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): November 7, 2019

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 2.02. Results of Operations and Financial Condition.

On November 7, 2019, Proteostasis Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2019. A copy of the press release issued in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit Name
99.1	Press Release issued by the Company on November 7, 2019, furnished herewith.

EXHIBIT INDEX

Exhibit No.	Exhibit Name
99.1	Press Release issued by the Company on November 7, 2019, 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: November 7, 2019

PROTEOSTASIS THERAPEUTICS, INC.

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

Exhibit 99.1

Proteostasis Therapeutics Reports Third Quarter 2019 Financial Results and Provides Corporate Update

BOSTON, Mass. – November 7, 2019 – 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 financial results for the third quarter ended September 30, 2019 and provided a corporate update.

"With equally strong demand from both US and ex-US clinical centers, we were able to complete enrollment in a little over four months for our 28-day global Phase 2 study of our doublet and triplet cystic fibrosis transmembrane conductance regulator (CFTR) combinations, and we now expect to report top line results later this quarter," said Meenu Chhabra, President and Chief Executive Officer of Proteostasis Therapeutics. "CFTR modulator therapy is on the threshold of transforming CF from a life limiting disease into a chronic condition, increasing life span and quality of life. Yet standard of care CFTR modulator treatment still leaves behind many people with CF, as tolerability, efficacy, access and eligibility remain disparate across patient populations. PTI is committed to delivering additional CFTR modulator treatment options to address these significant unmet needs."

Recent Highlights and Upcoming Milestones

Earlier this week, PTI announced the completion of enrollment in the Company's 28-day, Phase 2 study evaluating its proprietary doublet (PTI-808 and PTI-801) and triplet (PTI-808, PTI-801 and PTI-428) CFTR modulator combinations, at doses selected based on the totality of dose range finding data from approximately 250 CF subjects studied thus far. The study design targeted up to 30 F508del homozygous and up to 30 F508del heterozygous subjects. Study endpoints include safety, changes in sweat chloride concentration and changes in percent predicted FEV_1 ($ppFEV_1$). Due to rapid enrollment from centers in the United States, Canada, Western Europe, and New Zealand, data from the study are now expected in the fourth quarter of 2019 instead of the first quarter of 2020.

Data from the Company's CF clinical development programs were recently highlighted at the North American Cystic Fibrosis Conference in presentations delivered by Patrick Flume, M.D., Professor of Medicine and Pediatrics, Medical University of South Carolina and Jennifer L. Taylor-Cousar, M.D., M.S.C.S., Associate Professor of Medicine and Pediatrics, and Co-Director and CF Therapeutics Development Network Director of the Adult CF Program at National Jewish Health.

Last month, PTI hosted a cystic fibrosis patient summit on the disparity in access to CFTR modulator treatments. The event featured members of the CF community, including thought leaders, people with CF and CF advocates, and panel discussions focused on current unmet needs in CF.

In July, PTI announced the appointment of Geoffrey S. Gilmartin, M.D., M.M.Sc., as the Company's Chief Medical Officer (CMO), and Andrey E. Belous, M.D., Ph.D., as a Senior Medical Director. Dr. Gilmartin served previously as the medical lead for the Kalydeco label expansion program at Vertex Pharmaceuticals Inc. Dr. Belous joined the Company from Galapagos NV, where he most recently served as a Medical Director for the Company's Phase 3 program in Idiopathic Pulmonary Fibrosis (IPF).

Third Quarter 2019 Financial Results

Proteostasis reported a net loss of approximately $12.8 million for the three months ended September 30, 2019, as compared to a net loss of $18.4 million for the same period in the prior year.

There was no revenue for the three months ended September 30, 2019, as compared to $1.1 million for the same period in the prior year. The decrease of $1.1 million is due to the termination of the Company's collaboration agreement with Astellas.

Research and development expenses for the three months ended September 30, 2019 were $10.1 million, as compared to $15.6 million for the same period in the prior year. The decrease was primarily due to a decrease in clinical-related research activities.

General and administrative expenses for the third quarter of 2019 were $3.2 million, as compared to $4.2 million for the same period in the prior year. The decrease in general and administrative expenses in these periods was due primarily to lower professional fees and facility expenses.

Cash, cash equivalents and short-term investments totaled $77.8 million as of September 30, 2019, compared to $88.0 million as of June 30, 2019. We believe that our existing cash, cash equivalents and short-term investments are sufficient to fund our operations into 2021, allowing us to complete our Phase 2 study and fund activities supporting our pathway to product registrations.

About Proteostasis Therapeutics, Inc.

Proteostasis Therapeutics, Inc. is a clinical stage biopharmaceutical company developing small molecule therapeutics to treat cystic fibrosis and other diseases caused by dysfunctional protein processing. Headquartered in Boston, MA, the Proteostasis Therapeutics team focuses on identifying therapies that restore protein function. 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 sufficiency of the cash and cash resources to fund the our operating plans, expenses and capital expenditure requirements, the further development of the our programs, the potential of our proprietary combination therapies for the treatment of CF, the potential benefit to patients of our proprietary combination therapies, the ongoing trials of our product candidates, the expected timing for completion and reporting of top line results of our Phase 2 clinical trial and our expectations regarding expanding available therapeutic options for CF patients. 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 potential of our proprietary combination therapies for the treatment of CF, the potential benefit of our proprietary combination therapies to patients, expected completion of our clinical studies and cohorts for our clinical programs, including our planned Phase 2 program and initiation of a pivotal or registrational study, 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), in the commercialization and acceptance of new therapies, and those set forth in our Annual Report on Form 10-K for the year ended December 31, 2018, our Quarterly Report on Form 10-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.

CONDENSED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue	$ —	$ 1,055	$ 5,000	$ 2,840
Operating expenses:				
Research and development	10,145	15,591	43,217	36,595
General and administrative	3,154	4,150	10,781	11,931
Total operating expenses	13,299	19,741	53,998	48,526
Loss from operations	(13,299)	(18,686)	(48,998)	(45,686)
Interest income	224	171	879	530
Other income, net	242	87	850	224
Net loss	$ (12,833)	$ (18,428)	$ (47,269)	$ (44,932)
Net loss per share—basic and diluted	$ (0.25)	$ (0.50)	$ (0.93)	$ (1.26)
Weighted average common shares outstanding—basic and diluted	51,099,307	36,694,957	51,058,339	35,734,159

CONDENSED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	September 30, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	$ 77,761	$ 118,379
Total assets	94,038	136,142
Total liabilities	23,917	21,800
Total stockholders' equity	70,121	114,342

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