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): December 31, 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.)

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))

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.

The Company has completed a phase 1 study of PTI-428 as an add on to subjects who are currently on Kalydeco®. The two-center, double blinded and placebo-controlled study investigated four doses (10, 25, 50, 100mg) of PTI-428 in cystic fibrosis (CF) subjects on background Kalydeco therapy. Across the four dose levels and placebo, 15 subjects total were dosed with PTI-428 or placebo for two weeks.

The study met the primary and secondary objectives and confirmed that the safety and pharmacokinetic profile of the drug was as expected. Exploratory analyses were not performed due to the small number of enrolled subjects.

Safe Harbor

To the extent that statements in this report 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 report include, without limitation, statements regarding the potential of our proprietary candidate as an add on therapy for the treatment of CF, and the potential benefit to patients of our proprietary candidate as an add on therapy. 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 comments delay, change or do not permit trial commencement, or intended label, or the 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 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 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.

Kalydeco® is a trademark of Vertex Pharmaceuticals Incorporated.

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: December 31, 2018

PROTEOSTASIS THERAPEUTICS, INC.

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