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): March 10, 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 March 10, 2020, Proteostasis Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2019. 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 March 10, 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: March 10, 2020

PROTEOSTASIS THERAPEUTICS, INC.

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

Proteostasis Therapeutics Reports Fourth Quarter and Year-End 2019 Financial Results and Provides Corporate Update

BOSTON, Mass. – March 10, 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) through theratyping, today announced financial results for the fourth quarter and full year ended December 31, 2019, and provided a corporate update.

“Proteostasis made important progress throughout 2019 in delivering on our goal of bringing more treatment choices to patients with CF,” said Meenu Chhabra, President and Chief Executive Officer of Proteostasis Therapeutics. “With our Phase 2 trials complete, we are moving forward with a Phase 3 clinical development plan that embraces the pursuit of personalized medicine in CF through theratyping. Our mission is to deliver combinations of our investigational agents to preselected patients identified as responders to our therapies through the *ex vivo* testing of their own organoids. We believe that the theratyping path, or the process of matching CFTR modulators to individual CF patients based on a laboratory assay regardless of CFTR genotype, has the potential to become a patient-friendly and cost-effective approach to treatment for patients with CF, thereby increasing access to treatment options and optimizing risk-benefit and cost-effectiveness of CFTR modulators.”

Ms. Chhabra continued, “Through our next set of clinical trials that may be registrational trials, we will continue to explore the potential of our proprietary CFTR modulators - posenacaftor, dirocaftor and nesolicaftor - in rare and common CF mutations using both traditional and novel study approaches. We look forward to initiating these trials later this year and to providing updates, beginning with the CHOICES trial, soon thereafter.”

Fourth Quarter and Recent Highlights

Last month, Proteostasis announced the completion of enrollment of 502 patients with CF in the HIT-CF Europe project, a research project which aims to provide better treatment and improve lives for people with CF and rare mutations. 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 expected to be completed in the first half of 2020. 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.

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 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.

In December 2019, Proteostasis announced results from a Phase 2, 28-day clinical trial designed to assess the safety, tolerability and efficacy, of the Company's once-daily proprietary combinations, 600 mg of posenacaftor (PTI-801) and 300 mg of dirocaftor (PTI-808), with or without 10 mg of nesolicaftor (PTI-428), or placebo. The results demonstrated that the combination was generally well-tolerated in the trial, with the majority of reported adverse events mild to moderate in severity. Homozygous subjects receiving the triple combination experienced a mean absolute improvement in $ppFEV_1$ of 8 percentage points (p £ 0.01) and a reduction in sweat chloride concentration of -29 mmol/L ($p < 0.0005$) at day 28 compared to pooled placebo. In a population with high disease burden, the combination demonstrated compelling improvements in lung function and sweat chloride, including improved outcomes in the most challenging settings, including subjects with at least two pulmonary exacerbations within 12 months prior to study entry.

During the fourth quarter of 2019 through the date of this release, Proteostasis announced several peer-reviewed publications and medical meetings presentations, as well as a Company-hosted event:

- In February 2020, the Company co-authored an article, titled "*Amplifiers co-translationally enhance CFTR biosynthesis via PCBP1-mediated regulation of CFTR mRNA*," which was published in the *Journal of Cystic Fibrosis*. The publication highlights nonclinical data on the mechanism of action of nesolicaftor (PTI-428).
- In January 2020, the Company presented a poster, entitled "Intestinal Organoid Models as a Path for Personalized Therapy Development in Cystic Fibrosis," at the Keystone Symposia on Tissue Organoids. The poster highlighted the results from an *ex vivo* study of the Company's proprietary CFTR modulators in organoids from individuals with CF who are ineligible for the current standard of care CFTR modulator therapies due to their genotype, a population of approximately 2,300 adults in Europe alone.
- In October 2019, the Company was noted in a presentation highlighting data from the Company's CF clinical development programs at the North American Cystic Fibrosis Conference that was 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.
- In October 2019, the Company hosted a CF patient summit featuring members of the CF community, including thought leaders, people with CF and CF advocates, and panel discussions focused on current unmet needs in CF.

Year End 2019 Financial Results

Proteostasis reported a net loss of approximately $59.1 million for the year ended December 31, 2019, as compared to a net loss of $61.8 million for the year ended December 31, 2018.

The Company recorded $5.0 million of revenue for the year ended December 31, 2019, as compared to $2.8 million for the same period in the prior year. Revenue for the year ended December 31, 2019 was related to the Company's agreement with Genentech, Inc., while revenue for the year ended December 31, 2018 was related to the Company's agreement with Astellas Pharma Inc., which was terminated in the fourth quarter of 2018.

Research and development expenses for the year ended December 31, 2019 were $52.3 million, as compared to $50.3 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 2019 were $13.8 million, as compared to $15.7 million for the same period in the prior year. The decrease in general and administrative expenses was due primarily to a decrease in professional fees and facilities-related expenses.

Cash, cash equivalents and short-term investments totaled $69.5 million as of December 31, 2019, compared to $118.4 million as of December 31, 2018. 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.

Fourth Quarter 2019 Financial Results

Proteostasis reported a net loss of approximately $11.9 million for the three months ended December 31, 2019, as compared to a net loss of $16.9 million for the same period in the prior year.

There was no revenue in either the three months ended December 31, 2019, or in the same period in the prior year.

Research and development expenses for the three months ended December 31, 2019 were $9.1 million, as compared to $13.7 million for the same period in the prior year. The decrease in research and development expenses for the three months ended December 31, 2019 was primarily due to a decrease in clinical-related activities.

General and administrative expenses for the three months ended December 31, 2019 were $3.1 million, as compared to $3.8 million for the same period in the prior year. The decrease in general and administrative expenses for three months ended December 31, 2019 was due primarily to a decrease in professional fees.

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, a potential Phase 3 clinical trial and therapeutic potential of the therapies for the treatment of CF; expected timing of the data readouts from the Company's ongoing clinical trials; the potential results of ongoing

clinical trials; 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," "might", "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 we, therefore cannot assure you that our plans, intentions, expectations or strategies will be attained or achieved. Such risks and uncertainties include, without limitation, uncertainties regarding the expected timing of the initiation of, patient enrollment in, data from, and our completion of, our planned Phase 3 clinical trials with our combination therapy candidates, nesolicaftor (PTI-428), posenacaftor (PTI-801), and dirocaftor (PTI-808); uncertainties regarding our initiation of registrational or pivotal studies, submission of marketing authorization applications, cash guidance, and HIT CF consortium subject recruitment, *ex vivo* testing and conduct of clinical trials with our drug candidates; 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 another 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); and uncertainties 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). For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section titled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the Securities and Exchange Commission on March 10, 2020, as well as other filings the Company makes with the Securities and Exchange Commission from time to time. We assume 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 December 31,		Years Ended December 31,	
	2019	2018	2019	2018
Revenue	$ —	$ —	$ 5,000	$ 2,840
Operating expenses:				
Research and development	9,101	13,717	52,319	50,312
General and administrative	3,056	3,780	13,835	15,710
Total operating expenses	12,157	17,497	66,154	66,022
Loss from operations	(12,157)	(17,497)	(61,154)	(63,182)
Interest income	215	342	1,093	872
Other income, net	86	255	936	478
Net loss	$ (11,856)	$ (16,900)	$ (59,125)	$ (61,832)
Net loss per share—basic and diluted	$ (0.23)	$ (0.36)	$ (1.16)	$ (1.61)
Weighted average common shares outstanding—basic and diluted	51,351,763	46,687,910	51,139,531	38,495,103

CONDENSED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	December 31, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	$ 69,467	$ 118,379
Total assets	84,724	136,142
Total liabilities	22,346	21,800
Total stockholders' equity	62,378	114,342

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