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 12, 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))

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 12, 2019, Protagonist Therapeutics, Inc. reported its financial results for the quarter and year ended December 31, 2018. A copy of the press release titled "Protagonist Therapeutics Reports Fourth Quarter and Full Year 2018 Financial Results" is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto and is incorporated herein by reference.

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 that 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press release, dated March 12, 2019, titled "Protagonist Therapeutics Reports Fourth Quarter and Full Year 2018 Financial Results".

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 12, 2019

By: /s/ Niall Murphy
Niall Murphy
Principal Accounting Officer

Exhibit 99.1

Protagonist Therapeutics Reports Fourth Quarter and Full Year 2018 Financial Results

— Preliminary results from the Phase 2 TRANSCEND study of the hepcidin mimetic PTG-300 for the treatment of beta thalassemia expected in the second half of 2019 —

— U.S. Investigational New Drug (IND) filing by Janssen to support a Phase 2 study of oral IL-23 receptor antagonist PTG-200 (partnered with Janssen Biotech) in Crohn's disease expected in the first half of 2019 —

— Results of the Phase 1 study of oral, gut-restricted alpha-4-beta-7-integrin-targeted therapy PN-943 in healthy volunteers expected in the first half of 2019 —

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

NEWARK, Calif., March 12, 2019 — Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today reported its financial results for the fourth quarter and full year ended December 31, 2018, and provided a corporate update on its clinical development programs.

"We continue to advance three different clinical development candidates discovered from our proprietary peptide engineering platform and have sufficient financial resources to support these programs and reach important milestones through the end of 2020," commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. "We are pleased to have initiated a global Phase 2 trial of PTG-300 for the treatment of beta thalassemia and expect preliminary results in the second half of 2019. Based on the broad applicability of the mechanism of action of PTG-300, we see strong potential for its development in multiple indications, and plan to initiate a second indication for PTG-300 in the second half of the year. With our partner, Janssen Biotech, we are working towards filing a U.S. Investigational New Drug (IND) application in the first half of 2019 to support a global Phase 2 study of PTG-200 in Crohn's patients. In addition, we are moving forward with the development of our oral, gut-restricted alpha-4-beta-7 integrin antagonist, PN-943, for the treatment of inflammatory bowel disease. Safety, pharmacokinetic, and pharmacodynamic results from the Phase 1 study of PN-943 in healthy volunteers are expected in the first half of 2019."

Product Development Update:

PTG-300

- The Company announced the initiation of dosing in the TRANSCEND study, a single-arm, open-label global Phase 2 study of PTG-300, an injectable hepcidin mimetic, in patients with transfusion-dependent or non-transfusion dependent beta thalassemia. Preliminary results from this Phase 2 trial are expected in the second half of 2019.

- The Company expects to begin clinical development of PTG-300 in a second indication in the second half of 2019.

- The Company received Orphan Drug Designation from the European Medicines Agency for PTG-300. PTG-300 had previously received Orphan Drug Designation and Fast Track Designation from the U.S. FDA.

PTG-200

- Top-line results from a Phase 1 study of PTG-200, an oral peptide IL-23 receptor antagonist partnered with Janssen Biotech, demonstrated that the drug was well tolerated, with no serious adverse events or dose-limiting toxicities observed.

- Protagonist and Janssen Biotech are working towards filing a U.S. IND application to support a global Phase 2 clinical study in patients with Crohn's disease. This IND filing would trigger a milestone payment from Janssen Biotech of $25 million under the exclusive license and collaboration agreement between Janssen Biotech and Protagonist (Janssen License and Collaboration Agreement). The U.S. IND filing is expected in the first half of 2019.

PN-943

- Protagonist announced initiation of dosing in a Phase 1 study of PN-943, which is being developed as a potential novel oral therapy for patients with inflammatory bowel disease. The study will evaluate safety, pharmacokinetics, and pharmacodynamic readouts of target engagement as measured by blood receptor occupancy in healthy volunteers. Top-line results from this Phase 1 study are expected in the first half of 2019.

- The Phase 1 data will inform the design of a Phase 2 study of PN-943 in patients with ulcerative colitis, with an expected U.S. IND filing in late 2019.

- Preclinical research findings of PN-943 have been accepted for oral presentation on Sunday, May 19, 2019, at the Digestive Diseases Week conference in San Diego.

Financial Results

Protagonist reported a net loss of $13.9 million and $38.9 million, respectively, for the fourth quarter and full year 2018, as compared to a net loss of $3.1 million and $37.0 million, respectively, for the same periods of 2017. The increase in net loss for the fourth quarter of 2018 as compared to the prior year period was driven primarily by numerous factors such as nearing the end of the revenue recognition phase of the $50.0 million upfront payment received from Janssen in 2017, a net decrease in license and collaboration revenue affected by an increase in variable consideration and the additional time required to deliver the services to Janssen, and increases in research and development (R&D) expenses. The increase in net loss for the full year 2018 as compared to the prior year was driven primarily by increases in R&D and general and administrative (G&A) expenses, partially offset by an increase in license and collaboration revenue and higher interest income. The net loss for the fourth quarter and full year 2018 included non-cash stock-based compensation of $2.1 million and $6.9 million, respectively, as compared to $1.2 million and $4.2 million, respectively, for the same periods of 2017.

License and collaboration revenue was $2.4 million and $30.9 million, respectively, for the fourth quarter and full year 2018, as compared to $11.3 million and $20.1 million, respectively, for the same periods of 2017. The decrease in license and collaboration revenue for the fourth quarter of 2018 as compared to the prior year period was primarily related to nearing the end of the revenue recognition phase of the $50.0 million upfront payment received from Janssen in 2017 coupled with the additional estimated time remaining to complete our increased compound supply services under the Janssen License and Collaboration Agreement. Protagonist estimates these services will be completed during the first half of 2019 compared to the previous estimate of end of 2018. The increase in license and collaboration revenue for the full year of 2018 as compared to the prior year was primarily driven by a full year of services performed under the Janssen License and Collaboration Agreement during 2018, compared to five months of revenue during 2017 following the signing of the agreement. The Company has determined that the transaction price of the Janssen License and Collaboration Agreement was $60.7 million at December 31, 2018, an increase in variable consideration of $6.8 million from the transaction price of $53.9 million at December 31, 2017.

R&D expenses were $14.2 million and $59.5 million, respectively, for the fourth quarter and full year 2018, as compared to $11.7 million and $46.2 million, respectively, for the same periods of 2017. The increases in R&D expenses were primarily due to costs related to contract manufacturing and the preparation for and conduct of clinical trials for our product candidates. R&D expenses for the fourth quarter and full year 2018 included increases in salaries and employee-related expenses due to an increase in R&D personnel.

G&A expenses for the fourth quarter and full year 2018 were $3.5 million and $13.7 million, respectively, as compared to $3.1 million and $11.8 million, respectively, for the same periods of 2017. The increases in G&A expenses were primarily due to increases in salaries and employee-related expenses to support the growth of our operations.

Interest income for the fourth quarter and full year 2018 was $0.7 million and $2.5 million, respectively, as compared to $0.5 million and $0.9 million, respectively, for the same periods of 2017. The increase in interest income is primary the result of the increasing interest rate environment during 2018.

Protagonist ended 2018 with $128.9 million in cash, cash equivalents and investments. Protagonist expects to have sufficient financial resources to fund operations to the end of 2020.

Conference Call and Webcast Information

Protagonist executives will host a conference call at 4:30 p.m. EDT 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 9688334. The call will also be webcast and will be accessible from "Events & Presentations" in the Investors section of the Company's website at www.protagonist-inc.com. A replay will be available on the Company's website approximately two hours after the call and will remain available for 60 days.

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 for the potential treatment of anemia and iron overload related to rare blood diseases with an initial focus on beta thalassemia. PTG-200 is an oral peptide interleukin-23 receptor antagonist in development for the treatment of Crohn's disease. The company has entered into 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 antagonist peptide in development for the treatment of inflammatory bowel disease.

Protagonist is headquartered in Newark, California, with pre-clinical and clinical staff in California and discovery operations in both California and Brisbane, Queensland, Australia. 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 initiation and availability of results of our clinical trials and the sufficiency of our financial resources. In some cases, you can identify these statements by forward-looking words such as "anticipate," "believe," "may," "will," "expect," 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, our ability to operate in a competitive industry and compete successfully against competitors that have greater resources than we do, and our ability to obtain and adequately protect intellectual property rights for our product candidates. We discuss many of these risks in greater detail under the heading "Risk Factors" contained in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission. 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)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
License and collaboration revenue - related party	$ 2,353	$ 11,282	$ 30,925	$ 20,063
Operating expenses:				
Research and development	14,248	11,724	59,497	46,181
General and administrative	3,517	3,071	13,697	11,779
Total operating expenses	17,765	14,795	73,194	57,960
Loss from operations	(15,412)	(3,513)	(42,269)	(37,897)
Interest income	748	461	2,546	940
Loss before income tax benefit	(14,664)	(3,052)	(39,723)	(36,957)
Income tax benefit	799	—	799	—
Net loss	$ (13,865)	$ (3,052)	$ (38,924)	$ (36,957)
Net loss per share, basic and diluted	$ (0.57)	$ (0.15)	$ (1.74)	$ (2.09)
Weighted-average shares used to compute net loss per share, basic and diluted	24,186,356	20,195,519	22,364,515	17,694,505

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

	December 31, 2018	December 31, 2017
Consolidated Balance Sheet Data:		
Cash, cash equivalents and available-for-sale securities	$ 128,853	$ 155,459
Working capital	$ 111,345	$ 108,392
Total assets	$ 139,472	$ 163,734
Deferred revenue — related party	$ 8,223	$ 31,752
Accumulated deficit	$ (140,474)	$ (101,550)
Total stockholders' equity	$ 112,515	$ 120,632

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