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 3, 2021**

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 3, 2021, Protagonist Therapeutics, Inc. reported its financial results for the quarter ended September 30, 2021. A copy of the press release titled "Protagonist Therapeutics Reports Third Quarter 2021 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated November 3, 2021, titled "Protagonist Therapeutics Reports Third Quarter 2021 Financial Results and Provides Corporate Update."
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 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.

SIGNATURE

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 3, 2021

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

Exhibit 99.1

Protagonist Therapeutics Reports Third Quarter 2021 Financial Results and Provides Corporate Update

Resumption of the Phase 2 study of rusfertide in polycythemia vera now underway, following swift removal of the FDA clinical hold

Positive proof -of- concept data for rusfertide in hereditary hemochromatosis to be presented at The Liver Meeting® hosted by the American Association for the Study of Liver Diseases

PN-235 moves into a psoriasis indication, Phase 2 study initiation planned for early 2022

NEWARK, Calif., November 3, 2021—Protagonist Therapeutics, Inc. (Nasdaq: PTGX) ("Protagonist" or "the Company") today reported its financial results for the third quarter ended September 30, 2021 and provided a corporate update.

"We are excited to share the substantial progress made thus far in all of our clinical programs, highlighted by the presentation of proof-of-concept data on rusfertide in hereditary hemochromatosis at the upcoming AASLD meeting, and the new rusfertide data in polycythemia vera, which will be presented by the year's end," said Dinesh V. Patel, Ph.D., President and Chief Executive Officer. "We were very pleased that the FDA reached a swift resolution regarding the clinical hold placed on rusfertide, and we are in the process of resuming all rusfertide clinical studies. Additionally, we are highly encouraged with the rate of enrollment in the Phase 2 study of our oral alpha-4-beta-7 integrin antagonist PN-943, for ulcerative colitis, an indication with a large patient population and unmet treatment need. We maintain our guidance of a data readout in Q2 2022, and in anticipation of this, we are excited that Dr. Scott Plevy has joined our team as Executive Vice President and Therapeutic Head, Gastroenterology. As a renowned gastroenterologist, Dr. Plevy will oversee the clinical development of PN-943 and other future programs focused on gastrointestinal diseases. Finally, our oral IL-23 receptor antagonist program, in partnership with Janssen, continues to make demonstrated progress, with PN-235 now advancing into a Phase 2 study in psoriasis in early 2022."

Third Quarter 2021 Recent Developments and Upcoming Milestones

Rusfertide: Subcutaneous Injectable Hepcidin Mimetic for Polycythemia Vera (PV) and Other Blood Disorders

- On October 11, 2021, Protagonist announced that the U.S. Food and Drug Administration (FDA) removed the full clinical hold on rusfertide's clinical studies after the Company provided the FDA with all requested information, including the individual patient clinical safety reports, updated the investigator brochure and patient informed consent forms, conducted a comprehensive review of the most recent safety database, and added new safety and stopping rules in the study protocols. This was in response to the Company receiving a communication from the FDA that Protagonist's clinical studies for rusfertide had been placed on clinical hold on September 17, 2021. Protagonist has been working closely with study investigators and clinical trial sites to resume enrollment and dosing of patients in ongoing clinical trials with rusfertide.

- An abstract highlighting new, preliminary data from a Phase 2 proof-of-concept study in hereditary hemochromatosis (HH) has been selected for oral presentation by Dr. Kris Kowdley, from the Liver Institute Northwest in Seattle. These data will be presented on November 13, 2021 at The Liver Meeting® 2021, hosted by the American Association for the Study of Liver Diseases (AASLD).
- The Company intends to report updated data from the Phase 2 study of rusfertide in polycythemia vera (PV) by the end of 2021.
- The Company is on track to initiate the Phase 3 study of rusfertide in PV in Q1 2022.
- The Company resolved its collaboration agreement dispute with Zealand Pharma, reducing future development and sales milestone payments and royalties owed to Zealand for rusfertide under the companies' 2012 collaboration agreement. Under the new terms of the agreement, future development and sales milestone payments (other than $2.5 million in near-term milestones) and royalties for rusfertide have been reduced by 50 percent. Milestones and royalty payments will be due for sales and milestones achieved by either Protagonist or any future rusfertide licensee or partner. Protagonist will also make a $1.5 million payment to Zealand in August 2022.

PN-943: Oral, gut-restricted, alpha-4-Beta-7 Integrin Antagonist for Ulcerative Colitis

- We are continuing to see steady progress in the enrollment and execution of the Phase 2 IDEAL study of PN-943 in ulcerative colitis. This study includes a 12-week induction period and a 40-week open label extension. Topline data from the 12-week induction period is expected in the second quarter of 2022.
- Scott Plevy, M.D., renowned expert in translational and clinical research in gastroenterology and immunology, was appointed Executive Vice President and Therapeutic Head, Gastroenterology, and he will oversee clinical operations and development of Protagonist's ongoing and future programs in gastrointestinal diseases, including PN-943.

Oral IL-23 Receptor Antagonists (collaboration between Janssen Biotech, Inc. and Protagonist)

- Following a pre-specified interim analysis criteria, a portfolio decision was made to stop further development of the first-generation IL-23 receptor antagonist (IL-23R) candidate PTG-200 (JNJ-67864238), in favor of continued development of the two second generation candidates PN-235 (JNJ-77242113) and PN-232 (JNJ-75105186) with superior product profiles. In particular:
  - The Phase 1 study of PN-235 is completed, and a Phase 2 study in psoriasis is anticipated to initiate in early 2022.
  - The Phase 1 study with PN-232 is under progress with study completion expected by mid-2022.
  - Additional development in IBD is expected to initiate in 2022.
- Protagonist will earn a $25 million milestone in connection with the initiation of the first Phase 2 study of a second-generation candidate, and a $10 million milestone in connection with the initiation of the second Phase 2 study of a second-generation candidate. Protagonist remains eligible for up to approximately $900 million in development-related milestone payments, in addition to the $87.5M in milestones already earned.
- Protagonist received a $7.5 million milestone payment from Janssen, triggered by the completion of the clinical data collection Phase 1 activities for PN-235 (JNJ-2113).

Third Quarter 2021 Financial Results

- **Cash, Cash Equivalents and Marketable Securities**: Cash, cash equivalents and marketable securities as of September 30, 2021, were $352.5 million. The Company expects current cash, cash equivalents and marketable securities to be sufficient to fund its planned operating and capital expenditures through 2024.

- **License and Collaboration Revenue:** License and collaboration revenues were $10.3 million and $18.7 million for the three and nine months ended September 30, 2021, respectively, as compared to $13.1 million and $23.0 million reported for the same periods of 2020. The Company recognized $8.0 million as a cumulative catch-up amount during the three months ended September 30, 2021, following the amendment of its collaboration agreement for the development of IL-23 receptor antagonist assets with Janssen Biotech. This cumulative catch-up was primarily the result of an acceleration of our cumulative performance completed under our obligation, following the amendment to the collaboration which reduced the remaining services the Company is responsible to conduct. We are nearing completion of our remaining services to be provided to Janssen under the collaboration, in particular, both the ongoing Phase 1 trials in PN-235 and PN-232, are expected to be complete in the fourth quarter of 2021 and second quarter 2022, respectively. Revenue for the prior year's third quarter of 2020 also included an estimate update for services completed versus remaining services to be performed under the Janssen collaboration agreement which accelerated revenue recognition.

- **Research and Development ("R&D") Expenses:** R&D expenses for the three and nine months ended September 30, 2021, were $37.0 million and $87.6 million, respectively, as compared to $16.0 million and $55.0 million, respectively, for the same periods of 2020. The increases were primarily due to additional costs associated to advancing our clinical trials with our pipeline assets rusfertide and PN-943, as well as our second-generation IL-23 receptor antagonist assets under the Janssen collaboration (PN-235 and PN-232). The increases also relate to higher research spending and employee related costs, including stock-based compensation expenses following recent hiring in support of our advancing research and development programs. Following the amendment to the Zealand collaboration agreement we also recorded $4.0 million in the quarter ended September 30, 2021 in R&D expense related to these collaboration payments.

- **General and Administrative ("G&A") Expenses:** G&A expenses for the three and nine months ended September 30, 2021, were $7.3 million and $19.9 million, respectively, as compared to $4.9 million and $13.6 million for the same periods of 2020. The increases were primarily related to professional fees, insurance costs and employee compensation related expenses, including stock-based compensation expenses, supporting the growth in our operations.

- **Stock Based Compensation ("SBC") Expenses:** SBC expenses for the three and nine months ended September 30, 2021, were $4.8 million and $11.4 million, respectively, as compared to $1.8 million and $5.9 million, respectively, for the same periods of 2020. SBC increases included in R&D and G&A expenses are primarily attributable to the addition of new employees and related stock grants in support of the Company's continued growth coupled with the increase in the Company's stock price at grant date which is used in the SBC expense calculation.

- **Net Loss:** The third quarter 2021 net loss was $33.8 million, or a net loss of $0.70 per share, and the nine months ended September 30, 2021, net loss was $88.6 million, or a net loss of $1.94 per share, compared to the third quarter of 2020 net loss of $7.8 million, or a net loss of $0.21 per share, and the nine months ended September 30, 2020, net loss of $47.3 million, or a net loss of $1.45 per share.

About Protagonist

Protagonist Therapeutics is a biopharmaceutical company with multiple peptide-based investigational new chemical entities in different stages of development, all derived from the Company's proprietary technology platform.

Protagonist's pipeline includes rusfertide (PTG-300), an investigational, injectable hepcidin mimetic currently in a Phase 2 proof-of-concept clinical trial for polycythemia vera (PV), a Phase 2 study in PV subjects with high hematocrit levels, and a Phase 2 study for hereditary hemochromatosis. The Company plans to initiate a single, global Phase 3 randomized, placebo-controlled trial evaluating the efficacy and safety of a once weekly, subcutaneously self-administered dose of rusfertide.

The Company is also evaluating an orally delivered, gut-restricted alpha-4-beta-7 integrin specific antagonist peptide (PN-943) currently in a Phase 2 study in adults with moderate to severe active ulcerative colitis (UC). The Company is targeting ulcerative colitis as the initial indication.

The Company has a worldwide license and collaboration agreement with Janssen Biotech, Inc., for the development of oral peptide IL-23 receptor antagonists. Compounds in development include PN-235 and PN-232, both second-generation oral interleukin-23 receptor antagonist candidates. The Phase 1 study of PN-235 is completed, and Janssen is expected to initiate a Phase 2 study in psoriasis in Q1 2022. The phase 1 study with PN-232, the second 2nd generation candidate, is under progress with study completion expected by mid-2022. Additional research in IBD is expected to initiate in 2022.

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 Company’s clinical development program for rusfertide. 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 agreements, 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 most recently filed periodic reports on Form 10-K and Form 10-Q 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.

Contacts

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
License and collaboration revenue - related party	$ 10,286	$ 13,114	$ 18,740	$ 22,978
Operating expenses:				
Research and development [1]	36,956	15,995	87,633	55,020
General and administrative [1]	7,256	4,891	19,936	13,644
Total operating expenses	44,212	20,886	107,569	68,664
Loss from operations	(33,926)	(7,772)	(88,829)	(45,686)
Interest income	122	87	321	820
Interest expense	—	(19)	—	(471)
Loss on early repayment of debt	—	—	—	(585)
Other expense, net	—	(59)	(136)	(37)
Loss before income tax expense	(33,804)	(7,763)	(88,644)	(45,959)
Income tax expense	—	—	—	(1,305)
Net loss	$ (33,804)	$ (7,763)	$ (88,644)	$ (47,264)
Net loss per share, basic and diluted	$ (0.70)	$ (0.21)	$ (1.94)	$ (1.45)
Weighted-average shares used to compute net loss per share, basic and diluted	47,987,184	37,386,881	45,705,782	32,647,524

[1] Amount includes non-cash stock-based compensation expense.

PROTAGONIST THERAPEUTICS, INC.
Stock-based Compensation (Unaudited)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 2,611	$ 1,006	$ 6,241	$ 3,098
General and administrative	2,164	882	5,130	2,834
Total stock-based compensation expense	$ 4,775	$ 1,888	$ 11,371	$ 5,932

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

	September 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 352,470	$ 307,809
Working capital	288,531	275,365
Total assets	373,175	324,468
Deferred revenue-related party	2,241	14,477
Accumulated deficit	(372,455)	(283,811)
Total stockholders' equity	329,660	279,606