UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____to _____

Commission file number: 001-37695

Proteostasis Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-8436652**
(State or Other jurisdiction of Incorporation or organization)	**(I.R.S. Employer Identification No.)**
80 Guest Street, Suite 500	
Boston, Massachusetts	**02135**
(Address of Principal Executive Offices)	**(Zip Code)**

(617) 225-0096
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of exchange on which registered
Common stock, par value $0.001 per share	PTI	The Nasdaq Stock Market LLC

Securities registered pursuant to the Section 12(g) of the Act: None

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 12, 2020, there were 52,184,755 shares of the registrant's common stock, $0.001 par value per share, outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or this report, including the sections entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Statements that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements are often identified by the words, “aim,” “anticipate,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “project,” “seek,” “should,” “target,” “will,” “would” or the negative of these terms or other comparable terminology intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements about:

- the success of our efforts, and those of our advisors, in executing on, our strategic alternatives, while preserving our cash balance to the extent practicable, including our proposed merger, or the Merger, with Yumanity Therapeutics, Inc, or Yumanity;
- the expected benefits of and potential value created by the Merger for our stockholders;
- the likelihood of the satisfaction of certain conditions to the completion of the Merger and whether and when the Merger will be consummated;
- the risk of unanticipated costs, liabilities or delays relating to the Merger, including the outcome of any legal proceedings relating to the Merger;
- the possibility of any change, effect, development, matter, state of facts, series of events or circumstances that could give rise to the termination of the agreement with Yumanity related to the Merger, including a termination of such agreement under circumstances that could require us to pay a termination fee to Yumanity;
- our ability to implement the reverse stock split, including receiving the necessary stockholder approvals;
- our ability to dispose of our intellectual property and assets relating to our cystic fibrosis clinical program, or the CF Assets;
- our ability to control and correctly estimate our operating expenses and our expenses associated with the Merger;
- our ability to operate as a stand-alone company if the Merger is not consummated;
- our expectations regarding the impact of the ongoing coronavirus disease 2019, or COVID-19, pandemic, including the expected duration of disruption and immediate and long-term impact and effect on our business and operations; and
- other forward-looking statements discussed elsewhere in this report.

You should refer to “Risk Factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this report.

Any forward-looking statements in this report reflect our current views with respect to future events and with respect to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part II, Item 1A. Risk Factors and elsewhere in this report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This report contains estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this report. Unless otherwise expressly stated, we obtained this industry, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, not prove to have been accurate.

Proteostasis Therapeutics, Inc.

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PART I — FINANCIAL INFORMATION

Item 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

PROTEOSTASIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 35,752	$ 25,008
Short-term investments	5,000	44,459
Prepaids and other current assets	821	1,404
Total current assets	41,573	70,871
Operating lease, right-of-use asset	11,682	12,631
Property and equipment, net	268	394
Restricted cash	828	828
Total assets	$ 54,351	$ 84,724
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 882	$ 2,283
Accrued expenses	3,670	6,864
Operating lease liabilities	1,231	1,153
Short-term borrowings	369	—
Total current liabilities	6,152	10,300
Derivative liability	3	3
Operating lease liabilities, net of current portion	11,109	12,043
Total liabilities	17,264	22,346
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding as of September 30, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value; 125,000,000 shares authorized; 52,180,380 and 52,116,629 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	52	52
Additional paid-in capital	400,635	398,979
Accumulated other comprehensive income	—	7
Accumulated deficit	(363,600)	(336,660)
Total stockholders' equity	37,087	62,378
Total liabilities and stockholders' equity	$ 54,351	$ 84,724

The accompanying unaudited notes are an integral part of these condensed consolidated financial statements.

PROTEOSTASIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue	$ —	$ —	$ —	$ 5,000
Operating expenses:				
Research and development	1,240	10,145	12,342	43,217
General and administrative	4,536	3,154	12,489	10,781
Restructuring costs	2,401	—	2,401	—
Total operating expenses	8,177	13,299	27,232	53,998
Loss from operations	(8,177)	(13,299)	(27,232)	(48,998)
Interest income	8	224	269	879
Interest expense	(4)	—	(13)	—
Other income, net	4	242	36	850
Net loss	$ (8,169)	$ (12,833)	$ (26,940)	$ (47,269)
Net loss per share—basic and diluted	$ (0.16)	$ (0.25)	$ (0.52)	$ (0.93)
Weighted average common shares outstanding—basic and diluted	52,177,557	51,099,307	52,157,355	51,058,339
Other comprehensive income:				
Unrealized gain (loss) on investments	—	(17)	(7)	15
Comprehensive loss	$ (8,169)	$ (12,850)	$ (26,947)	$ (47,254)

The accompanying unaudited notes are an integral part of these condensed consolidated financial statements.

PROTEOSTASIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at June 30, 2020	52,147,656	$ 52	$ 400,315	$ —	$ (355,431)	$ 44,936
Stock-based compensation expense	—	—	287	—	—	287
Issuance of common stock pursuant to employee stock purchase plan	28,205	—	33	—	—	33
Issuance of common stock for restricted stock units	4,519	—	—	—	—	—
Other comprehensive income (loss)	—	—	—	—	—	—
Net loss	—	—	—	—	(8,169)	(8,169)
Balances at September 30, 2020	52,180,380	$ 52	$ 400,635	$ —	$ (363,600)	$ 37,087

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2019	52,116,629	$ 52	$ 398,979	$ 7	$ (336,660)	$ 62,378
Stock-based compensation expense	—	—	1,598	—	—	1,598
Issuance of common stock pursuant to employee stock purchase plan	59,232	—	58	—	—	58
Issuance of common stock for restricted stock units	4,519	—	—	—	—	—
Other comprehensive income (loss)	—	—	—	(7)	—	(7)
Net loss	—	—	—	—	(26,940)	(26,940)
Balances at September 30, 2020	52,180,380	$ 52	$ 400,635	$ —	$ (363,600)	$ 37,087

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at June 30, 2019	51,099,307	$ 51	$ 393,872	$ 33	$ (311,971)	$ 81,985
Stock-based compensation expense	—	—	961	—	—	961
Issuance of common stock for payment of consulting services	29,669	—	25	—	—	25
Other comprehensive income (loss)	—	—	—	(17)	—	(17)
Net loss	—	—	—	—	(12,833)	(12,833)
Balances at September 30, 2019	51,128,976	$ 51	$ 394,858	$ 16	$ (324,804)	$ 70,121

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2018	50,808,422	$ 51	$ 391,825	$ 1	$ (277,535)	$ 114,342
Exercise of stock options	2,543	—	3	—	—	3
Stock-based compensation expense	—	—	2,710	—	—	2,710
Issuance of common stock for payment of consulting services	102,302	—	242	—	—	242
Issuance of common stock pursuant to employee stock purchase plan	52,284	—	78	—	—	78
Vesting of restricted stock units	163,425	—	—	—	—	
Other comprehensive income (loss)	—	—	—	15	—	15
Net loss	—	—	—	—	(47,269)	(47,269)
Balances at September 30, 2019	51,128,976	$ 51	$ 394,858	$ 16	$ (324,804)	$ 70,121

The accompanying unaudited notes are an integral part of these condensed consolidated financial statements.

PROTEOSTASIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (26,940)	$ (47,269)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	126	150
Non-cash lease expense	949	909
Accretion of short-term investments	(38)	(850)
Stock-based compensation expense	1,598	2,710
Stock issued for consulting services	—	242
Changes in operating assets and liabilities:		
Prepaids and other current assets	583	548
Other assets	—	(112)
Accounts payable	(1,401)	2,184
Accrued expenses	(3,194)	716
Operating lease liabilities	(856)	(783)
Net cash used in operating activities	(29,173)	(41,555)
Cash flows from investing activities:		
Purchases of short-term investments	(16,227)	(63,040)
Proceeds received from maturities of short-term investments	55,717	111,017
Purchases of property and equipment	—	(9)
Net cash provided by investing activities	39,490	47,968
Cash flows from financing activities:		
Proceeds from exercise of stock options	—	3
Proceeds from issuance of common stock pursuant to employee stock purchase plan	58	78
Proceeds from issuance of short-term borrowings	1,220	—
Repayment of short-term borrowings	(851)	—
Net cash provided by financing activities	427	81
Net increase in cash, cash equivalents and restricted cash	10,744	6,494
Cash, cash equivalents and restricted cash at beginning of period	25,836	29,638
Cash, cash equivalents and restricted cash at end of period	$ 36,580	$ 36,132

The accompanying unaudited notes are an integral part of these condensed consolidated financial statements.

1. Nature of the Business

Proteostasis Therapeutics, Inc. (the "Company") was incorporated in Delaware on December 13, 2006. The Company is a clinical stage biopharmaceutical company committed to the discovery and development of novel therapeutics to treat cystic fibrosis ("CF") through theratyping, or the process of matching modulators to individual response to treatment regardless of cystic fibrosis transmembrane conductance regulator ("CFTR") mutations. CF is a disease caused by defects in the function or abundance of CFTR protein.

Since its inception, the Company has devoted substantially all of its efforts to organizing and staffing the Company, business planning, raising capital, acquiring and developing product and technology rights, and conducting research and development activities. It has funded its operations to date with proceeds from the sale of preferred stock, the issuance of convertible promissory notes, proceeds from its initial public offering in February 2016, proceeds from its follow-on public offerings, and payments received in connection with collaboration agreements and a research grant, as well as funds from the sale of stock under at-the-market offering programs.

In August 2020, the Company announced that after consideration of various financing and strategic alternatives for its CF portfolio, with the goal of maximizing stockholder value of these assets, it has decided to continue its operations while exploring business and strategic options related to its research and discovery platform and intellectual property portfolio.

On August 14, 2020, the Company formed Pangolin Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the Company ("Merger Sub").

After conducting a process of evaluating strategic alternatives for the Company, on August 22, 2020, the Company entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") with Yumanity Therapeutics, Inc., a Delaware corporation ("Yumanity"), Yumanity Holdings, LLC, a Delaware limited liability company ("Holdings) and the Merger Sub, which was subsequently amended on November 6, 2020. Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, including approval of the transaction by the Company's stockholders and Yumanity's stockholders and the consolidation of Yumanity and Holdings prior to the closing of the transaction, Merger Sub will be merged with and into Yumanity (the "Merger"), with Yumanity surviving the Merger as a wholly-owned subsidiary of the Company. If the Merger is completed, the business of the Company will become the business of Yumanity.

The Merger is expected to be treated by the Company as a reverse merger accounted for as an asset acquisition in accordance with accounting principles generally accepted in the United States ("GAAP"). For accounting purposes, Yumanity is considered to be acquiring the Company in the Merger. In accordance with the accounting guidance under Accounting Standard Updates (or "ASU") 2017-01, the Merger is considered an asset acquisition. Accordingly, the assets and liabilities of the Company will be recorded as of the closing date of the Merger at the purchase price of the accounting acquirer. The Merger is expected to close in the fourth quarter of 2020, subject to the approval by the Company's stockholders at a special meeting of the Company's stockholders to be held on December 16, 2020, as well as other customary conditions. Upon completion of the Merger, the combined company will be renamed Yumanity Therapeutics, Inc., and is expected to trade on the Nasdaq Capital Market under the ticker symbol "YMTX".

On August 22, 2020, due to the entry into of the Merger Agreement with Yumanity, the Company's Board of Directors (the "Board") committed to reducing its workforce by approximately 79% to a total of five full-time employees, who will remain with the Company until the closing of the Merger to assist with its day-to-day business operations, including the maintenance of the sale and disposition of the Company's intellectual property and assets relating to its cystic fibrosis clinical program (the "CF Assets"), and those activities necessary to complete the proposed Merger. The Company has also retained its core intellectual property, licenses, collaborations with research institutions and universities, and proprietary equipment. The Company has incurred certain restructuring costs related to a reduction in its workforce, totaling $2.4 million through September 30, 2020. At September 30, 2020, the Company has have accrued one-time termination benefits of $1.6 million, of which the majority of this amount is anticipated to be incurred in the fourth quarter of 2020. In addition to restructuring costs, the Company has incurred approximately $1.6 million in other merger-related costs, which are included in the general and administrative costs on the Company's statement of operations and consists primarily of professional fees.

Although the Company has entered into the Merger Agreement and intends to consummate the Merger, there is no assurance that it will be able to successfully consummate the Merger on a timely basis, or at all. If, for any reason, the Merger does not close, the Company's Board may elect to, among other things, attempt to complete another strategic transaction like the Merger, attempt to sell or otherwise dispose of the Company's various assets, resume the Company's research and development activities and continue to operate the Company's business or dissolve and liquidate its assets. If the Company decides to dissolve and liquidate its assets, it would be required to pay all of its debts and contractual obligations, and set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left, if any, to distribute to the Company's stockholders after paying its debts and other obligations and setting aside funds for reserves. If the Company were to continue its business, it would need to raise a substantial amount of cash to fund ongoing operations and future development activities for its existing product candidates.

The Company has not generated any commercial revenue since inception. As a result, the Company has incurred recurring losses and requires significant cash resources to execute its business plans. In accordance with ASC 205-40, *Going Concern* ("ASC 205-40"), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements are issued. As of September 30, 2020, the Company had an accumulated deficit of $363.6 million. The Company has incurred losses and negative cash flows from operations since its inception. During the nine months ended September 30, 2020, the Company incurred losses of $26.9 million and used $29.2 million of cash in operations. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future. The Company currently expects that its cash, cash equivalents and short-term investments of $40.8 million will be sufficient to fund its operating expenses and capital requirements, based upon its current operating plan, for at least 12 months from the date that these consolidated financial statements are issued.

The novel coronavirus ("COVID-19") pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets and may affect the Company's operations and those of third parties on which the Company relies. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce the Company's ability to access capital, which could negatively impact the Company's short-term and long-term liquidity and the Company's and Yumanity's ability to complete the Merger on a timely basis or at all. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. The Company does not yet know the full extent of potential delays or impacts on its business, financing or other activities or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on the Company's liquidity, capital resources, operations and business and those of the third parties on which the Company relies.

2. Summary of Significant Accounting Policies

Unaudited Interim Consolidated Financial Information

The condensed balance sheet as of December 31, 2019 was derived from audited financial statements but does not include all disclosures required by GAAP. The accompanying condensed consolidated financial statements, as of September 30, 2020 and for the three and nine months ended September 30, 2020, are unaudited and have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. The Company believes that the disclosures are adequate to make the information presented not misleading. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto for the year ended December 31, 2019 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 10, 2020. In the opinion of management, all adjustments, consisting only of normal recurring adjustments, as necessary for the fair statement of the Company's financial position as of September 30, 2020, results of its operations for the three and nine months ended September 30, 2020, stockholders' equity for the three and nine months ended September 30, 2020, and cash flows for the nine months ended September 30, 2020, have been made. The results of operations for the three and nine months ended September 30, 2020 are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2020.

Summary of Significant Accounting Policies

The Company's significant accounting policies, which are disclosed in the audited financial statements for the year ended December 31, 2019 and the notes thereto, are included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 10, 2020 (the "Annual Report"). There were no changes to significant accounting policies during the three and nine months ended September 30, 2020.

Risks and Uncertainties

The Company is monitoring the potential impact of the ongoing COVID-19 pandemic, if any, on the carrying value of certain assets. To date, the Company has not experienced material business disruption, nor has it incurred impairment of any assets as a result of the COVID-19 pandemic. The extent to which these events may impact the Company's business, clinical development and regulatory efforts, and the value of its common stock, will depend on future developments, which are highly uncertain and cannot be predicted at this time. The duration and intensity of these impacts and resulting disruption to the Company's operations is uncertain and the Company will continue to assess the financial impact. In addition, to the extent the ongoing COVID-19 pandemic adversely affects the Company's business and results of operations, including the ability to execute the proposed Merger, it may also have the effect of heightening many of the other risks and uncertainties discussed in the Annual Report.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, revenue recognition, the accrual for research and development expenses, and the valuation the derivative liability. Estimates are periodically reviewed in light of changes in circumstances, facts, and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Reclassifications

Certain prior year amounts have been reclassified for consistency with the current year presentation. An adjustment has also been made to the condensed statement of cash flows for the period ended September 30, 2019, to reclassify non-cash lease expense out of depreciation and amortization.

Consolidation

These consolidated financial statements include Pangolin Merger Sub, Inc., the Company's wholly-owned subsidiary. All intercompany transactions and balances are eliminated in consolidation.

Recently Adopted Accounting Pronouncements

ASU No. 2018-13, *Fair Value Measurement (Topic 820): Changes to the Disclosure Requirements for Fair Value Measurement*

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"). The new standard modifies the disclosure requirements on fair value measure in Topic 820, including removals of existing disclosures, modifications of existing disclosures, and additions of new disclosures. Certain amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair values measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim of annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted for any removed or modified disclosure. The new standard is effective for the Company on January 1, 2020. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

Recently Issued Accounting Pronouncements

ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). The FASB subsequently issued amendments to ASU 2016-13, which have the same effective date and transition date of January 1, 2022, as the Company is a smaller reporting company. These standards require that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, these standards now require allowances to be recorded instead of reducing the amortized cost of the investment. These standards limit the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases. Based on the composition of the Company's investment portfolio and other financial assets, current market conditions and historical credit loss activity, the adoption of these standards is not expected to have a material impact on the Company's condensed consolidated financial statements.

3. Short-Term Investments

The following table summarizes the Company's short-term investments as of September 30, 2020 and December 31, 2019 (in thousands):

	September 30, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	$ 5,000	$ —	$ —	$ 5,000
	$ 5,000	$ —	$ —	$ 5,000

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government-sponsored enterprise securities	$ 20,456	$ 2	$ (1)	$ 20,457
U.S. treasury securities	23,996	7	(1)	24,002
	$ 44,452	$ 9	$ (2)	$ 44,459

Short-term investments represent holdings of available-for-sale debt securities and are reported at fair value with unrealized gains and losses reported net of taxes, if material, in other comprehensive income. The Company did not have any realized gains or losses on its short-term investments for the three and nine months ended September 30, 2020 and 2019, respectively. There were no other-than-temporary impairments recognized for the three and nine months ended September 30, 2020 and 2019, respectively.

4. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	Fair Value Measurements as of September 30, 2020 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 27,820	$ —	$ —	$ 27,820
U.S. treasury securities	—	5,999	—	5,999
U.S. government-sponsored enterprise securities	—	1,000	—	1,000
Short-term investments:				
U.S. treasury securities	—	5,000	—	5,000
	$ 27,820	$ 11,999	$ —	$ 39,819
Liabilities:				
Derivative liability	$ —	$ —	$ 3	$ 3

	Fair Value Measurements as of December 31, 2019 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 23,906	$ —	$ —	$ 23,906
Short-term investments:				
U.S. government-sponsored enterprise securities	—	20,457	—	20,457
U.S. treasury securities	—	24,002	—	24,002
	$ 23,906	$ 44,459	$ —	$ 68,365
Liabilities:				
Derivative liability	$ —	$ —	$ 3	$ 3

During the periods ended September 30, 2020 and December 31, 2019, there were no transfers between Level 1, Level 2, and Level 3.

The derivative liability relates to a cash settlement option associated with the change of control provision in the Company's Cystic Fibrosis Foundation, Inc. ("CFF") agreement, which meets the definition of a derivative. The fair value of the derivative liability is based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the derivative instrument was originally determined using the Monte-Carlo simulation analysis. In determining the fair value of the derivative liability, the inputs impacting fair value include the fair value of the Company's common stock, expected term of the derivative instrument, expected volatility of the common stock price, risk-free interest rate, expected sales-based milestone payments, discount rate, probability of a change of control event, and the probability that the counterparty would elect to accept the alternative cash payment in lieu of its right to the future sales-based milestone payments.

The fair value of the derivative liability was not material at September 30, 2020 and December 31, 2019.

5. Prepaids and Other Current Assets

Prepaids and other current assets consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Prepaid clinical, manufacturing and scientific expenses	$ 80	$ 767
Prepaid insurance expenses	684	125
Other prepaid expenses and other current assets	57	512
	$ 821	$ 1,404

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Accrued payroll and related expenses	2,334	3,203
Accrued research and development expenses	$ 685	$ 3,186
Accrued professional fees	635	397
Accrued other	16	78
	$ 3,670	$ 6,864

7. Short-Term Borrowings

As of September 30, 2020, the Company had short-term borrowings of $0.4 million consisting of a Commercial Insurance Premium Finance and Security Agreement (the "Finance and Security Agreement") entered into on February 27, 2020. The Finance and Security Agreement has a ten-month repayment period with an annual interest rate of 2.59% and a maturity of December 11, 2020. Collateral under the Finance and Security Agreement includes the right, title, and interest in the underlying business insurance policies. As of September 30, 2020, the Company has paid less than $0.1 million in interest on short-term borrowings.

8. Stock-Based Compensation

2016 Stock Option and Incentive Plan

On February 3, 2016, the Company's stockholders approved the 2016 Stock Option and Incentive Plan (the "2016 Plan"), which became effective on February 9, 2016. The 2016 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock units, restricted stock awards and other stock-based awards. The number of shares initially reserved for issuance under the 2016 Plan was 1,581,839 shares. The number of shares of common stock that may be issued under the 2016 Plan will automatically increase each January 1, beginning January 1, 2017, by the lesser of 3% of the shares of the Company's common stock outstanding on the immediately preceding December 31, or an amount determined by the Company's board of directors or the compensation committee of the board of directors. The shares of common stock underlying any awards that are forfeited, canceled, repurchased, or are otherwise terminated by the Company under the 2016 Plan and the 2008 Equity Incentive Plan, as amended (the "2008 Plan") will be added back to the shares of common stock available for issuance under the 2016 Plan. On January 1, 2020, an additional 1,563,498 shares were reserved for issuance under the 2016 Plan. As of September 30, 2020, the total number of shares of the Company's common stock reserved for issuance under the 2016 Plan was 6,914,838, of which 2,749,403 shares are available for future issuance under the 2016 Plan.

2016 Employee Stock Purchase Plan

On February 3, 2016, the Company's stockholders approved the 2016 Employee Stock Purchase Plan (the "2016 ESPP"), which became effective in connection with the completion of the Company's initial public offering. A total of 138,757 shares of common stock were initially reserved for issuance under the 2016 ESPP. In addition, the number of shares of common stock that may be issued under the 2016 ESPP will automatically increase each January 1, beginning January 1, 2017, by the lesser of (i) 138,757 shares of common stock, (ii) 1% of the Company's shares of common stock outstanding on the immediately preceding December 31, or (iii) an amount determined by the Company's board of directors or the compensation committee of the board of directors.

During the nine months ended September 30, 2020, 59,232 shares of common stock were issued pursuant to the 2016 ESPP. As of September 30, 2020, the total number of shares reserved under the 2016 ESPP was 552,537 shares. The Company recognized less than $0.1 million of stock-based compensation during the three and nine months ended September 30, 2020 related to the 2016 ESPP.

Restricted Stock Units (RSUs)

On February 4, 2020, the Company's Board approved payment to be made to a nonemployee through a grant of RSUs based on the February 4, 2020 closing share price of the Company's common stock. The requisite service period for the awards was from February 4, 2020 to August 4, 2020 (the vesting period). The Company recognized employee stock-based compensation expense for the RSU grant on a straight-line basis over the vesting period of the awards. As of September 30, 2020, 4,519 RSUs have vested and the Company recognized less than $0.1 million of stock-based compensation expense during the three and nine months ended September 30, 2020.

On June 29, 2020, the Company's Board approved the grant of RSU awards with an aggregate fair market value equal to the RSU value of $1.2 million (each, an "Award") to two consultants (each, a "Grantee") in consideration for services. Each Award shall vest in full immediately prior to, but subject to the occurrence of, a specific strategic event (the "Vesting Date"), so long as the respective Grantee remains in service to the Company through the Vesting Date. If the Awards vest as provided for above, the Company shall issue a number of shares of stock equal to the RSU value, divided by the volume-weighted average price per share of the Company's stock for the 10-day period ending on the Vesting Date. The Company also has the option to issue each Grantee the respective cash equivalent of the Award in part or in full satisfaction of the delivery of the stock in connection with the vesting of each Award. The Company believes equity classification of the RSUs is appropriate as the Company, not the Grantee, has the ability to determine whether to settle the Awards in cash or shares as of the reporting date and it reasonably expects to deliver the share equivalent of the Awards at the settlement date. As of September 30, 2020, the Company did not recognize compensation costs associated with the Awards as the occurrence of such strategic event is outside of the Company's control and therefore, cannot be considered probable.

Stock-Based Compensation

Stock-based compensation expense, including shares issued to consultants for services, was classified in the statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ (52)	$ 460	$ 443	$ 1,228
General and administrative	340	501	1,155	1,724
	$ 288	$ 961	$ 1,598	$ 2,952

The following table summarizes the Company's stock option activity for the nine months ended September 30, 2020 (in thousands except share and per share amounts):

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2019	4,364,839	$ 5.30	7.32	$ 132
Granted	1,663,000	1.56		
Forfeited	(1,862,404)	3.52		
Outstanding at September 30, 2020	4,165,435	$ 4.60	6.90	$ 7
Exercisable at September 30, 2020	2,776,235	$ 5.58	6.19	$ 7
Vested and expected to vest at September 30, 2020	4,082,185	$ 4.65	7.03	$ 7

The grant date fair value of options granted during the period was $1.8 million, or $1.09 per share on a weighted-average basis, and will be recognized as compensation expense over the requisite service period of four years.

As of September 30, 2020, there was $1.6 million of unrecognized compensation cost related to employee and nonemployee unvested stock options granted under the 2016 Plan, which is expected to be recognized over a weighted-average remaining service period of 2.1 years. Stock compensation costs have not been capitalized by the Company.

Prior to 2013, the Company issued options to purchase 203,964 shares of common stock to nonemployees, primarily members of the Company's scientific advisory board, that vest upon the achievement of specified development and clinical milestones. As of September 30, 2020, options for the purchase of 83,250 shares held by nonemployees remained unvested, pending achievement of the specified milestones.

9. Restructuring Costs

On August 22, 2020, due to the entry into the Merger Agreement with Yumanity, the Company's Board committed to reducing its workforce by approximately 79% to a total of five full-time employees, who will remain with the Company until the closing of the proposed Merger to assist with its day-to-day business operations, including the maintenance of the rights of all or any part of the Company's intellectual property portfolio relating to its cystic fibrosis clinical programs (the "CF Assets"), and those activities necessary to complete the proposed Merger. All employees affected by the workforce reduction are eligible to receive, among other things, severance payments based on the applicable employee's level and years of service with the Company and the continuation of group health insurance coverage for a specified time period post-termination. In addition, certain affected employees are eligible for an extension of the post-termination exercise period for their outstanding stock options. Each affected employee's eligibility for the severance benefits was contingent upon such employee's execution of a separation agreement, which includes a general release of claims against the Company.

The following table represents activity related to the Company's restructuring costs liability for nine months ended September 30, 2020 (in thousands):

	One-Time Termination Benefits
Balance at December 31, 2019	$ —
Costs incurred and charged to expense	2,401
Costs paid or otherwise settled	(796)
Balance at September 30, 2020	$ 1,605

As a result of the workforce reduction, the Company has recorded restructuring costs, primarily related to severance-related payments, in the amount of $2.4 million. The Company expects to incur total restructuring costs between $4.2 million to $4.7 million related to the Company's restructuring plan.

10. Significant Agreements

Genentech

In December 2018, the Company entered into a Technology Transfer and License Agreement (the "Genentech Agreement") with Genentech, Inc. ("Genentech") under which the Company granted Genentech an exclusive worldwide license for technology and materials relating to potential therapeutic small molecule modulators of an undisclosed target within the proteostasis network. The rights do not include CFTR modulators and are unrelated to the Company's investigational medicines or other ongoing research programs in cystic fibrosis. In connection with the terms of the Genentech Agreement, the Company was entitled to a nonrefundable cash payment of $5.0 million following the successful completion of the technology and materials transfer to Genentech and future milestone payments in the aggregate of approximately $96.0 million upon the achievement of specified development, regulatory, and commercial milestones. In addition, Genentech is obligated to pay the Company tiered royalties in the low single-digits based on net sales of products covered by the licenses granted under the Genentech Agreement. There are no cancellation, termination, or refund provisions in the Genentech Agreement that contain material financial consequences to the Company. Unless earlier terminated, the Genentech Agreement continues in full force and effect until the passing or expiration of all royalty payment obligations. Reciprocal termination rights under the agreement include termination for breach and termination for bankruptcy. Genentech may terminate the Genentech Agreement in its entirety, for convenience, upon thirty days' notice to the Company.

The Company evaluated the Genentech Agreement in accordance with the provisions of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). The Company's obligations under the Genentech Agreement are the following promises: (i) exclusive license to certain intellectual property associated with a specific target, and (ii) technology and materials transfer related to the intellectual property underlying the licensed technology. The Company determined that the exclusive license is not distinct from the associated technology and materials transfer because the customer cannot benefit from, or utilize, the license without the technology and materials transfer. Specifically, the Company concluded that the exclusive license is not capable of being distinct from the associated technology and materials transfer because Genentech does not have the knowledge or expertise to fully exploit potential product candidates without the accompanying technology and materials provided pursuant to the transfer, and no other third party can perform the transfer due to the Company's proprietary knowledge and specialized expertise with respect to the licensed intellectual property. Accordingly, the Company concluded that these promises should be combined into a single performance obligation (the "License and Transfer Performance Obligation").

The Company measured the transaction price solely in reference to the $5.0 million payment due upon receipt of notice from Genentech regarding the satisfactory completion of the technology and materials transfer. None of the variable consideration payable under the arrangement has been included in the transaction price. As of September 30, 2020, the Company has not achieved any research, development, regulatory, or commercial milestones, or earned any royalties under the Genentech Agreement. The Company utilizes "the most likely" amount method to estimate the amount of research, development, and regulatory milestone payments to be received. As part of the evaluation for the research and development milestone payments, the Company considers several factors including the stage of research and development of the compounds included in the arrangement, the risk associated with the remaining research and development work required to achieve the milestone, and the Company's level of involvement in the research and development activities.

Regulatory milestone payments are triggered upon the first commercial sale following receipt of regulatory approval from the FDA or other global regulatory authorities; therefore, such amounts will be excluded from the transaction price until the associated regulatory approval is received. The commercial milestone payments and royalties are subject to the royalty recognition constraint whereby such amounts will be recognized as revenue upon the later of: (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the payment has been allocated has been satisfied, or partially satisfied, because the exclusive license is deemed to be the sole or predominant item to which the payments relate. As all performance obligations are satisfied, the Company will recognize royalty revenue at the date the sales occur. The Company did not adjust the promised amount of consideration for the effects of a significant financing component because the Company expects that the period between when the promised goods and services are transferred and when the customer pays for those goods and services will be one year or less. There were no changes in the transaction price for the nine months ended September 30, 2020.

The transaction price of $5.0 million allocated to the combined performance obligation was recognized as revenue in February 2019 at the point in time that Genentech provided notice regarding the satisfactory completion of the technology and materials transfer. Upon that successful execution of the technology and materials transfer, control was deemed to be transferred for both the exclusive license and the technology and materials transfer promises, therefore the risks and rewards of ownership had been conveyed. As of September 30, 2020, the Company did not have any receivables or deferred revenue related to the Genentech Agreement because no payments under the arrangement became due, nor had the underlying performance obligation been satisfied.

11. Income Taxes

The Company did not record a federal or state income tax benefit for its losses for the three and nine months ended September 30, 2020 and 2019, respectively, due to the conclusion that a full valuation allowance is required against the Company's deferred tax assets. All the Company's losses before income taxes were generated in the United States.

12. Net Loss per Share

Basic and diluted net loss per share was calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Numerator:				
Net loss	$ (8,169)	$ (12,833)	$ (26,940)	$ (47,269)
Denominator:				
Weighted average number of common shares outstanding—basic and diluted	52,177,557	51,099,307	52,157,355	51,058,339
Net loss per share—basic and diluted	$ (0.16)	$ (0.25)	$ (0.52)	$ (0.93)

The following common stock equivalents have been excluded from the computation of diluted weighted-average shares outstanding, because such securities had an antidilutive impact:

	September 30,	
	2020	2019
Options to purchase common stock	4,165,435	4,545,064
Restricted stock units (1)	—	—
	4,165,435	4,545,064

(1) Certain restricted stock units are excluded from the table as the number of shares of stock to be issued will be determined based on a computation at the vesting date, as described in Note 8.

13. Leases

The Company has an operating lease for office and laboratory space for its corporate headquarters in Boston, Massachusetts. The lease commenced in January 2018 and rent payments began in April 2018. This lease has a ten-year initial term with an option to extend for seven additional years.

The Company has the right to terminate the lease in the event of the inability to use the space due to substantial damage while the lessor has the right to terminate the lease if the Company defaults on the lease financial obligations. Per the terms of the lease agreement, the Company does not have any residual value guarantees. In calculating the present value of the lease payments, the Company utilized its incremental borrowing rate, which is based on rates that would be incurred to borrow on a collateralized basis over a term equal to the lease payments in a similar economic environment. The Company has allocated all the contract considerations to the one lease component. This may result in the initial and subsequent measurement of the balances of the right-of-use asset and lease liability for leases being greater than if the policy election was not applied. The Company's real estate lease in Boston is considered a net lease, as the non-lease components (i.e., common area maintenance) are paid separately from rent, based on actual costs incurred. Therefore, the variable non-lease components were not included in the right-of-use asset and liability and are reflected as an expense in the period incurred.

As of September 30, 2020, and December 31, 2019, assets under operating lease were $11.7 million and $12.6 million, respectively. The elements of lease expense were as follows (in thousands):

	For the Three Months Ended September 30,	
	2020	2019
Lease cost		
Operating lease cost	$ 462	$ 462
Variable lease cost (1)	158	182
Total lease cost	$ 620	$ 644

	For the Nine Months Ended September 30,	
	2020	2019
Lease cost		
Operating lease cost	$ 1,387	$ 1,387
Variable lease cost (1)	420	494
Total lease cost	$ 1,807	$ 1,881
Other information		
Operating cash flows used for operating leases	$ 1,296	$ 1,261
Weighted-average remaining lease term	7.59 years	8.59 years
Weighted-average discount rate	4.50%	4.50%

(2) The variable lease costs for the three and nine months ended September 30, 2020 and 2019 include common area maintenance charges.

Future lease payments under noncancelable leases as of September 30, 2020 (in thousands):

Future Operating Lease Payments	
2020	$ 437
2021	1,780
2022	1,829
2023	1,880
2024	1,931
Thereafter	6,825
Total lease payments	14,682
Less: imputed interest	(2,342)
Total operating lease liabilities	$ 12,340

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and the results of operations should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q, or Quarterly Report, and our audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the Securities and Exchange Commission, or the SEC, on March 10, 2020, or the Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section in our Annual Report and in this Quarterly Report, our actual results could differ materially from the results described, in or implied by, the forward-looking statements contained in the following discussion and analysis. Such factors may be amplified by the COVID-19 pandemic and its potential impact on our business and the global economy.

Overview

We are a clinical stage biopharmaceutical company committed to the discovery and development of novel therapeutics to treat cystic fibrosis, or CF, through theratyping, or the process of matching modulators to individual response to treatment regardless of cystic fibrosis transmembrane conductance regulator, or CFTR, mutations. CF is a disease caused by defects in the function or abundance of CFTR protein.

Since our inception in 2006, we have devoted substantially all our resources to organizing and staffing our company, business planning, raising capital, acquiring and developing product and technology rights, and conducting research and development activities for our product candidates. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations to date with proceeds received from equity offerings, the issuance of convertible promissory notes and, to a lesser extent, payments received in connection with collaboration agreements and a research grant.

In addition, we have entered into a sales agreement with H.C. Wainwright & Co., LLC, or HCW, with respect to an at-the-market, or ATM, offering program, or the ATM program. As of December 31, 2019, we have sold 987,653 shares of our common stock for total net proceeds of approximately $3.5 million under the ATM program. We did not sell any shares of our common stock under the ATM program during the nine months ended September 30, 2020.

To date, we have not generated significant revenue and have incurred significant operating losses. Our net losses were $8.2 million and $26.9 million for the three and nine months ended September 30, 2020, respectively. As of September 30, 2020, we had an accumulated deficit of $363.6 million. We require additional funding to fund our CF-focused pipeline and namely, our CHOICES program, and to advance our proprietary combination therapy candidates posenacaftor, dirocaftor, and nesolicaftor, through regulatory approval and into commercialization, if approved.

In August 2020, we announced that after consideration of various financing and strategic alternatives for our CF portfolio, with the goal of maximizing stockholder value of these assets, we have decided to continue our operations while exploring business and strategic options related to our research and discovery platform and intellectual property portfolio.

After conducting a diligent and extensive process of evaluating our strategic alternatives and careful evaluation and consideration of those proposals, and following extensive negotiation, on August 22, 2020, we entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, with Yumanity Therapeutics, Inc., a Delaware corporation, or Yumanity, Yumanity Holdings, LLC, a Delaware limited liability company, or Holdings, and Pangolin Merger Sub, Inc., a Delaware corporation and our wholly-owned subsidiary, or the Merger Sub. Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, including approval of the transaction by our stockholders and Yumanity's stockholders and the consolidation of Yumanity and Holdings prior to the closing of the Merger, Merger Sub will be merged with and into Yumanity, or the Merger, with Yumanity surviving the Merger as our wholly-owned subsidiary and the surviving corporation of the Merger. If the Merger is completed, our business will become the business of Yumanity.

On August 22, 2020, due to the entry into of the Merger Agreement with Yumanity, our Board of Directors, or the Board, committed to reducing our workforce by approximately 79% to a total of five full-time employees, who will remain with us until the closing of the Merger to assist with our day-to-day business operations, including the maintenance of the sale and disposition of intellectual property and assets relating to our cystic fibrosis clinical program, or the CF Assets, and those activities necessary to complete the proposed Merger. We have retained our core intellectual property, licenses, collaborations with research institutions and universities, and proprietary equipment. We have incurred certain restructuring charges related to a reduction in our workforce, totaling $2.4 million through September 30, 2020. At September 30, 2020 we have accrued one-time termination benefits of $1.7 million, of which the majority are anticipated to be incurred in the fourth quarter of 2020. We believe that our existing cash and cash equivalents will be sufficient to fund our anticipated stand-alone operating expenses and capital expenditures for the foreseeable

future; however, there can be no assurances as to the amount or timing of available cash, if any, left to distribute to our stockholders after paying the debts and our other obligations and setting aside funds for potential future claims.

We and Yumanity believe that the Merger will result in a clinical-stage biopharmaceutical company focused on discovering and developing disease-modifying treatments for neurodegenerative diseases based on Yumanity's discovery engine and pipeline of novel targets and product candidates.

We may not be successful in completing the Merger. If, for any reason, the Merger does not close and the Merger Agreement is terminated, the Board may elect to, among other things, attempt to complete another strategic transaction including a transaction similar to the Merger, continue to operate our business or to dissolve and liquidate our assets. If we decides to dissolve and liquidate our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims. As of September 30, 2020, we had cash and cash equivalents and short-term investments totaling approximately $40.8 million.

COVID-19 Business Update

The novel coronavirus, or COVID-19, pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets and may affect our operations and those of third parties on which we rely. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity and our ability and Yumanity's ability to complete the Merger on a timely basis or at all. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or other activities or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely.

Components of our Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future. We did not recognize any revenue during the three and nine months ended September 30, 2020. All our revenue during the nine months ended September 30, 2019 was derived from our Genentech Agreement.

Operating Expenses

Research and Development Expenses

Research and development expenses, which include costs of research services incurred in connection with our collaboration agreements and research grant, have historically consisted primarily of costs incurred in connection with the discovery and development of our product candidates, which include:

- employee-related expenses, including salaries, related benefits, travel, and stock-based compensation expense for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our product candidates under agreements with contract research organizations, or CROs, and contract manufacturing organizations, or CMOs;
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and supplies; and
- payments made under third-party licensing agreements.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers.

Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs, such as fees paid to consultants, central laboratories, contractors, CROs, and CMOs in connection with our clinical trials and preclinical development activities. We do not allocate employee costs, costs associated with our platform technology, facility expenses, including depreciation, or other indirect costs, to specific product development programs because these costs are deployed across multiple product development programs and, as such, are not separately classified. We use internal resources to manage our preclinical development activities and perform data analysis for such activities. These employees work across multiple development programs and, therefore, we do not track their costs by program.

The table below summarizes our research and development expenses incurred by program (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
CF	$ 674	$ 6,084	$ 6,285	$ 30,546
UPR	-	91	13	303
Unallocated expenses:				
Employee-related	11	2,755	4,412	8,107
Facility-related	186	499	908	1,577
Other	369	716	724	2,684
Total research and development expenses	$ 1,240	$ 10,145	$ 12,342	$ 43,217

In August 2020, after consideration of various financing and strategic alternatives for our CF portfolio, with the goal of maximizing stockholder value of these assets, our Board approved our entry into the proposed Merger. As a result of this decision, we stopped further research and development of our product pipeline and our pre-clinical programs, including the Unfolded Protein Response, or UPR, program, to reduce operating expenses. As a result, our research and development expenses for the fiscal year ending December 31, 2020 will decrease as compared to the fiscal year ended December 31, 2019.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, travel, and stock-based compensation for personnel in executive, finance, and administrative functions. General and administrative expenses also include facilities, which include direct and allocated expenses for rent and maintenance of facilities, depreciation, insurance, and supplies, as well as professional fees for legal, consulting, accounting, and audit services.

We anticipate that our general and administrative expenses in the fiscal year ending December 31, 2020 will decrease from the fiscal year ended December 31, 2019, with the exception of severance payments, as we continue to focus our efforts on preserving cash while we seek to maximize stockholder value. Over the longer term, however, these expenses could increase due to professional fees associated with the proposed Merger with Yumanity.

Restructuring Costs

Restructuring costs consist primarily of severance-related costs associated with the reduction in force in connection with the proposed Merger with Yumanity.

Interest Income

Interest income consists of interest earned on cash equivalents and short-term investments held by us during the reporting periods.

Interest Expense

Interest expense consists of interest paid on our short-term borrowings during the reporting periods.

Other Income (Expense), Net

Other income (expense), net, primarily consists of the amortization of premiums and discounts on our short-term investments and the gains or losses associated with the changes in the fair values of our derivative liability.

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions. These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements, and notes thereto, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 10, 2020.

During the nine months ended September 30, 2020, there were no material changes to our critical accounting policies. Our critical accounting policies are described under the heading, "Management's Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies and Significant Judgments and Estimates," in our Annual Report on Form 10-K for the year ended December 31, 2019 and the notes to the financial statements appearing elsewhere in this Quarterly Report. We believe that of our critical accounting policies, the following accounting policies involve the most judgment and complexity:

- revenue recognition;
- accrued research and development expenses; and
- stock-based compensation.

Accordingly, we believe the policies set forth above are critical to fully understanding and evaluating our financial condition and results of operations. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected.

Results of Operations

Comparison of Three Months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,		Increase
	2020	2019	(Decrease)
Revenue	$ —	$ -	$ -
Operating expenses:			
Research and development	1,240	10,145	(8,905)
General and administrative	4,536	3,154	1,382
Restructuring costs	2,401	-	2,401
Total operating expenses	8,177	13,299	(5,122)
Loss from operations	(8,177)	(13,299)	(5,122)
Interest income	8	224	(216)
Interest expense	(4)	—	(4)
Other income, net	4	242	(238)
Net loss	$ (8,169)	$ (12,833)	$ (4,664)

Revenue

There was no revenue for the three months ended September 30, 2020 or 2019.

Research and Development Expenses

Research and development expenses decreased to $1.2 million for the three months ended September 30, 2020, compared to $10.1 million for the three months ended September 30, 2019 due to our strategic shift in strategy related to our pursuit of the Merger with Yumanity. The decrease of $8.9 million was related to a decrease of approximately $5.4 million in clinical-related research activities as we wind down our CF programs, $2.7 million in employee-related expenses as we reduced our workforce, $0.5 million in professional fees, and $0.3 million in facility expenses.

General and Administrative Expenses

General and administrative expenses were $4.5 million for the three months ended September 30, 2020, compared to $3.2 million for the three months ended September 30, 2019. The increase of $1.3 million in general and administrative expenses was primarily due to an increase of $1.5 million in professional fees primarily related to our proposed Merger with Yumanity, $0.2 million in facility expenses, and $0.2 million in insurance expenses, offset by a decrease of $0.6 million in employee-related expenses.

Restructuring Costs

Restructuring costs were $2.4 million for the three months ended September 30, 2020, consisting primarily of severance-related costs associated with a reduction in force in connection with the proposed Merger with Yumanity. There were no restructuring costs for the three months ended September 30, 2019.

Interest Income

Interest income was less than $0.1 million for the three months ended September 30, 2020, compared to $0.2 million for the three months ended September 30, 2019. The decrease of $0.2 million in interest earned on cash equivalents and short-term investments is due to a decrease in average balance of invested cash held during the three months ended September 30, 2020, compared to the three months ended September 30, 2019.

Interest Expense

Interest expense was less than $0.1 million for the three months ended September 30, 2020 and consisted of interest paid on short-term borrowings. There was no interest expense for the three months ended September 30, 2019.

Other Income, Net

Other income was less than $0.1 million and $0.2 million for the three months ended September 30, 2020 and 2019, respectively. The decrease of $0.1 million in other income is primarily due to a decrease in net accretion of discounts on short-term securities in the three months ended September 30, 2020 compared to the three months ended September 30, 2019.

Comparison of Nine Months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the nine months ended September 30, 2020 and 2019 (in thousands):

	Nine Months Ended September 30,		Increase
	2020	2019	(Decrease)
Revenue	$ -	$ 5,000	$ (5,000)
Operating expenses:			
Research and development	12,342	43,217	(30,875)
General and administrative	12,489	10,781	1,708
Restructuring costs	2,401	-	2,401
Total operating expenses	27,232	53,998	(26,766)
Loss from operations	(27,232)	(48,998)	(21,766)
Interest income	269	879	(610)
Interest expense	(13)	—	(13)
Other income, net	36	850	(814)
Net loss	$ (26,940)	$ (47,269)	$ (20,329)

Revenue

There was no revenue for the nine months ended September 30, 2020, as compared to revenue of $5.0 million related to the Genentech Agreement recognized in the nine months ended September 30, 2019.

Research and Development Expenses

Research and development expenses decreased to $12.3 million for the nine months ended September 30, 2020, compared to $43.2 million for the nine months ended September 30, 2019 due to our strategic shift in strategy related to our pursuit of the Merger with Yumanity. The decrease of $30.9 million was due to a decrease of approximately $24.8 million in clinical-related research

activities as we wind down our CF programs, $3.8 million in employee-related expenses as we reduced our workforce, $1.7 million in professional fees, and $0.6 million in facility expenses.

General and Administrative Expenses

General and administrative expenses were $12.5 million for the nine months ended September 30, 2020, compared to $10.8 million for the nine months ended September 30, 2019. The increase of $1.7 million in general and administrative expenses was due to an increase of $1.3 million in professional fees primarily related to our proposed Merger with Yumanity, an increase of $0.5 million in facility expenses, and $0.5 million in insurance expenses, partially offset by a decrease of $0.5 million in employee-related expenses.

Restructuring Costs

Restructuring costs were $2.4 million for the nine months ended September 30, 2020, consisting primarily of severance-related costs associated with a reduction in force in connection with the proposed Merger with Yumanity. There were no restructuring costs for the nine months ended September 30, 2019.

Interest Income

Interest income was $0.3 million for the nine months ended September 30, 2020, compared to $0.9 million for the nine months ended September 30, 2019. The decrease of $0.6 million in interest earned on cash equivalents and short-term investments is due to a decrease in average balance of invested cash held during the nine months ended September 30, 2020, compared to the nine months ended September 30, 2019.

Interest Expense

Interest expense was less than $0.1 million for the nine months ended September 30, 2020 and consisted of interest paid on short-term borrowings. There was no interest expense for the nine months ended September 30, 2019.

Other Income, Net

Other income was less than $0.1 million and $0.9 million for the nine months ended September 30, 2020 and 2019, respectively. The decrease of $0.8 million in other income is primarily due to a decrease in net accretion of discounts on short-term securities in the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant operating losses. We have generated limited revenue to date from our collaboration agreements and research grant. We have not yet commercialized any of our product candidates, which are in various phases of preclinical development and clinical trials and we do not expect to generate revenue from sales of any product for several years, if at all. We have funded our operations to date with proceeds received from equity offerings, the issuance of convertible promissory notes and, to a lesser extent, payments received in connection with collaboration agreements and a research grant. We also received an aggregate of approximately $3.5 million under our ATM program.

As of September 30, 2020, we had cash, cash equivalents and short-term investments of approximately $40.8 million and an accumulated deficit of $363.6 million. During the nine months ended September 30, 2020, we incurred a loss of $26.9 million and used $29.2 million of cash in operations.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented (in thousands):

	Nine Months Ended September 30,	
	2020	2019
Cash used in operating activities	$ (29,173)	$ (41,555)
Cash provided by investing activities	39,490	47,968
Cash provided by financing activities	427	81
Net increase in cash, cash equivalents and restricted cash	$ 10,744	$ 6,494

Operating Activities

Net cash used in operating activities was $29.2 million during the nine months ended September 30, 2020, primarily driven by our net loss of $26.9 million and changes in operating assets and liabilities of $4.9, partially offset by non-cash charges of $2.6 million. Our net loss was primarily attributed to our research and development activities associated with our clinical trials and preclinical studies. Changes in operating assets and liabilities were primarily related to a decrease of $3.2 million in accrued expenses, a decrease of $1.4 million in accounts payable, a decrease of $0.9 million in operating lease liabilities, and an increase in prepaid and other current assets of $0.6 million. Non-cash charges include $1.6 million of stock-based compensation and $0.9 million of non-cash lease expense.

Net cash used in operating activities was $41.6 million during the nine months ended September 30, 2019, primarily driven by our net loss of $47.3 million, offset by non-cash charges of $3.2 million and changes in operating assets and liabilities of $2.6 million. Our net loss was primarily attributed to our research and development activities associated with our preclinical studies and clinical trials. Non-cash charges include $2.7 million of stock-based compensation, $1.1 million of depreciation and amortization and non-cash lease expense, $0.2 million of stock issued for consulting services, partially offset by $0.8 million of accretion of short-term investments. Changes in operating assets and liabilities were primarily related to an increase of $2.2 million in accounts payable and an increase of $0.7 million in accrued expenses and a decrease in prepaid and other current assets of $0.5 million, partially offset by a decrease of $0.8 million in operating lease liabilities.

Investing Activities

During the nine months ended September 30, 2020, net cash provided by investing activities was $39.5 million, consisting of proceeds received from maturities of short-term investments of $55.7 million, partially offset by purchases of our short-term investments of $16.2 million.

During the nine months ended September 30, 2019, net cash provided by investing activities was $48.0 million, consisting of proceeds received from maturities of short-term investments of $111.0 million, partially offset by purchases of short-term investments of $63.0 million.

Financing Activities

During the nine months ended September 30, 2020, net cash provided by financing activities was $0.4 million, primarily related to proceeds from the issuance of short-term borrowings of $1.2 million, offset by payments made on short-term borrowings of $0.9 million.

During the nine months ended September 30, 2019, net cash provided by financing activities was less than $0.1 million, resulting from the issuance of common stock pursuant to our employee stock purchase plan as well as stock option exercises.

Future Funding Requirements

We expect that our cash, cash equivalents, and short-term investments as of September 30, 2020 will enable us to fund our operating expenses and capital requirements, based upon our current operating plan, for at least 12 months from the date of this filing and through the completion of the Merger. If the Merger is not successful, and we determine to operate as a stand-alone entity, we will require additional funding to fund our pipeline and advance our proprietary candidates through regulatory approval and into commercialization, if approved.

If, for any reason, the Merger does not close and the Merger Agreement is terminated, the Board may elect to, among other things, attempt to complete another strategic transaction including a transaction similar to the Merger, continue to operate our business or to dissolve and liquidate our assets, including the CF Assets. In addition, if our Board were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our Company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our remaining cash assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our Company. If a dissolution and liquidation were pursued, our Board, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. As of September 30, 2020, we had cash and cash equivalents and short-term investments totaling approximately $40.8 million. However, there can be no assurances as to the amount or timing of available cash, if any, left to distribute to our stockholders after paying the debts and our other obligations and setting aside funds for potential future claims.

In the event we are unable to complete the Merger, we continue will to pursue cost saving initiatives to reduce operating expenses, but we will also need to raise additional funds to pursue our business strategy and explore sources of equity or debt financing. We may seek to raise such capital through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not currently have any committed external source of funds and additional funding may not be available on favorable terms or at all.

Contractual Obligations and Commitments

Under various agreements, we will be required to make milestone payments and pay royalties and other amounts to third parties.

We enter into contracts in the normal course of business with CROs for clinical trials, preclinical research studies, testing and other services, and products for operating purposes. These contracts generally provide for termination upon notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

Item 4. Management's Evaluation of our Disclosure Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our President and Chief Executive Officer, who is our principal executive officer and our interim principal financial officer, to allow timely decisions regarding required disclosure.

As of September 30, 2020, our management, with the participation of our principal executive officer, who is also our interim principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer, who is also our interim principal financial officer, has concluded based upon the evaluation described above that, as of September 30, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements, employment and other matters.

Between October 14 and October 28, 2020, one putative class action lawsuit (captioned Aniello v. Proteostasis Therapeutics, Inc., et al., No. 1:20-cv-08578 (S.D.N.Y. filed Oct. 14, 2020)), and five individual lawsuits (captioned Culver v. Proteostasis Therapeutics, Inc., et al, 1:20-cv-08595 (S.D.N.Y. filed Oct. 15, 2020); Donolo v. Proteostasis Therapeutics, Inc. et al, 1:20-cv-01400 (D. Del. filed Oct. 16, 2020); Straube v. Proteostasis Therapeutics, Inc., et al, 1:20-cv-08653 (S.D.N.Y. filed Oct. 16, 2020); Beck v. Proteostasis Therapeutics, Inc., et al, 1:20-cv-08783 (S.D.N.Y. filed Oct. 21, 2020); Dreyer v. Proteostasis Therapeutics, Inc., et al, 1:20-cv-05193 (E.D.N.Y. filed Oct. 28, 2020)) were filed in federal court by alleged Proteostasis stockholders challenging the Merger. The complaints name us and our board of directors as defendants. The Aniello complaint names Yumanity as an additional defendant. The Donolo complaint names Yumanity and Pangolin Merger Sub, Inc., a wholly owned subsidiary of Proteostasis, as additional defendants. The complaints assert violations of Section 14(a) of the Securities Exchange Act of 1934, or the Exchange Act, and Rule 14a-9 promulgated thereunder against us and the individual defendants, and assert violations of Section 20(a) of the Exchange Act against the individual defendants. The Donolo complaint asserts an additional violation of Section 20(a) of the Exchange Act, against Yumanity. The Aniello complaint asserts additional claims for breach of fiduciary duty against the individual defendants and aiding and abetting against us and Yumanity. The plaintiffs contend that the Registration Statement on Form S-4 filed with the Securities and Exchange Commission on September 23, 2020 omitted or misrepresented material information regarding the Merger. The complaints seek injunctive relief, rescission, or rescissory damages, dissemination of a registration statement that discloses certain information requested by the plaintiff, and an award of plaintiffs' costs, including attorneys' fees and expenses. We are not party to any other material litigation in any court.

There can be no assurance that we or any defendant will be successful. At present, we are unable to estimate potential losses, if any, related to these lawsuits.

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the risk factors discussed in Part I, Item 1A "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2019. With the exception of the risk factors below, there have been no material changes in or additions to the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2019 and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2020 and June 30, 2020.

Risks Related to the Merger

Failure to complete the Merger may result in us paying a termination fee or reimbursing expenses and could harm our common stock price and future business and operations.

If the Merger is not completed, we are subject to the following risks:

- if the Merger Agreement is terminated under certain circumstances, we will be required to pay third party expenses incurred by Yumanity up to a maximum of $703,000;
- if the Merger Agreement is terminated under certain circumstances, we will be required to pay Yumanity a termination fee equal to $2,100,000;
- the Merger Agreement contains covenants relating to our solicitation of competing acquisition proposals and the conduct of our business between the date of signing the Merger Agreement and the completion of the Merger. As a result, significant business decisions and transactions before the completion of the Merger require the consent of Yumanity. Accordingly, we may be unable to pursue business opportunities that would otherwise be in its respective best interests as standalone companies. If the Merger Agreement is terminated after we have invested significant time and resources in the transaction process, we will have a limited ability to continue its current operations without obtaining additional financing to fund its operations;
- some of our suppliers, collaborators and other business partners may seek to change or terminate their relationships with us, as applicable, as a result of the Merger;
- our management team may be distracted from day to day operations as a result of the Merger;
- the price of our common stock may decline and remain volatile; and
- we have incurred and expect to continue to incur significant expenses related to the Merger, some which must be paid even if the Merger is not completed.

In addition, if the Merger Agreement is terminated and our board of directors determines to seek another business combination, there can be no assurance that either we will be able to find a partner willing to provide equivalent or more attractive consideration than the consideration to be provided by each party in the Merger on a timely basis, or at all. Our collaborators and other business partners and investors in general may also view the failure to complete the Merger as a poor reflection on its business or prospects, which could adversely affect their respective businesses.

The Merger may be completed even though material adverse changes may result from the announcement of the Merger, industry-wide changes and other causes.

In general, either we can refuse to complete the Merger if there is a material adverse change affecting the other party between August 22, 2020, the date of the Merger Agreement, and the Closing. However, certain types of changes do not permit either party to refuse to complete the Merger, even if such change could be said to have a material adverse effect on us, including:

- any effect resulting from the execution, delivery, announcement or performance of obligations under the Merger Agreement or the announcement or pendency or anticipated consummation of the Merger or any related transactions;
- any natural disaster, any public health event (including any epidemic, pandemic, or disease outbreak (including the novel coronavirus ("COVID-19") pandemic) or any act of terrorism, sabotage, military action or war (whether or not declared) or escalation or any worsening thereof;
- any change in United States generally accepted accounting principles ("GAAP") or any change in applicable laws, rules or regulations or the interpretation thereof;
- any conditions generally affecting the industries in which Yumanity and we and their and our respective subsidiaries participate or the United States or global economy or capital markets as a whole to the extent such conditions do not have a disproportionate impact on Yumanity or us and their and our respective subsidiaries, as applicable;
- any failure by Yumanity or us to meet internal projections or forecasts or third-party revenue or earnings predictions for any period ending on or after the date of the Merger Agreement; or
- the resignation or termination of any of our directors or officers or any director or officer of Yumanity.

If adverse changes occur and we and Yumanity still complete the Merger, the combined organization stock price may suffer. This in turn may reduce the value of the Merger to our stockholders.

Some of our and Yumanity's officers and directors have interests in the Merger that are different from yours and that may influence them to support or approve the Merger without regard to your interests.

Certain of our and Yumanity's officers and directors participate in arrangements that provide them with interests in the Merger that are different from yours, including, among others, the continued service as an officer or director of the combined organization, severance benefits, the acceleration of stock option vesting, continued indemnification and the potential ability to sell an increased number of shares of common stock of the combined organization in accordance with Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"). For example, we have entered into post-employment compensation arrangements with its named executive officers.

Based on the terms of their respective employment agreements and the retention program, our executive officers will be entitled to receive a total value of approximately $1.7 million (collectively, not individually) in connection with the consummation of the Merger and the associated termination of their employment, not including the value associated with the acceleration of their outstanding equity awards.

Additionally, our directors and officers are parties to the support agreements and lock-up agreements with us and Yumanity.

Our board of directors was aware of these interests and considered them, among other matters, in the decision to approve the Merger Agreement.

The market price of the combined organization's common stock following the Merger may decline as a result of the Merger.

The market price of our common stock may decline as a result of the Merger for a number of reasons including if:

- investors react negatively to the prospects of the combined organization's business and prospects from the Merger;
- the effect of the Merger on the combined organization's business and prospects is not consistent with the expectations of financial or industry analysts; or

- the combined organization does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts.

Our stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.

If the combined organization is unable to realize the full strategic and financial benefits currently anticipated from the Merger, our stockholders will have experienced substantial dilution of their ownership interests in their respective companies without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined organization is able to realize only part of the strategic and financial benefits currently anticipated from the Merger.

During the pendency of the Merger, we may not be able to enter into a business combination with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect their respective businesses.

Covenants in the Merger Agreement impede our ability to make acquisitions or dispositions or complete other transactions that are not in the ordinary course of business, subject to certain exceptions, pending completion of the Merger. As a result, if the Merger is not completed, the parties may be at a disadvantage to their competitors during that period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from, among other things, soliciting, initiating, knowingly encouraging or entering into certain extraordinary transactions, such as a merger, sale of assets or other business combination outside the ordinary course of business, with any third party. Any such transactions could be favorable to such party's stockholders.

Certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit us from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when, among other things, such party's board of directors determines in good faith that an unsolicited acquisition proposal constitutes or would reasonably be expected to result in, a superior offer and that failure to cooperate with the proponent of the proposal would reasonably be expected to be inconsistent with the fiduciary duties of the Board of Directors of such party under applicable law. In addition, if we or Yumanity terminate the Merger Agreement under certain circumstances, including terminating because of a decision of a board of directors to recommend a superior proposal, we or Yumanity would be required to pay to the other party a termination fee equal to $2,100,000, in the case of us, or $4,380,000, in the case of Yumanity. This termination fee may discourage third parties from submitting alternative takeover proposals to us or Yumanity or their stockholders, and may cause the respective boards of directors to be less inclined to recommend an alternative proposal.

Our stockholders may not receive any payment on the contingent value rights, or CVRs, and the CVRs may otherwise expire valueless.

The right of our stockholders to receive any future payment for or derive any value from the CVRs will be contingent solely upon our (or the combined organization's) ability to monetize all or any part of the CF Assets, as defined in the Merger Agreement, specified in the CVR Agreement, as defined in the Merger Agreement, and the consideration received being greater than the amounts permitted to be reimbursed to us under the CVR Agreement. If we are unable to monetize the CF Assets within the time periods specified in the CVR Agreement or the consideration received is not greater than the amounts permitted to be reimbursed to us, no payments will be made under the CVR Agreement, and the CVRs will expire valueless.

Following the effective time of the merger, Yumanity (as successor in interest to us) will have sole authority over whether and how to pursue the continued development of the CF Assets (if at all), and Yumanity's only obligations will be to reasonably cooperate with the requests of the CVR Holders' Representative to carry out the intent and purpose of the CVR Agreement and not to terminate or intentionally negatively impact the CF Assets during the nine-month period following the effective time of the merger.

Furthermore, the CVRs will be unsecured obligations of the combined organization and all payments under the CVRs, all other obligations under the CVR Agreement and the CVRs and any rights or claims relating thereto will be subordinated in right of payment to the prior payment in full of all current or future senior obligations of the combined organization.

The tax treatment of the CVRs is uncertain.

We intend to treat the issuance of the CVRs to the persons who prior to completion of the merger were our stockholders as a distribution of property with respect to our common stock. However, there is no authority directly on point addressing the U.S. federal income tax treatment of contingent value rights with characteristics similar to the CVRs. Therefore, it is possible that the issuance of the CVRs may be treated as a distribution of equity with respect to our stock, as an "open transaction," or as a "debt instrument" for U.S. federal income tax purposes, and such questions are inherently factual in nature.

Our stockholders may not receive any separate consideration for the CF Assets.

In its instructions for preparation of its opinion regarding the fairness of the Exchange Ratio, as defined in the Merger Agreement, we instructed MTS not to assign any value to the CF Assets in light of our ongoing negotiations with potential purchasers of the CF Assets. Additionally, we believe the CVR Agreement would appropriately capture the value of the CF Assets for a CF Asset Monetization. As discussions for the disposition of the CF Assets remain ongoing, and no agreement for the sale of the CF Assets has been reached currently, there can be no guarantee that any such arrangement will be reached, either prior to consummation of the Merger or after, or even if at all. The CF Assets also may or may not be commercially viable and we may not find a purchaser for the CF Assets prior to the consummation of the Merger. The relative valuations of the parties used in arriving at the Exchange Ratio do not attribute any additional incremental value to us for the CF Assets as such assets were intended to be disposed of prior to the Merger, or covered by the CVR Agreement post-Merger. If there is no disposition of the CF Assets prior to consummation of the Merger or during the time periods specified in the CVR Agreement, we may not receive any separate consideration for the CF Assets.

If the conditions to the Merger are not met, the Merger will not occur.

Even if the Merger is approved by our stockholders and Yumanity's stockholders, specified conditions must be satisfied or waived to complete the Merger. These conditions are set forth in the Merger Agreement. We cannot assure you that all of the conditions will be satisfied. If the conditions are not satisfied or waived, the Merger will not occur or will be delayed, and we may lose some or all of the intended benefits of the Merger.

Certain stockholders could attempt to influence changes which could adversely affect our operations, financial condition and the value of our common stock.

Our stockholders may from time-to-time seek to acquire a controlling stake in us, engage in proxy solicitations, advance stockholder proposals or otherwise attempt to effect changes. Campaigns by stockholders to effect changes at publicly-traded companies are sometimes led by investors seeking to increase short-term stockholder value through actions such as financial restructuring, increased debt, special dividends, stock repurchases or sales of assets or the entire company. Responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, and could disrupt our operations and divert the attention of our board of directors and senior management from the pursuit of the Merger. These actions could adversely affect our operations, financial condition, ability to consummate the merger and our common stock value.

We and Yumanity are involved in litigation in connection with the Merger, which could divert the attention of our management and harm the combined organization's business, and insurance coverage may not be sufficient to cover all related costs and damages.

Stockholder litigation frequently follows the announcement of certain significant business transactions, such as a business combination transaction. Between October 14 and October 28, 2020, one putative class action lawsuit (captioned *Aniello v. Proteostasis* Therapeutics, *Inc., et al*., No. 1:20-cv-08578 (S.D.N.Y. filed Oct. 14, 2020)), and five individual lawsuits (captioned *Culver v.* Proteostasis *Therapeutics, Inc., et al*, 1:20-cv-08595 (S.D.N.Y. filed Oct. 15, 2020); *Donolo v. Proteostasis Therapeutics, Inc. et al*, 1:20-cv-01400 (D. Del. filed Oct. 16, 2020); *Straube v. Proteostasis Therapeutics, Inc., et al*, 1:20-cv-08653 (S.D.N.Y. filed Oct. 16, 2020); *Beck v.Proteostasis Therapeutics, Inc., et al*, 1:20-cv-08783 (S.D.N.Y. filed Oct. 21, 2020); *Dreyer v. Proteostasis Therapeutics, Inc., et al*, 1:20-cv-05193 (E.D.N.Y. filed Oct. 28, 2020)) were filed in federal court by alleged our stockholders challenging the Merger. The complaints name us and our board of directors as defendants. The *Aniello* complaint names Yumanity as an additional defendant. The *Donolo* complaint names Yumanity and Pangolin Merger Sub, Inc., a wholly owned subsidiary of Protestasis, as additional defendants. The complaints assert violations of Section 14(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 14a-9 promulgated thereunder against us and the individual defendants, and assert violations of Section 20(a) of the Exchange Act against the individual defendants. The *Donolo* complaint asserts an additional violation of Section 20(a) of the Exchange Act against Yumanity. The *Aniello* complaint asserts additional claims for breach of fiduciary duty against the individual defendants and aiding and abetting against us and Yumanity. The plaintiffs contend that the Registration Statement on Form S-4, filed with the SEC on September 23, 2020 omitted or misrepresented material information regarding the Merger. The complaints seek injunctive relief, rescission, or rescissory damages, dissemination of a registration statement that discloses certain information requested by the plaintiff, and an award of plaintiffs' costs, including attorneys' fees and expenses. There can be no assurance, however, that we will be successful.

We may become involved in additional matters in connection with the Merger, and the combined organization may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business and the combined organization. At present, we are unable to estimate potential losses, if any, related to the lawsuit.

Risks Related to our Capital Requirements, Finances and Operations if the Merger is Not Completed

There is no assurance that the proposed Merger between we and Yumanity will be completed in a timely manner or at all. If the Merger with Yumanity is not consummated, our business could suffer materially, and our stock price could decline.

The consummation of the Merger between us and Yumanity is subject to a number of closing conditions, including approval by our and Yumanity's respective stockholders and other customary closing conditions. The parties are targeting a Closing of the transaction in the fourth calendar quarter of 2020, however, there can be no assurance that the Merger will be consummated within this desired timeframe, or at all.

If the Merger between us and Yumanity is not consummated, we may be subject to a number of material risks, and its business and stock price could be adversely affected, as follows:

- we have incurred and expects to continue to incur significant expenses related to the Merger with Yumanity, even if the Merger is not consummated;
- we could be obligated to pay Yumanity a $2,100,000 termination fee and expense reimbursements up to $703,000 in connection with the termination of the Merger Agreement, depending on the reason for the termination;
- the market price of our common stock may decline to the extent that the current market price reflects a market assumption that the Merger will be completed; and
- Nasdaq could determine to delist our common stock, which could have an adverse effect on the value of our common stock and any future ability to raise capital.

If the Merger is not completed, we may be unsuccessful in completing an alternative strategic transaction on terms that are as favorable as the terms of the proposed transaction with Yumanity, or at all, and we may be unable to reestablish a viable operating business.

We have generated limited revenue to date from its collaboration agreements and research grant, and have not generated revenue from any product sales. Our assets currently consist primarily of cash, cash equivalents and short-term investments, our intellectual property portfolio, license and collaboration agreements, our remaining assets, our listing on The Nasdaq Stock Market and the Merger Agreement with Yumanity. While we have entered into the Merger Agreement with Yumanity, the consummation of the Merger with Yumanity may be delayed or may not occur at all. If the Merger is not completed, our board of directors may elect to pursue an alternative strategic transaction similar to the proposed Merger with Yumanity. Attempting to complete an alternative transaction will be costly and time consuming. If the Merger with Yumanity is not completed and our board of directors determines to pursue an alternative transaction, the terms of any such alternative transaction may not be as favorable to us and our stockholders as the terms of the Merger with Yumanity, and we can make no assurances that such an alternative transaction would occur at all. Further, if the Merger with Yumanity is not completed, given the level of investment and time that would be required to redesign our products or pursue the development of products and services pursuant to its collaboration agreements, it is unlikely that we would be able to obtain the funding required to recommence its product development activities on terms favorable to our stockholders, or at all.

If the Merger is not completed, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that the Merger will be completed. If the Merger is not completed, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to its stockholders will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund its operations. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our company, we would be required under Delaware corporate law to pay its outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to its stockholders. As a result of this requirement, a portion of our remaining cash assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our company. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of our liquidation, dissolution or winding up.

If we were to continue to advance our research and development activities and pursue development of any of our pipeline products, it would require substantial additional funding. Raising additional capital would cause dilution to its existing stockholders, and may restrict its operations or require it to relinquish rights to its technologies or to a product candidate.

We currently do not have any committed external source of funds and does not expect to generate any commercial revenue in the foreseeable future. We believe that our existing cash, cash equivalents and marketable securities and interest thereon will be sufficient to fund its projected operating requirements under its current operating plan. We have based our estimates on assumptions that may prove to be wrong, and it may use its available capital resources sooner than it currently expects if its operating plans change. If the Merger is not completed and our current operating plans change and we determines to pursue further research and development activities, we will require substantial additional funding to operate, and would expect to finance these cash needs through a combination of equity offerings, debt financings, government or other third-party funding and licensing or collaboration arrangements.

To the extent that we raise additional capital through the sale of equity or convertible debt, the ownership interests of our stockholders will be diluted. In addition, the terms of any equity or convertible debt we agree to issue may include liquidation or other preferences that adversely affect the rights of our stockholders.

Convertible debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, and declaring dividends, and may impose limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct its business.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. Furthermore, the COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital, when and if needed. If adequate funds are not available to us on a timely basis, it may be required to curtail or cease its operations.

If the Merger is not completed, raising additional funding through debt or equity financing could be difficult or not successful at all, would be dilutive and may cause the market price of our common stock to decline further.

If the Merger is not completed, raising additional funding through debt or equity financing could be difficult or unavailable altogether given the turbulent financial markets. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the issuance of those securities would result in substantial dilution for our current stockholders and the terms may include liquidation or other preferences that adversely affect the rights of our current stockholders. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline further and existing stockholders may not agree with its financing plans or the terms of such financings.

The issuance of shares of our common stock to Yumanity's stockholders in the Merger will dilute substantially the voting power of our current stockholders.

If the Merger is completed, each outstanding share of Yumanity capital stock will be converted into the right to receive approximately 4.3084 shares of our common stock, subject to adjustment to account for the proposed reverse stock split. Immediately following the Merger, our stockholders and optionholders are expected to own, or hold rights to acquire, approximately 29.1% of our common stock on a fully diluted basis as defined in the Merger Agreement, and Yumanity's stockholders, optionholders and warrantholders are expected to own, or hold rights to acquire, approximately 70.9% of our common stock on a fully diluted basis as defined in the Merger Agreement. Accordingly, the issuance of shares of our common stock to Yumanity's stockholders in the Merger will reduce significantly the relative voting power of each share of our common stock held by our current stockholders. Consequently, our stockholders as a group will have significantly less influence over the management and polices of the combined organization after the Merger than prior to the Merger.

We have incurred and will continue to incur significant transaction costs in connection with the Merger.

We have incurred and will continue to incur significant transaction costs in connection with the Merger. We estimate that we will incur aggregate direct transaction costs of approximately $12.2 million associated with the Merger and approximately $0.2 million for its portion of shared transaction expenses, as well as additional costs associated with the commencement of the combined organization's operation as a public company, which cannot be estimated accurately at this time.

Our ability to use net operating loss ("NOL") carryforwards and other tax attributes may be limited in connection with the Merger and other ownership changes.

We have incurred substantial losses during its history and does not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire (if at all). At September 30, 2020, we had federal and state NOL carryforwards of approximately $308.8 million and $295.4 million, respectively. Such federal and state NOL carryforwards will begin to expire in 2026 and 2030, respectively unless previously utilized. At September 30, 2020, we had federal and state research and development credit carryforwards of approximately $11.6 million and $4.1 million, respectively. The federal research and development credit carryforwards will begin expiring in 2027 and 2025, respectively, unless previously utilized.

Federal NOLs incurred in tax years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five tax years preceding such loss, and NOLs arising in tax years beginning after December 31, 2020 may not be carried back. Because we had no taxable income in prior years, it does not anticipate carrying back any of its net operating losses. Moreover, federal NOLs generated in taxable years ending after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs may be limited to 80% of our taxable income annually for tax years beginning after December 31, 2020. Our NOL carryforwards are subject to review and possible adjustment by the U.S. Internal Revenue Service (the "IRS"), and state tax authorities. Under Sections 382 and 383 of the Code, our federal NOL and research and development tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50 percentage points. Our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including in connection with the Merger. Similar rules may apply under state tax laws. We have not yet determined the amount of the cumulative change in its ownership resulting from the Merger or other transactions, or any resulting limitations on its ability to utilize its NOL carryforwards and other tax attributes. If we earn taxable income, such limitations could result in increased future tax liability to our company and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Risks Related to Our Business

We have not yet begun a Phase 3 clinical trial of our triple combination of posenacaftor, dirocaftor, and nesolicaftor in patients with the most common F508del mutation and if such trial fails to materialize or fails to demonstrate safety and efficacy to the satisfaction of regulatory authorities or does not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our lead product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of our proprietary triple combination product candidates, we or a potential collaborator must conduct extensive trials to demonstrate the safety and efficacy of our proprietary triple combination in humans. We will not be able to submit an NDA or MAA unless and until we receive data demonstrating that a pivotal trial has achieved its primary endpoints.

Despite the results reported in our Phase 2 clinical trials, we do not know whether a potential Phase 3 clinical trial will demonstrate adequate efficacy and safety to result in regulatory approval to market our proprietary triple combination to address the treatment of rare CFTR mutations in any particular jurisdiction. We also do not know if we will have the funds or the operational capacity to proceed with the initiation of a Phase 3 clinical trial given our focus and attention on the proposed Merger.

Clinical testing is expensive and difficult to design and implement, can take many years to complete and is inherently uncertain as to the outcome. A failure of one or more trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not accurately predict the success of later trials, and interim results of a trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials.

We have incurred significant losses since our inception. We will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability.

We are a clinical stage biopharmaceutical company. We have incurred significant net losses in each year since our inception, including net losses of $8.3 million and $27.0 million for the three and nine months ended September 30, 2020, respectively. As of September 30, 2020, we had an accumulated deficit of $363.7 million.

We do not have any drugs that have received regulatory approval. Our business is dependent on our ability to successfully complete preclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize our current and future drug candidates in a timely manner. If the Merger is not successful, and we determine to operate as a stand-alone entity, we will require additional funding to fund our pipeline and advance our proprietary candidates through regulatory approval and into commercialization, if approved.

To date, we have financed our operations primarily through the sale of equity securities, debt financings, payments received in connection with collaboration agreements and a research grant, as well as funds from the sale of stock under at-the-market offering programs. We have devoted substantially all of our efforts to organizing and staffing our Company, business planning, raising capital, acquiring and developing product and technology rights, and conducting research and development activities. We have not completed the development of any of our product candidates. We do not have any products approved for sale and have not generated any commercial revenue since inception. We also expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future, and will require additional funding to pursue our business strategy. In the event that the Merger fails to close, we will need additional funding to continue our operations.

While we continue to pursue cost saving initiatives to reduce operating expenses, we may also need to raise additional funds and periodically explore sources of equity or debt financing. We may seek to raise such capital through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. However, additional funding may not be available on favorable terms or at all.

Risks Related to Regulatory Approval of Our Product Candidates

Payor approval and reimbursement may not be available for posenacaftor, dirocaftor, nesolicaftor, any proprietary combination therapy candidates and our other product candidates, or third-party therapies taken with our drugs, which could make it difficult or impossible for us to sell our products profitably.

Market acceptance and sales of posenacaftor, dirocaftor or nesolicaftor, any proprietary combination therapy candidates, or any other product candidates that we develop, will depend in part on the extent to which reimbursement for these products and related third party treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers, health maintenance organizations and pharmacy benefit management organizations, decide which medications they will pay for, at what tier level and establish reimbursement levels. In the United States, non-governmental payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. A primary trend in the United States healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Even if we are successful in gaining reimbursement in one country, that does not mean we will achieve reimbursement at the same levels or at all in any other country. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. Reimbursement levels may be impacted by factors including, without limitation, the perceived safety and efficacy of our products relative to the cost (and relative to the perceived safety and efficacy and cost for available competitive products), the views of independent research organizations on drug pricing and the political climate, many of which factors we cannot control. Also, reimbursement amounts may reduce the demand for, or the price of, our products. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize posenacaftor, dirocaftor, nesolicaftor, any proprietary combination therapy candidates, or any other product candidates that we develop. We will also be required to establish systems and programs that assist patients in determining the reimbursement level and in some instances establishing patient economic support programs to alleviate the economic burden of co-pays and/or co-insurance. These patient support programs are complex, costly and require knowledge and expertise that we currently do not possess.

There have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell any future products profitably. For example, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. On July 24, 2020, the Trump administration announced four executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals, including a policy that would tie certain Medicare Part B drug prices to international drug prices and also expanded the policy to cover certain Part D drugs; one that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for plans, pharmacies, and pharmaceutical benefit managers; and one that reduces costs of insulin and epipens to patients of federally qualified health centers. Although a number of these and other measures may require additional authorization to become effective,

Congress and the Trump administration have both stated that they will continue to seek new legislative and/or administrative measures to control drug costs. These legislative and regulatory changes may negatively impact the reimbursement for any future products, following approval. The availability of generic treatments may also substantially reduce the likelihood of reimbursement for any future products, including posenacaftor, dirocaftor and nesolicaftor or any proprietary combination therapy candidates. The application of user fees to generic drug products will likely expedite the approval of additional generic drug treatments. We expect to experience pricing pressures in connection with the sale of posenacaftor, dirocaftor, nesolicaftor, any proprietary combination therapy candidates, and any other product candidate that we develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. We cannot predict the likelihood, nature, or extent of health reform initiatives that may arise from future legislation or administrative action, particularly as a result of the recent presidential election. However, we expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products, which could result in reduced demand for our products or additional pricing pressure.

In addition, there may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, however reimbursement and levels of reimbursement may also vary within a country based on the individual decisions of private payors.

Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any of our product candidates, including posenacaftor, dirocaftor and nesolicaftor and any proprietary combination therapy candidates, could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Risks Related to Government Regulation

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and health information privacy and security laws. Some of these laws were recently amended, and their interpretation following such amendments remains unclear. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Our current and future operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal anti-kickback statute. These laws may impact, among other things, our research, proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal anti-kickback statute which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;
- the federal false claims laws, including civil whistleblower or qui tam actions, and civil monetary penalties, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly or willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statement using or making any false or fraudulent document, in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, and as amended by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to HIPAA, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on entities subject to the rule, such as health plans, clearinghouses and certain healthcare providers and their business associates that create, use or disclose individually identifiable health information on their behalf as well as their covered subcontractors;
- the Federal Food, Drug, and Cosmetic Act, or FDCA, which prohibits, among other things, the distribution of adulterated or misbranded drugs or medical devices;
- the federal Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as ameded by the Health Care and Education Reconciliation Act of 2010, collectively referred to herein as the Affordable Care Act, or the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies to report to CMS information related to payments and other transfers of value made to physicians, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year; and
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws and regulations that require manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws that require the registration of pharmaceutical sales representatives.

Further, the ACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity can now be found guilty of fraud or false claims under ACA without actual knowledge of the statute or specific intent to violate it. In addition, ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes.

It is possible that some of our business activities could be subject to challenge by federal or state regulatory authorities under one or more of these laws. The scope and enforcement of these laws is uncertain and subject to change in the current environment of health care reform. Possible sanctions for violation of these laws include significant monetary fines, administrative, civil and criminal penalties, exclusion from Medicare, Medicaid and other government programs, forfeiture of amounts collected in violation of such prohibitions, imprisonment, and integrity oversight and ongoing monitoring. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming, and could have a material adverse effect on our business, financial condition and results of operations.

In addition, regulators globally are also imposing greater monetary fines for privacy violations. For example, in 2016, the E.U. adopted a new regulation governing data practices and privacy called the General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR applies to any company established in the E.U. as well as to those outside the E.U. if they collect and use personal data in connection with the offering goods or services to individuals in the E.U. or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements and onerous new obligations on services providers. Non-compliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of providing our products and services or even prevent us from offering certain services in jurisdictions that we operate in.

Health care reform measures could adversely affect our business.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs. For example, the ACA, which includes measures to significantly change the way health care is financed by both governmental and private insurers, was enacted in March 2010. Among the provisions of the ACA of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs;
- new requirements to report certain financial arrangements with physicians, as defined by thereunder, and teaching hospitals, including reporting any "transfer of value" made or distributed to physicians and teaching hospitals and reporting any ownership interests held by physicians and their immediate family members;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

At this time, the full effect that the ACA would have on our business remains unclear. There remain executive, judicial, Congressional and efforts by the current administration to challenge certain aspects of the ACA. Legislation has been drafted and enacted to repeal and replace parts of the ACA, but no comprehensive ACA replacement law has been enacted. However, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business. We cannot predict any initiatives that may be adopted in the future.

Individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In addition, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to generate revenues. Increases in importation or re-importation of pharmaceutical products from foreign countries into the United States could put competitive pressure on our ability to profitably price our products, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. We might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

Additionally, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. For example, on August 6, 2020, the Trump administration issued another executive order that instructs the federal government to develop a list of "essential" medicines and then buy them and other medical supplies from U.S. manufacturers instead of from companies around the world, including China. The order is meant to reduce regulatory barriers to domestic pharmaceutical manufacturing and catalyze manufacturing technologies needed to keep drug prices low and the production of drug products in the United States.

We cannot predict the likelihood, nature, or extent of health reform initiatives that may arise from future legislation or administrative action, particularly as a result of the recent presidential election. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit No.	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit No.	Filing Date
2.1	Agreement and Plan of Merger and Reorganization, dated August 22, 2020, by and among the Registrant, Yumanity, Holdings and Merger Sub.	8-K	001-37695	2.1	August 24, 2020
2.2	First Amendment to Merger Agreement, dated November 6, 2020, by and among the Registrant, Yumanity, Holdings and Merger Sub.	8-K	001-37695	2.1	November 6, 2020
2.3	Form of CVR Agreement by and between the Registrant and the CVR Rep.	8-K	001-37695	2.2	August 24, 2020
2.4	Form of PTI Support Agreement, dated August 22, 2020, by and between the Registrant, Yumanity and each of the parties named in each agreement therein.	8-K	001-37695	2.3	August 24, 2020
2.5	Form of Yumanity Support Agreement, dated August 22, 2020, by and between the Registrant, Yumanity and each of the parties named in each agreement therein.	8-K	001-37695	2.4	August 24, 2020
2.6	Form of PTI Lock-Up Agreement, dated August 22, 2020, by each of the parties named in each agreement therein.	8-K	001-37695	2.5	August 24, 2020
2.7	Form of Yumanity Lock-Up Agreement, dated August 22, 2020, by each of the parties named in each agreement therein.	8-K	001-37695	2.6	August 24, 2020
3.1	Fifth Amended and Restated Certificate of Incorporation of the Registrant.	S-3	333-228529	3.1	November 23, 2018
3.2	Third Amended and Restated By-laws of the Registrant.	8-K	001-37695	3.1	August 24, 2020
4.1	Specimen Common Stock Certificate.	S-1/A	333-208735	4.1	February 1, 2016
4.2	Third Amended and Restated Stockholders' Agreement of the Registrant.	S-1/A	333-208735	4.2	February 1, 2016
4.3	Form of Preferred Stock Warrant.	S-1	333-208735	4.3	December 23, 2015
4.4	Form of Senior Indenture	S-3	333-228529	4.6	November 23, 2018
4.5	Form of Subordinated Indenture	S-3	333-228529	4.7	November 23, 2018
31.1	Certification of Principal Executive Officer and Interim Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				Filed herewith
32.1*	Certification of Principal Executive Officer and Interim Principal Financial Officer and Principal Accounting Officer pursuant to 18 U.S.C. Section 1350., as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				Furnished herewith
101.INS	XBRL Instance Document.				Filed herewith
101.SCH	XBRL Taxonomy Extension Schema Document.				Filed herewith
101.CAL	XBRL Taxonomy Extension Calculation Document.				Filed herewith
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				Filed herewith

Exhibit No.	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit No.	Filing Date
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.				Filed herewith
101.PRE	XBRL Taxonomy Extension Presentation Link Document.				Filed herewith
104	Cover Page Interactive Data File—the cover page interactive data is embedded within the XBRL document or included within the Exhibit 101 attachments.				Filed herewith

*This certification is being furnished herewith and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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 thereunto duly authorized.

PROTEOSTASIS THERAPEUTICS, INC.

Date: November 16, 2020

By: /s/ Meenu Chhabra
Meenu Chhabra
President and Chief Executive Officer
(Principal Executive Officer and Interim Principal Financial Officer)

Exhibit 31.1

Certification

I, Meenu Chhabra, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2020 of Proteostasis Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 16, 2020

/s/ Meenu Chhabra
Meenu Chhabra
President and Chief Executive Officer
(Principal Executive Officer and Interim Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report on Form 10-Q of Proteostasis Therapeutics, Inc. (the "Company") for the period ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Meenu Chhabra, President and Chief Executive Officer (Principal Executive Officer and Interim Principal Financial Officer) hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to my knowledge:

1) the Report which this statement accompanies fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 16, 2020

/s/ Meenu Chhabra
Meenu Chhabra
President and Chief Executive Officer
(Principal Executive Officer and Interim Principal Financial Officer)