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

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**FORM 8-K**

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**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 4, 2020**

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**PROTAGONIST THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-37852**  
(Commission  
File Number)

**98-0505495**  
(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.)

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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:

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
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.

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## **Item 2.02. Results of Operations and Financial Condition.**

On November 4, 2020, Protagonist Therapeutics, Inc. (the “Company”) reported its financial results for the quarter ended September 30, 2020. A copy of the press release titled “Protagonist Therapeutics Reports Third 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.

## **Item 8.01. Other Events**

On November 4, 2020, the Company issued a press release announcing that multiple Company abstracts have been accepted for presentation at the 62<sup>nd</sup> American Society of Hematology Annual Meeting and Exposition to be held December 5-8, 2020. The press release is attached hereto as Exhibit 99.2.

Two of the abstracts include interim data from the Company’s ongoing Phase 2 study of PTG-300 in polycythemia vera. The interim data, which include results observed in 13 patients through August 5, 2020, supplement the previously reported initial data observed in seven patients in the study through a cutoff date of May 1, 2020. The updated interim data demonstrate that treatment with PTG-300 at individualized doses ranging from 10 mg to 80 mg for up to 28 weeks substantially reduced the need for therapeutic phlebotomy in all patients after the patients were adequately titrated to an effective dose in accordance with the study protocol. The two subjects who demonstrated hematocrits transiently above 45% remained below 45% after (i) phlebotomy and dose increase in one case and (ii) dose increase alone in the other case.

In addition, during treatment with PTG-300, erythrocyte (red blood cell) numbers decreased and mean corpuscular volume of erythrocytes increased overall. Serum ferritin levels increased progressively toward normal, reflecting an increase in iron stores. Other iron-related parameters (TSAT and serum iron values) increased modestly but remained below normal ranges. These findings, taken together, suggest a normalization of iron distribution in the body.

Patients enrolled in the 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 August 5, 2020 (range of 3 to 28 weeks, n=13 evaluable for efficacy).

The most frequent adverse events were injection site reactions in three of 13 patients. Most of the reactions were grade 1-2 and were transient in nature and no patient discontinued the drug.

The study is designed to monitor PTG-300’s safety profile and to obtain evidence of efficacy in polycythemia vera patients requiring frequent phlebotomies. The study was initially designed to enroll 30 patients but was expanded in May 2020 to enroll approximately 50 patients. The study design consists of a 28-week open-label dose escalation, reduction, or maintenance stage every four weeks from 10 mg to 80 mg 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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## Cautionary Note on Forward-Looking Statements

*This Current Report on Form 8-K 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 polycythemia vera, the Company's success at finding appropriate doses of PTG-300 for the treatment of polycythemia vera, and the results of the Phase 2 study of PTG-300 in polycythemia vera. In some cases, you can identify these statements by forward-looking words such as "will," "plan," "believe," "may," "potential," "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 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 Quarterly Report on Form 10-Q for the period ended September 30, 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 Form 8-K speak only as of the date of this Form 8-K. 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 Form 8-K.*

### Item 9.01. Financial Statements and Exhibits.

#### (d) Exhibits.

<b><u>Exhibit</u></b>	<b><u>Description</u></b>
<a href="#"><u>99.1</u></a>	<a href="#"><u>Press release, dated November 4, 2020, titled "Protagonist Therapeutics Reports Third Quarter Financial Results and Provides Corporate Update."</u></a>
<a href="#"><u>99.2</u></a>	<a href="#"><u>Press Release, dated November 4, 2020, titled "Protagonist Therapeutics to Present Updated Clinical Data for Hepcidin Mimetic PTG-300 in Polycythemia Vera at the American Society for Hematology (ASH) 2020 Annual Meeting."</u></a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 exhibits 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.

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**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.

Dated: November 4, 2020

**Protagonist Therapeutics, Inc.**

By: /s/ Don Kalkofen

Don Kalkofen

Chief Financial Officer

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## Protagonist Therapeutics Reports Third Quarter Financial Results and Provides Corporate Update

-- Updated Phase 2 results for hepcidin mimetic PTG-300 in polycythemia vera accepted for oral presentation at the ASH Annual Meeting in December 2020 --

-- PTG-300 received European Medicine Agency (EMA) Orphan Drug Designation for the treatment of polycythemia vera --

-- Company is advancing additional oral IL-23 receptor antagonists into clinical development in collaboration with Janssen --

NEWARK, Calif., November 4, 2020 -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today reported its financial results for the third quarter ended September 30, 2020, and provided a corporate update.

“The three clinical assets PTG-300, PN-943 and PTG-200, all discovered through our peptide technology platform, continue to make progress in Phase 2 clinical proof-of-concept studies,” commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. “We look forward to sharing updated clinical data in December from our Phase 2 study of PTG-300 in patients with polycythemia vera and see significant opportunity for PTG-300 to address unmet needs and improve upon the current standards of care.”

Dr. Patel continued, “We are moving forward with our ongoing Phase 2 clinical programs with the oral alpha-4-beta-7 integrin antagonist PN-943 in patients with ulcerative colitis, and the oral interleukin-23 receptor antagonist PTG-200 in patients with Crohn’s disease. In addition, we’re encouraged by the steady progress in our ongoing collaboration with Janssen, and recently announced the selection of two additional oral interleukin-23 receptor antagonists, PN-235 and PN-232, for advancement into clinical development. These candidates provide several strategic options for development in multiple indications.”

### Product Development and Corporate Update

PTG-300: Subcutaneous Injectable Hepcidin Mimetic for Polycythemia Vera and Other Blood Disorders

- Five presentations have been accepted for the American Society for Hematology (ASH) Annual meeting, taking place in a virtual format from December 5-8, 2020. Two posters and one oral presentation are related to PTG-300 and polycythemia vera and two posters describe the hepcidin mimetic mechanism of action and a hepcidin mimetic for oral delivery.
  - In October, PTG-300 was granted orphan designation by the European Medicines Agency for the treatment of polycythemia vera.
  - Complete enrollment of 50 patients in the PTG-300 polycythemia vera study is expected in mid-2021.
  - A pivotal study of PTG-300 in the treatment of polycythemia vera is expected to begin in the second half of 2021 pending dialog with regulatory authorities.
  - An open-label proof-of-concept study of PTG-300 in patients with hereditary hemochromatosis is in progress and results are expected in 2021.
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#### PN-943: Oral Alpha-4-Beta-7 Integrin Antagonist for Inflammatory Bowel Disease

- Protagonist has dosed patients in a global, randomized, double-blind, placebo-controlled Phase 2 study (the "IDEAL Study") evaluating safety, tolerability and efficacy of PN-943 in approximately 150 patients with moderate to severe ulcerative colitis.
- In light of the global COVID-19 pandemic, Protagonist has suspended guidance on a timeline for study completion.

#### Oral IL-23 Receptor Antagonists (Janssen Biotech and Protagonist Collaboration)

- Protagonist Therapeutics and Janssen Biotech are jointly conducting the development of PTG-200 (JNJ-67864238) through completion of a Phase 2 clinical proof of concept study in the treatment of Crohn's disease.
- Two additional oral peptide IL-23 receptor antagonist candidates from the collaboration agreement with Janssen Biotech, PN-235 (JNJ-77242113) and PN-232 (JNJ-75105186), have been selected for advancement into clinical development. A Phase 1 study of PN-235 is expected to begin in the fourth quarter of 2020.

#### Financial Update

- During the third quarter of 2020, the Company issued 333,000 shares through its at-the-market (ATM) program and raised \$6.4 million; shares were sold at an average price of \$19.65 per share.
- The Company also reported sales of an additional 918,000 shares through its ATM program during October 2020, raising \$18.9 million, at an average price of \$21.03 per share.

#### Financial Results

- **Cash, cash equivalents and marketable securities** as of September 30, 2020, were \$200.0 million. Protagonist estimates 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-2023.
  - **License and collaboration revenues** were \$13.1 million and \$23.0 million for the three and nine months ended September 30, 2020, respectively, in comparison to \$4.1 million and \$(2.5) million reported for the same periods of 2019. The increase in revenue in the third quarter of 2020 compared to 2019 was related to an estimate update for services completed versus remaining services to be performed under the Janssen collaboration agreement. This revised estimate accelerated our overall performance percentage completion under the current accounting performance obligation, coupled with continued delivery of Protagonist's services under the ongoing collaboration. The increase in year-over-year revenue was also related to a previously reported 2019 one-time cumulative adjustment related to the application of revenue recognition principles following the May 2019 amendment of the Janssen Biotech collaboration agreement that had reduced revenue by \$9.4 million for the nine months ended September 30, 2019.
  - **Research and Development (R&D) expenses** for the three and nine months ended September 30, 2020, were \$16.0 million and \$55.0 million, respectively, as compared to \$17.3 million and \$49.1 million for the same periods of 2019. 2020 expenses were primarily related to advancing our clinical development including the ongoing Phase 2 clinical trial for polycythemia vera with PTG-300, PN-943 Phase 2 study in ulcerative colitis, and the IL-23 receptor antagonist research collaboration activities with Janssen Biotech.
  - **General and Administrative (G&A) expenses** for the three and nine months ended September 30, 2020, were \$4.9 million and \$13.6 million, respectively, as compared to \$4.0 million and \$11.6 million for the same periods of 2019. The increases were primarily related to professional fees, insurance costs and salary related expenses to support the growth in operations.
  - **Net loss** for the three and nine months ended September 30, 2020, was \$7.8 million and \$47.3 million or a net loss of \$0.21 per share and \$1.45 per share, respectively, as compared to a net loss of \$16.4 million and \$59.7 million, or a net loss of \$0.61 per share and \$2.36 per share, respectively, for the same periods of 2019.
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## **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. PTG-300 is an injectable hepcidin mimetic in development for the treatment of polycythemia vera and other blood disorders. 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. In addition to PTG-200, two oral peptide interleukin-23 receptor antagonist candidates from a collaboration with Janssen Biotech, Inc., are in development and have been selected for advancement into clinical studies. 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](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 our product candidates to improve standards of care, our ability to fund operations into future periods, and our expectations regarding the timing of the initiation of clinical trials. 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, the impact of the current COVID-19 pandemic on our discovery and development efforts, 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. 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 quarter ended September 30, 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.

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**PROTAGONIST THERAPEUTICS, INC.**

**Selected Consolidated Balance Sheet Data**

**(In thousands)**

**(Unaudited)**

	<b>September 30, 2020</b>	<b>December 31, 2019</b>
Cash, cash equivalents and marketable securities	\$ 199,999	\$ 133,017
Working capital	165,588	109,905
Total assets	217,320	154,917
Long-term debt, net	--	9,794
Deferred revenue - related party	20,877	41,530
Accumulated deficit	(264,925)	(217,661)
Total stockholders' equity	169,590	79,964

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**PROTAGONIST THERAPEUTICS, INC.**

**Condensed Consolidated Statements of Operations**

(Amounts in thousands except share and per share data)

(unaudited)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2020</b>	<b>2019</b>	<b>2020</b>	<b>2019</b>
Revenue:				
License and collaboration revenue - related party	\$ 13,114	\$ 4,141	\$ 22,978	\$ (2,488)
Operating expenses:				
Research and development <sup>(1)</sup>	15,995	17,293	55,020	49,092
General and administrative <sup>(1)</sup>	4,891	4,015	13,644	11,642
Total operating expenses	20,886	21,308	68,664	60,734
Loss from operations	(7,772)	(17,167)	(45,686)	(63,222)
Interest income	87	762	820	2,134
Interest expense	(19)	--	(471)	--
Loss on early repayment of debt	--	--	(585)	--
Other expense, net	(59)	(106)	(37)	(145)
Loss before income taxes	(7,763)	(16,511)	(45,959)	(61,233)
Income tax (expense) benefit	--	102	(1,305)	1,547
Net loss	\$ (7,763)	\$ (16,409)	\$ (47,264)	\$ (59,686)
Net loss per common share, basic and diluted	\$ (0.21)	\$ (0.61)	\$ (1.45)	\$ (2.36)
Weighted-average shares used to compute net loss per share, basic and diluted	37,386,881	29,956,957	32,647,524	25,315,512

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

<b>Stock-based compensation</b>	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2020</b>	<b>2019</b>	<b>2020</b>	<b>2019</b>
Research and development	\$ 1,006	\$ 1,137	\$ 3,098	\$ 3,237
General and administrative	882	1,064	2,834	2,956
Total stock-based compensation expense	\$ 1,888	\$ 2,201	\$ 5,932	\$ 6,193

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**Contacts:**

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## **Protagonist Therapeutics to Present Updated Clinical Data for Hepcidin Mimetic PTG-300 in Polycythemia Vera at the American Society for Hematology (ASH) 2020 Annual Meeting**

NEWARK, Calif., November 4, 2020 -- Protagonist Therapeutics, Inc. (NASDAQ:PTGX) today announced the acceptance of one oral and four poster presentations at the American Society for Hematology (ASH) annual meeting, taking place in a virtual format December 5-8, 2020. The abstract data includes results as of early August 2020 from the ongoing Phase 2 study of PTG-300 in the treatment of polycythemia vera. Additional updated data from the study will be available during presentations at the conference.

"This year's ASH meeting provides an opportunity for Protagonist to share detailed findings of its PTG-300 hepcidin mimetic program for polycythemia vera (PV) at a major medical conference for the first time," commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. "We look forward to presenting updated results from our ongoing Phase 2 PTG-300 proof-of-concept PV study at the conference. We will also present an analysis of real world patient data and potential unmet needs in PV, as well as promising preclinical findings with a new oral hepcidin mimetic peptide. As a non-cytoreductive treatment option based on the activity of a natural hormone, PTG-300 has truly transformative potential for PV patients and we look forward to advancing PTG-300 on the path toward regulatory approval as efficiently as possible."

### Oral presentation:

- 1) Title: PTG-300 Eliminates the Need for Therapeutic Phlebotomy in Both Low and High-Risk Polycythemia Vera Patients (Abstract #482)  
Session: 634. Myeloproliferative Syndromes: Clinical: Clinical Trials in Polycythemia Vera  
Session Date: Sunday, December 6, 2020  
Presentation Time: 2:45 p.m. PST  
Presenter: Marina Kremyanskaya, M.D., Ph.D., Icahn School of Medicine at Mount Sinai

### Poster presentations:

- 2) Title: Hepcidin Mimetic (PTG-300) Reverses Iron Deficiency While Controlling Hematocrit in Polycythemia Vera Patients (Abstract #1689)  
Session: 102. Regulation of Iron Metabolism: Poster II  
Date: Sunday, December 6, 2020  
Presenter: Yelena Ginzburg, M.D., Icahn School of Medicine at Mount Sinai
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- 3) Title: Real-World Treatments and Thrombotic Events in Polycythemia Vera Patients: A Retrospective Analysis between 2018-2019 in US Population (Abstract #2998)  
Session: 624. Hodgkin Lymphoma and T/NK Cell Lymphoma—Clinical Studies: Poster III  
Date: Monday, December 7, 2020  
Presenter: Srđan Verstovsek, M.D., Ph.D., MD Anderson Cancer Center
- 4) Title: Mechanism of Systemic Iron Regulation and Hematocrit Control by Hepcidin Peptidomimetics in Pre-Clinical Models (Abstract #2594)  
Session: 102. Regulation of Iron Metabolism: Poster III  
Date: Monday, December 7, 2020  
Presenter: Roopa Taranath, Ph.D., Protagonist Therapeutics
- 5) Title: Hepcidin Peptidomimetics – Oral Efficacy in Pre-Clinical Disease Model of Iron Overload (Abstract #2592)  
Session: 102. Regulation of Iron Metabolism: Poster III  
Date: Monday, December 7, 2020  
Presenter: Roopa Taranath, Ph.D., Protagonist Therapeutics

Abstracts are available via the ASH meeting website at <https://www.hematology.org/meetings/annual-meeting>.

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