function improvement has not yet been established.”

Proteostasis also announced today that the protocol for the CF portion of its Phase 1/2 study of PTI-801, a new generation CFTR corrector with Fast Track designation from the FDA, has been endorsed by the Cystic Fibrosis Foundation Therapeutics Development Network (TDN) Protocol Review Committee and the European Cystic Fibrosis Society Clinical Trial Network (CTN). Screening of CF subjects for 14-day dosing in this study is in the process of being initiated, with initial data expected in Q4 2017. A total of 52 healthy volunteers have participated and completed the study. All AEs in the healthy volunteer portion of the study that have been reported to date were of mild or moderate intensity. No AEs were reported in more than one subject and no SAEs were reported. PTI-801 was found to be generally well tolerated. Preliminary PK assessments indicated that PTI-801 was well absorbed following single and multiple oral administrations, and suggest that it could be suitable for once daily dosing. *In vitro* studies have shown that the addition of PTI-801 to either a lumacaftor/ivacaftor or tezacaftor/ivacaftor combination increased the effect of both combinations by approximately three-fold.

The Company also announced today that its Investigational New Drug application with the U.S. Food and Drug Administration for PTI-808, a CFTR potentiator, is now active and that the Company has initiated a Phase 1 study in healthy volunteers. If positive efficacy results are achieved in the PTI-428 and PTI-801 programs, Proteostasis intends to initiate a triple combination study at the end of 2017 with all three agents (also known as PTI-NC-733). The study will explore different doses of PTI-808 with fixed dose combination of PTI-428 and PTI-801 in an F508del homozygous population who are not taking Orkambi®.

About Proteostasis Therapeutics, Inc.

Proteostasis Therapeutics, Inc. is a biopharmaceutical company dedicated to the discovery of groundbreaking therapies to treat diseases caused by dysfunctional protein processing, such as cystic fibrosis (CF). 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. 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 expected timing of the initiation of, patient enrollment in, data from, and our completion of, our clinical studies and cohorts for PTI-428, PTI-801, PTI-808 and our triple combination therapy candidate, PTI-NC-733. 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 in this release, (noting that these results are 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 Annual Report on Form 10-K for the year ended December 31, 2016, 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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