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 6, 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 August 6, 2020, Proteostasis Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 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 August 6, 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: August 6, 2020

PROTEOSTASIS THERAPEUTICS, INC.

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

Proteostasis Therapeutics Reports Second Quarter 2020 Financial Results

BOSTON, Mass. – August 6, 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 second quarter ended June 30, 2020.

“The COVID-19 pandemic has highlighted the unmet needs of the CF community and reaffirmed our commitment to providing more treatment choices for people living with CF,” said Meenu Chhabra, President and Chief Executive Officer of Proteostasis Therapeutics. “Our team continues to work tirelessly to advance our mission and we anticipate announcing data from the *ex vivo* portion of the CHOICES development program in the fourth quarter of 2020, and plan to move into the clinical portion by year-end.”

The CHOICES (Crossover trial based on Human Organoid Individual response in CF—Efficacy Study) development program is based on testing PTI drug combinations in an *ex vivo* study and, subsequently, in a clinical trial to assess the predictability of the organoid assay for clinical outcomes. The *ex vivo* portion of the study will quantify the functional response of patient-derived organoids to PTI investigational agents dirocaftor, posenacaftor and nesolicaftor. Enrollment of 502 patients with CF in the *ex vivo* portion of the study is now complete and the Company expects *ex vivo* data in the fourth quarter of 2020. The dataset will enable targeted enrollment into the clinical portion of the CHOICES trial of subjects with rare Cystic Fibrosis transmembrane conductance regulator (CFTR) mutations based on their individual *ex vivo* response. The clinical portion of the trial is expected to begin by the end of 2020. PTI and its HIT-CF partners are currently in the process of activating approximately 30 clinical sites in Europe to support the CHOICES execution. The results from the CHOICES clinical trial may serve as the basis for a potential Marketing Authorization Application with the European Medicines Agency (EMA) in 2021 through a novel regulatory pathway.

Recent Highlights

In June of this year, Proteostasis announced results from *in vitro* studies evaluating the use of PTI-129 as a potential treatment for COVID-19. PTI-129 is a pre-clinical, once-daily, oral small molecule identified through our Disease Relevant Translation (DRT™) platform and originally designed to treat protein misfolding disorders involving the unfolded protein response (UPR). In *in vitro* studies conducted at Calibr, the drug discovery division of Scripps Research, PTI-129 demonstrated the potential to reduce viral protein production in host cells by activating the adaptive branches of the UPR pathway and reducing the levels of misfolded cellular proteins.

Second Quarter 2020 Financial Results

Proteostasis reported a net loss of approximately $8.9 million for the three months ended June 30, 2020, as compared to a net loss of $20.0 million for the same period in the prior year.

The Company recorded no revenue in the three months ended June 30, 2020 and 2019.

Research and development expenses for the three months ended June 30, 2020 were $4.6 million, as compared to $16.9 million for the same period in the prior year. The decrease in research and development expenses for the three months ended June 30, 2020 was primarily due to a decrease in clinical-related activities and related work as the CF studies progressed to data read out in late 2019.

General and administrative expenses for the three months ended June 30, 2020 were $4.4 million, as compared to $3.7 million for the same period in the prior year. The increase in general and administrative expenses for three months ended June 30, 2020 was due primarily to an increase in professional fees supporting financing activities.

Cash, cash equivalents and short-term investments totaled $48.9 million as of June 30, 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 the expected development plan for the Company's CHOICES development program, including its design, scope and timing; the likelihood of clinical site activation; the anticipated timing of disclosure of results of data readouts; whether the results from the CHOICES clinical trial together with other available clinical data for the dirocaftor, posenacaftor and nesolicaftor combination will be sufficient to support submission of a marketing authorization application; and the potential of PTI-129 as a treatment for COVID-19 based on results from *in vitro* studies. 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 impacts of the COVID-19 pandemic on the Company's business, clinical trials and financial position, 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, unexpected safety or efficacy data observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected whether due to the COVID-19 pandemic or otherwise, changes in expected or existing competition, changes in the regulatory environment, the uncertainties and timing of the

regulatory approval process, the risks associated with clinical development including possible adverse events, unexpected litigation or other disputes as well as 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 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 filed with the Securities and Exchange Commission on March 10, 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue	$ —	$ —	$ —	$ 5,000
Operating expenses:				
Research and development	4,584	16,925	11,102	33,072
General and administrative	4,366	3,682	7,953	7,626
Total operating expenses	8,950	20,607	19,055	40,698
Loss from operations	(8,950)	(20,607)	(19,055)	(35,698)
Interest income	54	297	261	654
Interest Expense	(6)	—	(9)	—
Other income, net	9	292	32	608
Net loss	$ (8,893)	$ (20,018)	$ (18,771)	$ (34,436)
Net loss per share—basic and diluted	$ (0.17)	$ (0.39)	$ (0.36)	$ (0.67)
Weighted average common shares outstanding—basic and diluted	52,147,656	51,097,456	52,147,145	51,037,514

CONDENSED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	June 30, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	$ 48,866	$ 69,467
Total assets	63,968	84,724
Total liabilities	19,032	22,346
Total stockholders' equity	44,936	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