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): May 8, 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))

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. ☒

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Common stock, $0.001	**PTI**	**Nasdaq**

Item 2.02. Results of Operations and Financial Condition.

On May 8, 2019, Proteostasis Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended March 31, 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 May 8, 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: May 8, 2019

PROTEOSTASIS THERAPEUTICS, INC.

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

EXHIBIT 99.1

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

BOSTON, Mass.—May 8, 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 first quarter ended March 31, 2019 and provided a corporate update.

"During the first quarter, we reported a compelling safety and efficacy data set from our 14-day studies, which led us to prioritize the clinical development of our proprietary combination cystic fibrosis transmembrane conductance regulator (CFTR) modulators," said Meenu Chhabra, President and Chief Executive Officer of Proteostasis Therapeutics. "With no plateau in ppFEV1 improvement observed in these studies, we are advancing what we have identified as the optimal dose levels of our proprietary double and triple combination treatments into 28-day Phase 2 studies. Enrollment for these trials will complete by the end of 2019 with data shortly thereafter and inform our previously guided 2020 Phase 3 development plans. With a cash runway into 2021, we are positioned well for our Phase 3 program. At PTI, we remain steadfast in our goal to provide additional CFTR modulator treatment options to CF patients in need of alternatives to today's standard of care."

Recent Highlights and Upcoming Milestones

In March, PTI announced results from the Company's Phase 1 clinical studies of its proprietary CFTR modulators: PTI-801, a third-generation CFTR corrector; PTI-808, a novel CFTR potentiator; and PTI-428, a novel CFTR amplifier. This comprehensive data set included efficacy and safety data from 14-day studies in CF subjects of PTI's proprietary combination therapy (PTI-808, PTI-801 and PTI-428), as well as separate studies of PTI-801 and PTI-428 as add-on treatments to background tezacaftor/ivacaftor therapy.

Following the announcement of this broad data set, the Company is planning to conduct Phase 2, placebo-controlled studies in CF subjects with at least one *F508del* mutation. The studies will evaluate PTI-801 (600 mg) and PTI-808 (300 mg) with or without PTI-428 over a 28-day treatment period in up to 30 F508del homozygous and up to 30 F508del heterozygous patients and will potentially provide insight on the magnitude of PTI-428 contribution to efficacy. The trials will employ entry criteria comparable to those used in other CFTR modulator combination studies. PTI's CFTR modulators will also be evaluated in a homogeneous population over a longer duration. PTI expects to complete enrollment in the Phase 2 studies by the end of 2019 and initiate Phase 3 development in mid-2020, consistent with previous guidance.

First Quarter 2019 Financial Results

Proteostasis reported a net loss of approximately $14.4 million for the three months ended March 31, 2019, as compared to a net loss of $11.0 million for the same period in the prior year.

Revenue for the three months ended March 31, 2019 was $5 million, as compared to $0.9 million for the same period in the prior year. The increase of $4.1 million is due to the $5.0 million up front payment related to the Technology Transfer and License Agreement with Genentech, Inc. recognized in the first quarter of 2019, which was not present in the first quarter of 2018.

Research and development expenses for the three months ended March 31, 2019 were $16.1 million, as compared to $8.4 million for the same period in the prior year. The increase was primarily due to an increase in clinical-related activities.

General and administrative expenses for the first quarter of 2019 were $3.9 million, as compared to $3.8 million for the same period in the prior year. The increase in general and administrative expenses in these periods was due primarily to an increase in professional fees, partially offset by a decrease in employee-related expenses.

Cash, cash equivalents and short-term investments totaled $105.3 million as of March 31, 2019, compared to $118.4 million as of December 31, 2018. 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.

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 presentations and expected timing of the initiation of, patient enrollment in, data from, and the completion of, our clinical studies and cohorts for our clinical programs. 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 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 Annual Report on Form 10-K for the year ended December 31, 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.

PROTEOSTASIS THERAPEUTICS, INC.

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

	Three Months Ended March 31,	
	2019	2018
Revenue	$ 5,000	$ 942
Operating expenses:		
Research and development	16,148	8,400
General and administrative	3,943	3,823
Total operating expenses	20,091	12,223
Loss from operations	(15,091)	(11,281)
Interest income	357	165
Other income, net	316	90
Net loss	$ (14,418)	$ (11,026)
Net loss per share—basic and diluted	$ (0.28)	$ (0.32)
Weighted average common shares outstanding—basic and diluted	50,976,907	34,474,004

PROTEOSTASIS THERAPEUTICS, INC.

CONDENSED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	March 31, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	$105,331	$ 118,379
Total assets	123,493	136,142
Total liabilities	22,526	21,800
Total stockholders' equity	100,967	114,342

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