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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): March 10, 2020

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 March 10, 2020, Protagonist Therapeutics, Inc. reported its financial results for the quarter and year ended December 31, 2019. A copy of the press release titled "Protagonist Therapeutics Reports Fourth Quarter and Full Year 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 March 10, 2020, titled "Protagonist Therapeutics Reports Fourth Quarter and Full Year 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: March 10, 2020

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

Exhibit 99.1

Protagonist Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results

-- Therapeutic candidate PTG-300 under evaluation in Phase 2 proof of concept studies in multiple blood disorder indications --

-- Two differentiated, orally administered candidates PTG-200 and PN-943 in clinical-stage development for the treatment of inflammatory bowel disease --

-- Sufficient financial resources to support development of pipeline assets through the end of 2021 --

-- Management to host conference call today at 4:30 p.m. EDT --

NEWARK, Calif., March 10, 2020 -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today reported its financial results for the fourth quarter and full year ended December 31, 2019, and provided an update on its clinical development programs.

“We are pleased to have made great progress in 2019, creating multiple opportunities to execute on our clinical development plans with three platform-generated therapeutic candidates,” commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. “Our priorities for 2020 include evaluating PTG-300 in multiple blood disorders with the intent of selecting the first clinical indication for a pivotal study, continuing Phase 2 development of PTG-200 with our partner Janssen Biotech, and advancing PN-943 into Phase 2 development in ulcerative colitis. Our financial position provides us with sufficient resources through the end of 2021 which should enable us to reach definitive conclusions for all of the ongoing clinical proof of concept studies.”

Product Development Update

PTG-300: Injectable Hepcidin Mimetic for Blood Disorders

- The Company is conducting Phase 2 proof of concept studies with PTG-300 in patients with beta-thalassemia, polycythemia vera and hereditary hemochromatosis.
- In December 2019, the Company reported observations of dose-related reductions from high baseline serum iron and transferrin saturation (TSAT) levels in the ongoing open-label TRANSCEND Phase 2 study of PTG-300, supporting continued evaluation with additional dose regimens and longer follow-up time periods.
- An investigator-sponsored study of PTG-300 in patients with myelodysplastic syndromes, a fourth potential indication for PTG-300, is expected to begin in the first half of 2020.

PTG-200 (JNJ-67864238): Oral IL-23 Receptor Antagonist for Inflammatory Bowel Disease

- Protagonist Therapeutics and Janssen Biotech are jointly conducting the development of PTG-200 (or JNJ-67864238) through completion of a Phase 2a study in patients with moderate-to-severe Crohn's disease, with the anticipation of completion in the first half of 2021.
- Protagonist achieved milestones leading to payments from Janssen Biotech of $25 million received in 2019 triggered by the decision to advance PTG-200 in a Phase 2a study and expansion of the existing collaboration agreement, and $5 million received in early 2020 on the nomination of a second-generation oral IL-23 receptor antagonist.

PN-943: Oral Alpha-4-Beta-7 Integrin Antagonist for Inflammatory Bowel Disease

- Results from a Phase 1 study of PN-943 demonstrated a sustained and superior target engagement as compared with the first-generation oral alpha-4-beta-7 integrin antagonist PTG-100. These results were highlighted in an oral presentation at the 2019 Digestive Disease Week conference.
- The Company plans to initiate a Phase 2 study in patients with ulcerative colitis in the second quarter of 2020, with topline data expected in the second half of 2021.
- Preclinical research findings on PN-943 were presented on February 14, 2020, at the 15th Congress of the European Crohn's and Colitis Organization (ECCO) in Vienna.
- Preclinical research findings for PN-943 have been accepted for presentation at the 2020 Digestive Disease Week conference taking place May 2-5, 2020, in Chicago.

Financial Results

- **Cash, Cash Equivalents and Marketable Securities:** Cash, cash equivalents and marketable securities as of December 31, 2019 were $133.0 million. The Company expects current cash, cash equivalents and marketable securities and access to its debt facility to be sufficient to fund its planned operating and capital expenditures through year-end 2021.
- **License and Collaboration Revenue:** License and collaboration revenue of $2.7 million for the fourth quarter of 2019 was in line with $2.4 million for the same period of 2018. License and collaboration revenue for the full year 2019 was $0.2 million, compared to $30.9 million for 2018. The Company recognized $9.6 million of license and collaboration revenue for the full year 2019, which was offset by the one-time cumulative adjustment related to the application of revenue recognition principles following the May 2019 amendment of the Janssen Biotech collaboration agreement that reduced the revenue by $9.4 million for the year, resulting in net revenue recognition of $0.2 million for the full year 2019.
- **Research and Development ("R&D") Expenses:** R&D expenses for the fourth quarter and full year 2019 were $15.9 million and $65.0 million, respectively, as compared to $14.2 million and $59.5 million, respectively, for the same periods of 2018. The increases were primarily due to increased clinical development costs related to PTG-300 and PN-943, offset in part by lower clinical development costs related to PTG-200 and PTG-100.

- **General and Administrative ("G&A") Expenses:** G&A expenses for the fourth quarter and full year 2019 were $4.1 million and $15.7 million, respectively, as compared to $3.5 million and $13.7 million, respectively, for the same periods of 2018. The increases were primarily due to increases in salaries and employee-related expenses driven by increased headcount and professional services to support the growth in our operations.
- **Net Loss:** The fourth quarter net loss was $17.5 million, or a net loss of $0.63 per share, and the full year 2019 net loss was $77.2 million, or a net loss of $2.98 per share.

Conference Call and Webcast Information

Protagonist executives will host a conference call at 4:30 p.m. EDT/1:30 p.m. PDT today. To access the live call, dial 1-844-515-9178 (U.S./Canada) or 1-614-999-9313 (international) and refer to conference ID number 5591627. A live and archived webcast of the call will also be accessible in the Investors section of the Company's website at www.protagonist-inc.com.

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 address significant unmet medical needs and transform existing treatment paradigms for patients. The Company currently has three different assets in various stages of clinical development. All three were discovered through the use of the Company's peptide technology platform. PTG-300 is an injectable hepcidin mimetic in development for the potential treatment of iron overload and related blood disorders, including hereditary hemochromatosis and rare diseases such as beta-thalassemia and polycythemia vera. PTG-200 is an orally delivered, gut-restricted interleukin-23 receptor specific antagonist peptide in Phase 2 clinical development for the potential treatment of inflammatory bowel disease, with Crohn's disease as the initial indication. The Company has a worldwide license and collaboration agreement with Janssen Biotech, Inc., for the clinical development of PTG-200. PN-943 is an orally delivered, gut-restricted alpha-4-beta-7 integrin specific antagonist peptide in clinical development for the potential treatment of inflammatory bowel disease, with a Phase 2 ulcerative colitis study expected to commence in the second quarter of 2020.

Protagonist is headquartered in Newark, California. For further information, please visit 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 for our clinical programs, the potential of PTG-300 as a possible treatment for beta-thalassemia, polycythemia vera, hereditary hemochromatosis and myelodysplastic syndromes, our plans for future clinical trials, the potential of PTG-200 and PN-943 as possible treatments for inflammatory bowel disease, the initiation and availability of results of our clinical trials and the sufficiency of our financial resources, our ability to fund our clinical trials, 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, and 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 Annual Report on Form 10-K for the year ended December 31, 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.
Consolidated Statements of Operations
(In thousands, except share and per share data)

	For the Three Months Ended December 31,		For the Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
License and collaboration revenue - related party	$ 2,719	$ 2,353	$ 231	$ 30,925
Operating expenses:				
Research and development [1]	15,911	14,248	65,003	59,497
General and administrative [1]	4,107	3,517	15,749	13,697
Total operating expenses	20,018	17,765	80,752	73,194
Loss from operations	(17,299)	(15,412)	(80,521)	(42,269)
Interest income	679	748	2,813	2,566
Interest expense	(167)	--	(169)	--
Other income (expense), net	142	--	(1)	(20)
Loss before income tax (expense) benefit	(16,645)	(14,664)	(77,878)	(39,723)
Income tax (expense) benefit	(856)	799	691	799
Net loss	$ (17,501)	$ (13,865)	$ (77,187)	$ (38,924)
Net loss per common share, basic and diluted	$ (0.63)	$ (0.57)	$ (2.98)	$ (1.74)
Weighted-average shares used to compute net loss per share, basic and diluted	27,610,696	24,186,356	25,894,024	22,364,515

(1) Amounts include non-cash stock-based compensation expense as follows (in thousands):

	For the Three Months Ended December 31,		For the Year Ended December 31,	
Stock-based compensation	**2019**	**2018**	**2019**	**2018**
Research and development	$ 1,113	$ 1,000	$ 4,350	$ 3,424
General and administrative	1,047	1,072	4,003	3,495
Total stock-based compensation expense	$ 2,160	$ 2,072	$ 8,353	$ 6,919

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

	December 31, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	$ 133,017	$ 128,853
Working capital	$ 109,905	$ 111,345
Total assets	$ 154,917	$ 139,472
Long-term debt, net	$ 9,794	$ --
Deferred revenue - related party	$ 41,530	$ 8,223
Accumulated deficit	$ (217,661)	$ (140,474)
Total stockholders' equity	$ 79,964	$ 112,515

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