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): April 4, 2018

Proteostasis Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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

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

02139 (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:

- □ 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 8.01 Other Events.

On April 4, 2018, Proteostasis Therapeutics, Inc. announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for the Company's triple combination program for the treatment of cystic fibrosis. The Company's proprietary triple combination includes the following investigational agents: a cystic fibrosis transmembrane conductance regulator (CFTR) amplifier, a third generation corrector and a potentiator, known as PTI-428, PTI-801 and PTI-808, respectively.

The FDA's Fast Track program is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. An investigational drug that receives Fast Track program designation is eligible for more frequent communications between the FDA and the company relating to the development plan and clinical trial design, and may be eligible for priority review if certain criteria are met.

Safe Harbor

To the extent that statements in this Current Report on Form 8-K 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 Current Report on Form 8-K include, without limitation, statements regarding the expected benefits of fast track designation. Forward-looking statements made in this Current Report on Form 8-K 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 fast track designation, the FDA rescinds such designation if our development program does not continue to meet the criteria for fast track 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 Annual Report on Form 10-K for the year ended December 31, 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.

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: April 4, 2018 PROTEOSTASIS THERAPEUTICS, INC.

By: /s/ Meenu Chhabra

Meenu Chhabra President and Chief Executive Officer