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): **August 4, 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 August 4, 2021, Protagonist Therapeutics, Inc. reported its financial results for the quarter ended June 30, 2021. A copy of the press release titled "Protagonist Therapeutics Reports Second Quarter 2021 Financial Results and Recent Company Progress" 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 August 4, 2021, titled "Protagonist Therapeutics Reports Second Quarter 2021 Financial Results and Recent Company Progess."
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: August 4, 2021

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

Exhibit 99.1

Protagonist Therapeutics Reports Second Quarter 2021 Financial Results and Recent Company Progress

NEWARK, Calif., August 4, 2021—Protagonist Therapeutics, Inc. (Nasdaq: PTGX) ("Protagonist" or "the Company") today reported its financial results for the second quarter ended June 30, 2021, and an overview of recent company progress.

"The second quarter of 2021 was one of enormous progress, achievement, and growth for our Company," said Dinesh V. Patel, Ph.D., President and Chief Executive Officer. "In April, we announced completion of enrollment for our Phase 2 study of rusfertide in polycythemia vera, data from which supported the U.S. Food and Drug Administration's Breakthrough Therapy Designation. In mid-June, we shared updated results from this Phase 2 study in an oral presentation at the European Hematology Association's 2021 Virtual Congress. This data, from 63 patients, continues to demonstrate rusfertide's potential as the first-in-class, non-cytoreductive treatment option for this disease. The durability of effect and symptom improvements observed provided further support for the advancement of rusfertide into Phase 3 clinical development, expected to commence in early 2022."

Dr. Patel continued, "Looking ahead to the remainder of this year and into early 2022, Protagonist has multiple catalysts in view and underway. We intend to announce a third indication for rusfertide, beyond polycythemia vera and hereditary hemochromatosis. We look forward to sharing, for the first time, data from our clinical proof-of-concept study of rusfertide in hereditary hemochromatosis. In the fourth quarter, we are excited to share data from the completed Phase 2 study of rusfertide in polycythemia vera, meanwhile preparing diligently for the Phase 3 study. Finally, we remain intensely engaged in the successful execution of our Phase 2 study of PN-943 in ulcerative colitis and intend to share data from this study in the second quarter of 2022."

Second Quarter 2021 Recent Developments and Upcoming Milestones

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

- Completed enrollment in the Phase 2 study of rusfertide in PV.
- Reported updated results from the Phase 2 study of rusfertide in PV at the European Hematology Association (EHA) 2021 Virtual Congress, which was selected for an oral presentation. The Company expects to report further updated data in PV by the end of 2021.
- Secured Breakthrough Therapy Designation from the FDA for rusfertide in PV.
- Plan to announce third indication beyond PV and hereditary hemochromatosis (HH) by the end of 2021.

- Intend to report preliminary data from Phase 2 proof-of-concept study in HH by the end of 2021.

- On track to commence Phase 3 study of rusfertide in PV in early 2022.

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

- Announced significant progress in the enrollment and execution of the Phase 2 study of PN-943 in ulcerative colitis, revising guidance in anticipation of a sooner-than-expected data readout of the completed study. The Company expects to report results of the completed study in the second quarter of 2022.

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

- As disclosed in July 2021, the oral IL-23 receptor antagonists collaboration between Janssen Biotech and Protagonist has advanced and expanded through an amendment to the original agreement.

- The amended agreement provides for Janssen to lead worldwide development, manufacturing, and commercialization, and also broadens the range of indications contemplated for these drug candidates. Protagonist's development and expense obligations are now limited to the ongoing PTG-200 Phase 2a study in Crohn's disease and to the ongoing Phase 1 studies investigation PN-232 and PN-235.

- Under the amended agreement, Protagonist remains eligible for approximately $900M in future milestone payments, in addition to the $80M in payments already received under the original agreement.

- The Phase 1 study of PN-235, the first of the second-generation oral IL-23 receptor antagonists included in the Janssen collaboration, is in progress, with study completion expected in the fourth quarter of 2021.

- Announced the dosing of the first human subject in a Phase 1 study of PN-232, the second of the second-generation oral IL-23 receptor antagonist peptides included in the collaboration with Janssen.

Second Quarter 2021 Financial Results

Financial Update

- In the second quarter of 2021, Protagonist announced the commencement and closing of an underwritten public offering of 3,503,311 shares of its common stock, including 456,953 shares sold pursuant to the underwriters' option to purchase additional shares, at a price to the public of $37.75 per share. Aggregate gross proceeds to Protagonist from the offering were approximately $132.2 million, before deducting underwriting discounts and commissions and offering expenses.

Financial Results

- **Cash, Cash Equivalents and Marketable Securities:** Cash, cash equivalents and marketable securities as of June 30, 2021 were $380.4 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 $2.3 million and $8.5 million for the three and six months ended June 30, 2021, respectively, in comparison to $6.2 million and $9.9 million reported for the same periods of 2020. The revenue was lower in the second quarter and year to date 2021 compared to the prior year due primarily to the Company delivering a lower amount of collaboration related services during 2021 when compared to 2020. This follows as the Company in 2021 is now nearing completion of its remaining service obligations being provided under the collaboration. In particular, we are near the end of both the ongoing phase 1 trials in PN-235 & PN-232, which are expected to be completed in the fourth quarter of 2021 and early 2022, respectively.

- **Research and Development ("R&D") Expenses:** R&D expenses for the three and six months ended June 30, 2021 were $26.4 million and $50.7 million, respectively, as compared to $20.3 million and $39.0 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.

- **General and Administrative ("G&A") Expenses:** G&A expenses for the three and six months ended June 30, 2021 were $6.7 million and $12.7 million, respectively, as compared to $4.2 million and $8.8 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.

- **Net Loss:** The second quarter 2021 net loss was $30.8 million, or a net loss of $0.69 per share, and the six months ended June 30, 2021 net loss was $54.8 million, or a net loss of $1.23 per share, compared to the second quarter of 2020 net loss of $19.4 million, or a net loss of $0.59 per share, and the six months ended June 30, 2020 net loss of $39.5 million, or a net loss of $1.31 per share.

About Protagonist Therapeutics

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 discovery 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. Based on the feedback provided by the FDA and EU regulatory authorities, 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 has a worldwide license and collaboration agreement with Janssen Biotech, Inc., for the development of oral peptide IL-23 receptor antagonists. Compounds included in this agreement are PTG-200, PN-235 and PN-232. PTG-200 is an orally delivered, gut-restricted, interleukin-23 receptor specific antagonist peptide in a Phase 2 clinical trial for Crohn's disease. PN-235 and PN-232, both second-generation oral interleukin-23 receptor antagonist candidates, are currently in Phase 1 studies.

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, potential benefits of rusfertide for the treatment of PV, and commencement or completion of clinical trials and announcements of clinical data. 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
License and collaboration revenue - related party	$ 2,265	$ 6,217	$ 8,454	$ 9,864
Operating expenses:				
Research and development [1]	26,432	20,257	50,677	39,025
General and administrative [1]	6,715	4,177	12,680	8,753
Total operating expenses	33,147	24,434	63,357	47,778
Loss from operations	(30,882)	(18,217)	(54,903)	(37,914)
Interest income	97	207	199	733
Interest expense	—	(209)	—	(452)
Loss on early repayment of debt	—	(585)	—	(585)
Other (expense) income, net	(57)	512	(136)	22
Loss before income tax expense	(30,842)	(18,292)	(54,840)	(38,196)
Income tax expense	—	(1,129)	—	(1,305)
Net loss	$ (30,842)	$ (19,421)	$ (54,840)	$ (39,501)
Net loss per share, basic and diluted	$ (0.69)	$ (0.59)	$ (1.23)	$ (1.31)
Weighted-average shares used to compute net loss per share, basic and diluted	44,964,637	32,799,691	44,546,172	30,251,805

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

Stock-based Compensation (Unaudited)
(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 2,155	$ 1,026	$ 3,630	$ 2,092
General and administrative	1,781	970	2,966	1,952
Total stock-based compensation expense	$ 3,936	$ 1,996	$ 6,596	$ 4,044

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

	June 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 380,402	$ 307,809
Working Capital	328,845	275,365
Total assets	404,232	324,468
Deferred revenue-related party	2,009	14,477
Accumulated deficit	(338,651)	(283,811)
Total stockholders' equity	357,447	279,606