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): May 7, 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 May 7, 2020, Protagonist Therapeutics, Inc. (the "Company") reported its financial results for the quarter ended March 31, 2020. A copy of the press release titled "Protagonist Therapeutics Reports First Quarter Financial Results and Provides Corporate Update" is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto and is incorporated herein by reference.

The information in this Item 2.02, including Exhibit 99.1 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 in this Item 2.02 and in Exhibit 99.1 hereto shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01. Other Events.

On May 7, 2020, the Company issued a press release announcing initial data from the ongoing Phase 2 study of PTG-300 in patients with polycythemia vera. A copy of the press release titled "Protagonist Therapeutics Announces Initial Phase 2 Results with Hepcidin Mimetic PTG-300 in the Treatment of Polycythemia Vera" is attached hereto as Exhibit 99.2 and incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press release, dated May 7, 2020, titled "Protagonist Therapeutics Reports First Quarter Financial Results and Provides Corporate Update".
99.2	Press release, dated May 7, 2020, titled "Protagonist Therapeutics Announces Initial Phase 2 Results with Hepcidin Mimetic PTG-300 in the Treatment of Polycythemia Vera".

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: May 7, 2020

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

Exhibit 99.1

Protagonist Therapeutics Reports First Quarter Financial Results and Provides Corporate Update

-- Company selects the polycythemia vera indication for pivotal development of PTG-300 based on robust clinical responses --

-- Revised and focused development plans now provide sufficient capital to fund operations through mid-2022 --

-- Protagonist to host a conference call today to provide a corporate update, and details of initial Phase 2 polycythemia vera results to be presented by Ronald Hoffman, M.D., Director of the Myeloproliferative Diseases Program at The Icahn School of Medicine at Mount Sinai --

NEWARK, Calif., May 7, 2020 -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today reported its financial results for the first quarter ended March 31, 2020, and provided an update on clinical development programs.

“Based on the highly promising and consistent clinical responses achieved to date, we are pleased to announce polycythemia vera as the first indication for a pivotal study of PTG-300,” commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. “With an orphan drug development regulatory path forward, we are focused on rapidly advancing PTG-300 as a first-in-class non-cytoreductive hepcidin hormone mimetic agent for this indication with significant unmet need. With a highly focused development effort forward with PTG-300 for polycythemia vera, and deferring PN-943 Phase 2 initiation due to the current COVID-19 environment, we have reduced our operational expenditures and now have an additional six months of cash runway estimated to extend through mid-2022.”

Product Development Update

PTG-300: Injectable Hepcidin Mimetic

- Ÿ Initial Phase 2 results in patients with polycythemia vera from an ongoing study demonstrated that treatment with PTG-300 at individualized doses ranging from 10 mg to 80 mg for up to 28 weeks controlled hematocrit levels. All patients were phlebotomy free (except a single phlebotomy due to an unintended dose interruption in a patient who remains on study). Administration of PTG-300 was well tolerated and the safety profile was generally similar with results of prior studies, with injection site reactions and bruise as the only adverse events related to or possibly related to treatment. Results are available as of the May 1, 2020, cutoff date.
- Ÿ The results of the PTG-300 beta-thalassemia Phase 2 study will be presented at an upcoming medical conference in the second quarter of 2020.

- Protagonist will redirect the majority of its PTG-300 efforts to the polycythemia vera indication, while also continuing its exploration of PTG-300 in hereditary hemochromatosis. The Company is discontinuing clinical development for PTG-300 in beta-thalassemia and myelodysplastic syndromes.

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

- In collaboration with Janssen Biotech, we initiated a Phase 2 global study for PTG-200 (or JNJ-67864238) in moderate-to-severe Crohn's disease in the fourth quarter of 2019. Because of the global COVID-19 pandemic, guidance has been currently suspended on a timeline for study completion.

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

- A Phase 2 study of PN-943 in approximately 150 patients with moderate-to-severe ulcerative colitis is currently planned.
- In light of the global COVID-19 pandemic, Protagonist continues to review all aspects of the planned Phase 2 study and is currently suspending guidance on a timeline for study initiation. The Company is maintaining readiness to initiate the study as soon as conditions allow for safe accrual of subjects for the global study.

Financial Results

- **Cash, Cash Equivalents and Marketable Securities:** Cash, cash equivalents and marketable securities as of March 31, 2020, were $117.5 million. Due to the focusing of efforts on polycythemia vera and the delay in PN-943 trial initiation caused by the ongoing global COVID-19 pandemic and a related internal reorganization, the company believes its adjusted operating plans now provide sufficient financial resources from its cash, cash equivalents, marketable securities and access to its debt facility to fund its currently planned operating and capital expenditures through mid-2022. The company will continue to monitor events closely and may further adjust its operating plans as warranted.
- **License and Collaboration Revenue:** License and collaboration revenue of $3.6 million for the first quarter of 2020 increased in comparison to $1.6 million reported for the same period of 2019. License and collaboration revenue is generally earned over time as services are provided under the collaboration.
- **Research and Development ("R&D") Expenses:** R&D expenses for the first quarter 2020 were $18.8 million as compared to $12.4 million for the same period of 2019. The increase was primarily due to increased clinical development costs related to PTG-300, PN-943 and our IL-23 receptor antagonist collaboration with Janssen Biotech to develop PTG-200 and the related research collaboration efforts.
- **General and Administrative ("G&A") Expenses:** G&A expenses for the first quarter 2020 were $4.6 million, as compared to $3.8 million for the same period of 2019. The increase was primarily due to increases in salaries, employee-related expenses and professional services to support the growth in our operations.
- **Net Loss:** The first quarter 2020 net loss was $20.1 million, or a net loss of $0.72 per share, as compared to a net loss of $14.1 million, or a net loss of $0.58 per share, for the same period of 2019.

Conference Call and Webcast Information

Protagonist will host a conference call at 5 p.m. EDT / 2 p.m. PDT today to provide a corporate update. Ronald Hoffman, M.D., Director of the Myeloproliferative Diseases Program at The Icahn School of Medicine at Mount Sinai, will join the call to present initial results for PTG-300 in polycythemia vera. 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 4597494. A live and archived webcast 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 therapeutics to address significant unmet medical needs and transform existing treatment paradigms for patients. The Company currently has three clinical-stage assets. PTG-300 is an injectable hepcidin mimetic in development for the treatment of polycythemia vera and hereditary hemochromatosis. PTG-200 is an orally delivered, gut-restricted, interleukin-23 receptor specific antagonist peptide in development for the 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 development of PTG-200. PN-943 is an orally delivered, gut-restricted alpha-4-beta-7 integrin specific antagonist peptide in development for the treatment of inflammatory bowel disease, with ulcerative colitis as the initial targeted indication.

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 ongoing clinical programs, our plans for future clinical trials, the impact of the global COVID-19 pandemic, the potential of PTG-300 as a possible treatment for polycythemia vera, beta-thalassemia and hereditary hemochromatosis, 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," "estimate," "will," "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 Biotech, 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 and risks related to the global COVID-19 pandemic and actions taken to slow its spread. 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 period ended March 31, 2020, 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)
(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
License and collaboration revenue - related party	$ 3,647	$ 1,560
Operating expenses:		
Research and development [1]	18,768	12,444
General and administrative [1]	4,576	3,764
Total operating expenses	23,344	16,208
Loss from operations	(19,697)	(14,648)
Interest income	526	731
Interest expense	(243)	-
Other income (expense), net	(490)	(3)
Loss before income taxes	(19,904)	(13,920)
Income tax (expense)	(176)	(183)
Net loss	$ (20,080)	$ (14,103)
Net loss per common share, basic and diluted	$ (0.72)	$ (0.58)
Weighted-average shares used to compute net loss per share, basic and diluted	27,703,918	24,297,576

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

	Three Months Ended March 31,	
Stock-based compensation	**2020**	**2019**
Research and development	$ 1,066	$ 1,122
General and administrative	982	857
Total stock-based compensation expense	$ 2,048	$ 1,979

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

	March 31, 2020	December 31, 2019
Cash, cash equivalents and marketable securities	$ 117,513	$ 133,017
Working capital	$ 89,614	$ 109,905
Total assets	$ 134,901	$ 154,917
Long-term debt, net	$ 9,832	$ 9,794
Deferred revenue - related party	$ 39,045	$ 41,530
Accumulated deficit	$ (237,741)	$ (217,661)
Total stockholders' equity	$ 62,666	$ 79,964

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Exhibit 99.2

Protagonist Therapeutics Announces Initial Phase 2 Results with Hepcidin Mimetic PTG-300 in the Treatment of Polycythemia Vera

-- PTG-300 treatment demonstrates robust clinical response and provides clinically meaningful dose related control of hematocrit values on individual patient basis --

-- Results to be presented today by Ronald Hoffman, M.D., Director of the Myeloproliferative Diseases Program at The Icahn School of Medicine at Mount Sinai --

NEWARK, Calif., May 7, 2020 -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today announced initial data from the ongoing Phase 2 study of PTG-300 in patients with polycythemia vera. The current results demonstrate that treatment with PTG-300 at individualized doses ranging from 10 mg to 80 mg for up to 28 weeks provided dose-related control of hematocrit levels and eliminated the need for phlebotomy in all six out of six patients that received the dosing as per protocol. A seventh patient with 12 weeks of treatment had an unintended dose interruption, received a single phlebotomy, and remains on the study. In addition, positive symptomatic measurements related to the ability of PTG-300 to address iron deficiency in these frequently phlebotomized patients were observed, with increases in serum ferritin values approaching the range observed in healthy subjects. Patients enrolled in the current study had received at least three phlebotomies within a 24 week period prior to PTG-300 treatment and were treated for up to 28 weeks as of the cutoff date of May 1, 2020 (range of 4 to 28 weeks, n=7 evaluable for efficacy). Enrollment in the study continues and a total of eight patients have enrolled to date.

“While further follow up and data from additional patients will be needed to confirm the continuity of the robust clinical responses observed to date, we believe that this study provides a compelling rationale to initiate planning for a pivotal program in polycythemia vera,” commented Samuel Saks, M.D., Protagonist Chief Medical Officer. “As a peptide mimetic of the natural hepcidin hormone, PTG-300 is believed to limit the excess number of red blood cells in polycythemia vera by reducing iron available for red blood cell production. In the near term, we are expanding the current study to include additional patients as the Company focuses on these encouraging results. We will also be hosting a scientific planning meeting with leaders in the field of myeloproliferative neoplasms and working with patient advocates to discuss pivotal and future studies in polycythemia vera. Our goal with these studies is to work to address the broad populations of patients that may benefit from this new non-cytoreductive treatment.”

“These initial data demonstrate the potential of PTG-300 to almost entirely avoid the need for phlebotomy in the treatment of polycythemia vera by persistent control of hematocrit levels to below 45 percent,” commented Ronald Hoffman, M.D., Director of the Myeloproliferative Diseases Program at The Icahn School of Medicine at Mount Sinai and an investigator in the PTG-300 polycythemia vera study. “Previous studies have repetitively demonstrated that patients undergoing phlebotomy in addition to other therapies spend far too much time above the target hematocrit levels of 45 percent in the clinical guidelines. This is despite the fact that hematocrit levels above this target are associated with significant cardiovascular events such as heart attack and stroke. PTG-300 offers the possibility of maintaining patients consistently below 45 percent hematocrit levels with weekly administration of a mimetic of the endogenous iron regulator without the up and down excursions inherent in typical phlebotomy therapy. In addition, the reduction in phlebotomy may allow sufficient iron to be available systemically to avoid symptoms related to iron deficiency. The potential for weekly self-administration with PTG-300 is a meaningful advantage of this approach to treatment. These early results are very encouraging and suggest the potential for a paradigm shift for the treatment of polycythemia vera. We look forward to additional data from the expanded study in the future.”

Administration of PTG-300 was well tolerated and the safety profile was generally similar with results of prior studies, with injection site reactions and bruise as the only observed adverse events. With eight subjects enrolled to date, the study continues to accrue patients and none of the patients have discontinued treatment with PTG-300.

The study is designed to monitor the safety profile and to obtain evidence of efficacy in patients requiring frequent phlebotomies. Based on the initial findings, the study is being expanded and is now expected to enroll approximately 50 patients. The study design consists of a 16-week open-label dose escalation, reduction, or maintenance stage every four weeks from 10 mg to 80 mg and a 12-week maintenance period at doses that generate desired hematocrit levels followed by a randomized and blinded withdrawal stage up to 12 weeks. The study has an open-label extension for up to one year to monitor long-term safety and other effects. The primary endpoint is the proportion of responders during the blinded randomized withdrawal period. Other endpoints of this clinical proof-of-concept study include measurement of blood parameters (hematocrit and hemoglobin levels), reductions or delay in phlebotomy requirements and improvements in quality-of-life symptoms. Additional information is available at https://clinicaltrials.gov/ct2/show/NCT04057040.

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