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): August 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 August 7, 2019, Proteostasis Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 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 August 7, 2019, furnished herewith.

EXHIBIT INDEX

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

PROTEOSTASIS THERAPEUTICS, INC.

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

Exhibit 99.1

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

BOSTON, Mass. – August 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 second quarter ended June 30, 2019 and provided a corporate update.

"PTI continues to advance the clinical development of our proprietary combination cystic fibrosis transmembrane conductance regulator (CFTR) modulators. We recently initiated dosing in the 28-day global Phase 2 study of our doublet (PTI-808 and PTI-801) and triplet (PTI-808, PTI-801 and PTI-428) combinations in F508del homozygous and heterozygous CF subjects and we remain on track to report top line results from this study in the first quarter of 2020. The CF community continues to seek alternatives to today's standard of care CFTR modulator therapy, validating PTI's mission to provide additional disease-modifying treatment options for patients with CF," said Meenu Chhabra, President and Chief Executive Officer of Proteostasis Therapeutics.

Recent Highlights and Upcoming Milestones

During the first quarter, PTI appointed Dr. Badrul Chowdhury, the former FDA Director of Pulmonology, Allergy, and Rheumatology, to the Company's board of directors. Dr. Chowdhury is Senior Vice President and Chief Physician-Scientist, Respiratory Inflammation and Autoimmunity (RIA) Late Stage, R&D Biopharmaceuticals, at AstraZeneca. He was previously Director of the Division of Pulmonary, Allergy, and Rheumatology Products at the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER).

In May, the European Commission (EC) granted orphan drug designation (ODD) to PTI-428 for the treatment of cystic fibrosis. PTI-428 is the Company's proprietary CFTR amplifier that is currently in clinical development. In addition to ODD from the EC, PTI-428 has Orphan Drug Designation, Breakthrough Therapy Designation and Fast Track Designation from the U.S. Food and Drug Administration.

Data from the Company's CF clinical development programs were presented during three panel presentations at the 42nd European Cystic Fibrosis Society (ECFS) Conference in June. The panel presenters were Damian Downey, M.D., Clinical Senior Lecturer in Respiratory Medicine, Queen's University Belfast, Belfast, UK; Manu Jain, M.D., Professor of Medicine (Pulmonary and Critical Care) and Pediatrics, Northwestern Medicine (Feinberg School of Medicine), Chicago, IL, US; and Geoffrey Gilmartin of PTI.

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 most recently served as Chief Medical Affairs Officer of the Company. Dr. Belous joined the Company from Galapagos NV (NASDAQ:GLPG), where he most recently served as a Medical Director for the company's Phase 3 program in Idiopathic Pulmonary Fibrosis (IPF).

PTI announced in July that the first patient was dosed in the Company's 28-day, Phase 2 study evaluating its proprietary CFTR modulator combinations in CF subjects. The global, multicenter, randomized, placebo-controlled study is expected to enroll up to 30 F508del homozygous patients and up to 30 F508del heterozygous patients. Dose selection (600 mg of PTI-801 and 300 mg of PTI-808, with or without 10 mg PTI-428) was based on the totality of dose range finding data from approximately 250 CF subjects studied thus far. Study endpoints include safety, changes in sweat chloride concentration and changes in ppFEV1. Data from the study are expected in the first quarter of 2020.

Second Quarter 2019 Financial Results

Proteostasis reported a net loss of approximately $20.0 million for the three months ended June 30, 2019, as compared to a net loss of $15.5 million for the same period in the prior year.

There was no revenue for the three months ended June 30, 2019, as compared to $0.8 million for the same period in the prior year. Revenue for the three months ended June 30, 2018 was related to the collaboration agreement with Astellas, or the Astellas Agreement, which ended in the fourth quarter of 2018.

Research and development expenses for the three months ended June 30, 2019 were $16.9 million, as compared to $12.6 million for the same period in the prior year. The increase in research and development expenses was primarily due to an increase in clinical-related research activities, as well as increases in employee-related expenses and professional fees.

General and administrative expenses for the second quarter of 2019 were $3.7 million, as compared to $4.0 million for the same period in the prior year. The decrease in general and administrative expenses was primarily due to a decrease in professional fees and employee-related expenses.

Cash, cash equivalents and short-term investments totaled $88.0 million as of June 30, 2019, compared to $105.3 million as of March 31, 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 studies and initiate key activities to support our Phase 3 program. As part of its effort to deliver new treatment options to CF patients in geographies around the world, the Company also announced today that it is exploring partnership opportunities to maximize the value of its assets.

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 Company’s operating plans, expenses and capital expenditure requirements, the further development of the Company’s programs, 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, data from, the completion of, our clinical studies and cohorts for our clinical programs, including our planned Phase 2 program and initiation of a pivotal study. 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, our ability to fund our operations and planned clinical trials, 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 Form 10-Q for the quarter ended June 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.

PROTEOSTASIS THERAPEUTICS, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue	$ —	$ 843	$ 5,000	$ 1,785
Operating expenses:				
Research and development	16,925	12,604	33,072	21,004
General and administrative	3,682	3,957	7,626	7,780
Total operating expenses	20,607	16,561	40,698	28,784
Loss from operations	(20,607)	(15,718)	(35,698)	(26,999)
Interest income	297	194	654	359
Other income, net	292	46	608	136
Net loss	$ (20,018)	$ (15,478)	$ (34,436)	$ (26,504)
Net loss per share—basic and diluted	$ (0.39)	$ (0.43)	$ (0.67)	$ (0.75)
Weighted average common shares outstanding—basic and diluted	51,097,456	36,009,109	51,037,514	35,245,796

PROTEOSTASIS THERAPEUTICS, INC.

CONDENSED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	June 30, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	$ 88,021	$ 118,379
Total assets	105,749	136,142
Total liabilities	23,764	21,800
Total stockholders' equity	81,985	114,342

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