UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 6, 2019**

PROTAGONIST THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-37852**	**98-0505495**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Protagonist Therapeutics, Inc.
7707 Gateway Blvd., Suite 140
Newark, California 94560-1160
(Address of principal executive offices, including zip code)

(510) 474-0170
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001	PTGX	The Nasdaq Stock Market, LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02. Results of Operations and Financial Condition.

On November 6, 2019, Protagonist Therapeutics, Inc. reported its financial results for the quarter ended September 30, 2019. A copy of the press release titled "Protagonist Therapeutics Reports Third Quarter 2019 Financial Results," is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press release, dated November 6, 2019, titled "Protagonist Therapeutics Reports Third Quarter 2019 Financial Results."

The information in this report, including the exhibit hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of Section 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Protagonist Therapeutics, Inc., 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 hereunto duly authorized.

Protagonist Therapeutics, Inc.

Dated: November 6, 2019

By: /s/ Don Kalkofen
Don Kalkofen
Chief Financial Officer

Exhibit 99.1

Protagonist Therapeutics Reports Third Quarter 2019 Financial Results

— Preliminary Phase 2 results for hepcidin mimetic PTG-300 in beta-thalassemia are expected in the fourth quarter of 2019 —

— Company sponsored Phase 2 study of PTG-300 in hereditary hemochromatosis and investigator sponsored Phase 2 study in myelodysplastic syndrome are planned for early 2020 —

— Results of a Phase 2 study of oral IL-23 receptor antagonist PTG-200 in development with Janssen Biotech are expected in 2021 —

NEWARK, Calif., Nov. 6, 2019 — Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today reported its financial results for the third quarter ended September 30, 2019, and provided a corporate update.

“The progress of our three clinical candidates shows the strength and versatility of the Protagonist peptide engineering platform,” commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. “These maturing assets reflect our steady transition toward becoming a fully integrated company. In addition to the ongoing Phase 2 study in beta-thalassemia, we continue to explore the full potential of the hepcidin mimetic PTG-300 as one product with multiple clinical applications. We recently dosed the first patient in a Phase 2 open-label study for the potential treatment of polycythemia vera. We are on track to initiate a Phase 2 study with PTG-300 in hereditary hemochromatosis, and we expect an investigator sponsored study in myelodysplastic syndrome to begin in early 2020. In the portfolio of inflammatory bowel disease product candidates comprised of oral gut-restricted peptides, we plan to begin a Phase 2 study with the alpha-4-beta-7 integrin antagonist PN-943 in patients with ulcerative colitis in the second quarter of 2020, on the basis of a completed Phase 1 study. We also recently dosed the first patient in a Phase 2 study of oral interleukin-23 receptor antagonist PTG-200, partnered with Janssen Biotech, with results from this study expected in 2021. Finally, we continue to maintain a strong financial position, with available cash, investments and access to an established debt facility to support the development of pipeline assets through year-end 2021.”

Product Development and Corporate Update:

PTG-300

- Preliminary Phase 2 results from the ongoing study of PTG-300 for the treatment of beta-thalassemia are expected in the fourth quarter of 2019.
- An abstract relating to pre-clinical studies of hepcidin mimetic PTG-300 has been accepted for presentation at the American Society for Hematology (ASH) Annual meeting, taking place Dec. 7-10 in Orlando, Fla.
- The Company is planning to initiate a Phase 2 study in patients with hereditary hemochromatosis, a third indication of development for PTG-300, by early 2020.
- An investigator-sponsored study of PTG-300 in patients with myelodysplastic syndromes, which represents a fourth potential indication for PTG-300, is expected to begin in early 2020.

PTG-943

- Protagonist announced results from the multiple ascending dose (MAD) part of the Phase 1 study of PN-943 with two weeks of daily administration, demonstrating sustained target engagement and additional confirmation of superior target engagement as compared with the first generation oral alpha-4-beta-7 integrin antagonist PTG-100.
- Clinical data from the Phase 1 study of oral alpha-4-beta-7 integrin antagonist PN-943 were presented at the American College of Gastroenterology (ACG) Annual Scientific Meeting.
- The Company plans to initiate a Phase 2 study of PN-943 for the treatment of ulcerative colitis in the second quarter of 2020.

PTG-200 (JNJ-67864238)

- Data from the Phase 1 study of PTG-200, an oral peptide IL-23 receptor antagonist partnered with Janssen Biotech, were recently presented at the United European Gastroenterology Week conference and the American College of Gastroenterology (ACG) Annual Scientific Meeting.
- The first patient has been dosed in a Phase 2 study of PTG-200 (also referenced as JNJ-67864238) in patients with moderate to severe Crohn's disease. Protagonist Therapeutics and Janssen Biotech are jointly conducting the development of PTG-200 through completion of Phase 2 clinical proof of concept in the treatment of Crohn's disease.

Financing

- During the third quarter of 2019, the Company issued 1.9 million shares through its at-the-market (ATM) program and raised $23.9 million, at an average price of $12.44 per share.
- The Company recently announced it has entered into a four-year debt facility with MidCap Financial and Silicon Valley Bank providing access to an aggregate principal amount up to $50 million to support the ongoing Protagonist clinical development programs and related general corporate purposes.

Financial Results

Protagonist reported a net loss of $16.4 million and $59.7 million, respectively, for the third quarter and first nine months of 2019, as compared to a net loss of $8.7 million and $25.1 million, respectively, for the same periods of 2018. The increase in net loss for the third quarter of 2019 as compared to the prior year period was driven primarily by increased research and development (R&D) costs related to advancing its products in various clinical trials. The increase in net loss for the first nine months of 2019 as compared to the prior year period was driven primarily by the previously reported application of revenue accounting principles following the May 2019 Amendment to the Janssen collaboration agreement where the Company re-assessed overall timelines as well as re-estimated completed and remaining services, including a cumulative one-time adjustment of $9.4 million reported in the second quarter of 2019, and an increase in R&D costs related to advancing its products is various clinical trials. The net loss for the third quarter and first nine months of 2019 includes non-cash stock-based compensation of $2.2 million and $6.2 million, respectively, as compared to $2.0 million and $4.8 million, respectively, for the same periods of 2018.

R&D expenses for the third quarter and first nine months of 2019 were $17.3 million and $49.1 million, respectively, as compared to $12.1 million and $45.2 million, respectively, for the same periods of 2018. The increases in R&D expenses were primarily due to increased clinical development costs related to PTG-300 and PN-943, offset by lower cost related to pre-clinical and discovery expenses and other clinical development expenses.

General and administrative (G&A) expenses for the third quarter and first nine months of 2019 were $4.0 million and $11.6 million, respectively, as compared to $3.4 million and $10.2 million, respectively, for the same periods of 2018. The increases in G&A expenses were primarily due to increases in salaries and employee-related expenses driven by an increase in headcount and professional services expenses to support growth in operations.

Protagonist ended the third quarter with $137.7 million in cash, cash equivalents and marketable securities, and $10 million of the debt facility was funded at closing in October 2019. The Company expects cash, cash equivalents and marketable securities, and access to its debt facility will be sufficient to fund its planned operating and capital expenditures through year-end 2021.

About Protagonist Therapeutics, Inc.

Protagonist Therapeutics is a clinical stage biopharmaceutical company that utilizes a proprietary technology platform to discover and develop novel peptide-based drugs to transform existing treatment paradigms for patients with significant unmet medical needs. PTG-300 is an injectable hepcidin mimetic in development for the treatment of iron overload anemia and related rare blood diseases. PTG-200 is an oral, gut-restricted interleukin-23 receptor specific antagonist peptide in Phase 2 clinical development for the potential treatment of inflammatory bowel disease. The Company has a worldwide license and collaboration agreement with Janssen Biotech for the clinical development of PTG-200. PN-943 is an oral, gut-restricted alpha-4-beta-7 integrin specific antagonist peptide in clinical development for the potential treatment of inflammatory bowel disease, with ulcerative colitis as the initial intended indication.

Protagonist is headquartered in Newark, California. For further information, please visit http://www.protagonist-inc.com.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding our intentions or current expectations concerning, among other things, the potential of PTG-300 as a possible treatment for polycythemia vera and beta-thalassemia, the potential of PTG-200 and PN-943 as possible treatments for inflammatory bowel disease, the initiation of and enrollment of patients in our clinical trials, the results of clinical trials and the outlook for our other programs. In some cases, you can identify these statements by forward-looking words such as “plan,” “will,” “expect,” “potential,” or the negative or plural of these words or similar expressions. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, our ability to develop and commercialize our product candidates, our ability to earn milestone payments under our collaboration agreement with Janssen, our ability to use and expand our programs to build a pipeline of product candidates, our ability to obtain and maintain regulatory approval of our product candidates. Additional information concerning these and other risk factors affecting our business can be found in our periodic filings with the Securities and Exchange Commission, including under the heading “Risk Factors” contained in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2019, filed with the Securities and Exchange Commission. Forward-looking statements are not guarantees of future performance, and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this press release.

PROTAGONIST THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
License and collaboration revenue - related party	$ 4,141	$ 6,117	$ (2,488)	$ 28,572
Operating expenses:				
Research and development	17,293	12,145	49,092	45,249
General and administrative	4,015	3,361	11,642	10,180
Total operating expenses	21,308	15,506	60,734	55,429
Loss from operations	(17,167)	(9,389)	(63,222)	(26,857)
Interest income and other, net	656	654	1,989	1,798
Loss before income tax benefit	(16,511)	(8,735)	(61,233)	(25,059)
Income tax benefit	102	—	1,547	—
Net loss	$ (16,409)	$ (8,735)	$ (59,686)	$ (25,059)
Net loss per share, basic and diluted	$ (0.61)	$ (0.38)	$ (2.36)	$ (1.15)
Weighted-average shares used to compute net loss per share, basic and diluted	26,956,957	22,912,279	25,315,512	21,750,562

PROTAGONIST THERAPEUTICS, INC.
Selected Condensed Consolidated Balance Sheet Data
(In thousands)

	September 30, 2019	December 31, 2018
Condensed Consolidated Balance Sheet Data:		
Cash, cash equivalents and available-for-sale securities	$ 137,692	$ 128,853
Working capital	$ 113,247	$ 111,345
Total assets	$ 154,627	$ 139,472
Deferred revenue – related party	$ 38,678	$ 8,223
Accumulated deficit	$ (200,160)	$ (140,474)

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