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): January 13, 2020

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(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	**PTI**	**The Nasdaq Global 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 January 13, 2020, the Company announced the following information:

Proteostasis Therapeutics, Inc. announced a regulatory update following the completion of a scientific advice meeting with the Medicines and Healthcare Products Regulatory Agency (MHRA), UK, regarding its two pivotal studies, MORE and CHOICES.

Both studies are designed to explore the potential of Proteostasis' proprietary cystic fibrosis transmembrane conductance regulator (CFTR) modulator combinations that include dirocaftor, posenacaftor and nesolicaftor, a CFTR potentiator, corrector and amplifier, respectively. The MHRA's scientific advice outlined a clear path forward toward the initiation and execution of the proposed two-pronged Phase 3 program, including establishment of a common safety database to support the safety profile of the proprietary combination, all toward the goal of supporting a Marketing Authorization Application for dirocaftor, posenacaftor and nesolicaftor. Both trials are expected to begin in 2020 and can run concurrently, building on the safety and efficacy database Proteostasis has established to date in over 300 patients with CF. The Company will continue to seek additional advice from other major regulatory agencies throughout 2020.

The CHOICES trial (Crossover trial based on Human Organoid Individual response in CF - Efficacy Study) is designed to be the first ever personalized medicine-based study in CF. CHOICES seeks to translate promising responses from an *ex vivo* organoids study of PTI modulators in rare CF mutations that is part of a pan-European strategic initiative, known as HIT-CF (Human Individualized Therapy of CF), whose goal is to accelerate the development of, and access to, personalized therapies for CF patients. The MORE trial (Modulator Options to RestorE CFTR study) is designed as a global, Phase 3, randomized, placebo-controlled study in CF subjects with the common F508del homozygous mutation, and will seek to confirm the positive efficacy and tolerability results from a recently completed Phase 2 study of the Proteostasis CFTR modulator triple combination.

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 timing of patient enrollment in our clinical studies and cohorts for our clinical programs, including our planned Phase 3 programs and initiation of registrational or pivotal studies. 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, 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 Form10-Q for the quarter ended September 30, 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.

The above information is not an admission as to the materiality of any information therein. 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.

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: January 13, 2020

PROTEOSTASIS THERAPEUTICS, INC.

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