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 15, 2020

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 Stock Market LLC**

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 May 15, 2020, Proteostasis Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2020. A copy of this press release is attached hereto as Exhibit 99.1.

The information contained in this Item 2.02, including Exhibit 99.1, 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 to be incorporated by reference into any of the Company's filings with the Securities and Exchange Commission under the Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit Name
99.1	Press Release dated May 15, 2020.

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 15, 2020

PROTEOSTASIS THERAPEUTICS, INC.

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

Proteostasis Therapeutics Reports First Quarter 2020 Financial Results and Provides Corporate Update

BOSTON, Mass. – May 15, 2020 – Proteostasis Therapeutics, Inc. (Nasdaq:PTI), a clinical stage biopharmaceutical company dedicated to the discovery and development of groundbreaking therapies to treat cystic fibrosis (CF), today announced financial results for the first quarter ended March 31, 2020 and provided a corporate update.

“The COVID-19 pandemic exacerbates the needs and anxieties of the CF community, and has further intensified our dedication to bringing more treatment choices to patients with CF,” said Meenu Chhabra, President and Chief Executive Officer of Proteostasis Therapeutics. “We are utilizing traditional and novel study approaches to develop our new, proprietary CFTR modulators—posenacaftor, dirocaftor and nesolicaftor – for rare and common CF mutations. In recent months, we have met with regulators in Europe to advance our goal of initiating the first large, personalized medicine study in CF: CHOICES. Employing theratyping, this study will use a laboratory assay to match our CFTR modulators to individual CF patients regardless of their CFTR genotype. This has the potential to increase access to treatment options and optimize the risk-benefit and cost-effectiveness for patients treated with CFTR modulators.”

With the global spread of the ongoing COVID-19 pandemic in the first quarter of 2020, the Company implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on its employees and its business, including clinical trials, supply chains and third-party providers. The Company continues to closely monitor the COVID-19 situation as it evolves its business continuity plans and response strategy.

First Quarter and Recent Highlights

In April of this year, Proteostasis announced it received a High Strategic Fit score from the Clinical Trials Network (CTN) for the HIT-CF – CHOICES protocol. The CHOICES protocol was assessed and scored by CF medical experts, experienced study coordinators, statisticians and trained patient reviewers across multiple domains and it has received the maximum rating in the domain of ‘Fit with ECFS Strategic Priorities’. The European Cystic Fibrosis Society formed this Clinical Trial Network (ECFS-CTN) to enhance clinical research across 58 participating sites in 17 countries. Participating sites conduct only those CF trials that have been reviewed and accepted after the ECFS-CTN protocol review process.

Proteostasis also announced in April that it received Scientific Advice from the Dutch Medicines Evaluation Board (MEB) on the CHOICES program for the treatment of people living with CF. The Company and the MEB discussed the development plan for PTI’s triple combination of dirocaftor, posenacaftor and nesolicaftor in the Netherlands and across Europe. The MEB expressed support for PTI’s personalized medicine approach and its goal of delivering effective medicines to patients who currently have no treatment options. The MEB also supported the expansion of the Company’s personalized medicine approach in more common genotypes, including F508del homozygous and heterozygous patients.

In February of this year, Proteostasis announced the completion of enrollment of 502 patients with CF in the HIT-CF Europe project, a research project which aims to pave the path to personalized medicine in CF. HIT-CF is leading a European-based initiative that is conducting confirmatory trials to assess the

predictability of the organoid assay for clinical benefit, such as the CHOICES study (Crossover trial based on Human Organoid Individual response in CF - Efficacy Study). Proteostasis' drug combinations will be tested first in an *ex vivo* study. Then, responders and non-responders will be selected for the CHOICES study. Dosing in CHOICES is expected to begin in the second half of 2020, with preliminary clinical data anticipated to be reported in early 2021. We do not anticipate any material changes in these timelines due to COVID -19, but continue to monitor its potential impact on these activities.

In January of this year, Proteostasis announced a regulatory update following the completion of a scientific advice meeting with the Medicines and Healthcare Products Regulatory Agency in the United Kingdom (MHRA) that outlined a path forward for the initiation and execution of our Phase 3 program, including establishment of a common safety database to support the safety profile of the proprietary combination, and the potential filing of a Marketing Authorization Application for posenacaftor, dirocaftor and nesolicaftor. The Company announced that it will continue to seek additional advice from other major regulatory agencies throughout 2020.

First Quarter 2020 Financial Results

Proteostasis reported a net loss of approximately $9.9 million for the three months ended March 31, 2020, as compared to a net loss of $14.4 million for the same period in the prior year.

The Company recorded no revenue in the three months ended March 31, 2020, as compared to revenue of $5 million for the same period in the prior year.

Research and development expenses for the three months ended March 31, 2020 were $6.5 million, as compared to $16.1 million for the same period in the prior year. The decrease in research and development expenses for the three months ended March 31, 2020 was primarily due to a decrease in clinical-related activities.

General and administrative expenses for the three months ended March 31, 2020 were $3.6 million, as compared to $3.9 million for the same period in the prior year. The decrease in general and administrative expenses for three months ended March 31, 2020 was due primarily to a decrease in professional fees.

Cash, cash equivalents and short-term investments totaled $57.1 million as of March 31, 2020, compared to $69.5 million as of December 31, 2019. The Company believes that its existing cash, cash equivalents and short-term investments are sufficient to fund operations into the second half of 2021. However, additional funding will be necessary to advance the Company's proprietary combination therapy candidates through regulatory approval and into commercialization, if approved.

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.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the Company’s planned clinical development of its proprietary combination therapies, including expectations with regard to timing of future regulatory and development milestones for the Company’s product candidates; expected timing of the data readouts from the Company’s ongoing clinical trials; the potential results of ongoing clinical trials; the expectations of the dirocaftor, posenacaftor and nesolicaftor combination as a treatment for CF; the expected development plan for our CHOICES Phase 3 clinical trial, including its final protocol design; whether the results from the CHOICES Phase 3 clinical trial together with other available clinical data for the dirocaftor, posenacaftor and nesolicaftor combination will be sufficient to support submission of a marketing application; the potential for future regulatory approval in the Netherlands and throughout Europe of the dirocaftor, posenacaftor and nesolicaftor combination; the timing and potential outcome of any future discussions with the FDA or any other regulatory agency; the Company’s plans for its current cash resources, including its anticipated cash runway and ability to fund its current business plans, expenses and capital expenditure requirements; and the potential benefit to patients of the Company’s proprietary combination therapies, including those with rare genotypes. 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, although not all forward-looking statements contain these identifying words. Any forward-looking statements are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements, and the Company, therefore cannot assure you that its plans, intentions, expectations or strategies will be attained or achieved. Such risks and uncertainties include, without limitation, the potential of the Company’s proprietary combination therapies for the treatment of CF, the potential benefit of the Company’s proprietary combination therapies to patients, expected completion of the Company’s clinical trials and cohorts for its clinical programs, initiation of a pivotal or registrational study, the possibility final or future results from the Company’s 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 us (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 require the Company to run cohorts sequentially or conduct additional cohorts or pre-clinical or clinical trials), in the enrollment of CF patients in its 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 its 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 addition, the COVID-19 pandemic and the associated containment efforts have had a serious adverse impact on the economy, the severity and duration of which are uncertain. Government stabilization efforts will only partially mitigate the consequences. The extent and duration of the impact on the Company’s business and operations is highly uncertain, and that impact includes effects on the Company’s commercialization and marketing, manufacturing and supply chain, and clinical trial operations. Factors that will influence the impact on the Company’s business and operations include the duration and extent of the pandemic, the extent of imposed or recommended containment and mitigation measures, and the general economic consequences of the pandemic. The pandemic could have a material adverse impact on its business, operations and financial results for an extended period of time. For a discussion of other risks and uncertainties, and other important factors,

any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the section titled "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, and the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 15, 2020, as updated by the Company's subsequent filings with the Securities and Exchange Commission. The Company assumes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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

	Three Months Ended March 31,	
	2020	2019
Revenue	$ —	$ 5,000
Operating expenses:		
Research and development	6,518	16,148
General and administrative	3,587	3,943
Total operating expenses	10,105	20,091
Loss from operations	(10,105)	(15,091)
Interest income	207	357
Interest Expense	(3)	—
Other income, net	23	316
Net loss	$ (9,878)	$ (14,418)
Net loss per share—basic and diluted	$ (0.19)	$ (0.28)
Weighted average common shares outstanding—basic and diluted	52,146,633	50,976,907

CONDENSED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	March 31, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	$ 57,104	$ 69,467
Total assets	73,089	84,724
Total liabilities	19,949	22,346
Total stockholders' equity	53,140	62,378

CONTACTS:

Investors:
David Pitts / Claudia Styslinger
Argot Partners
212.600.1902
david@argotpartners.com / claudia@argotpartners.com

Media:
David Rosen
Argot Partners
212.600.1902
david.rosen@argotpartners.com