

**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 7, 2018

PROTAGONIST THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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.)

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 August 7, 2018, Protagonist Therapeutics, Inc. reported its financial results for the quarter ended June 30, 2018. A copy of the press release titled “Protagonist Therapeutics Reports Second Quarter 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.**

<u>Exhibit</u>	<u>Description</u>
99.1	<u>Press release, dated August 7, 2018, titled “Protagonist Therapeutics Reports Second Quarter 2018 Financial Results”.</u>

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: August 7, 2018

By: /s/ Thomas P. O'Neil
Thomas P. O'Neil
Chief Financial Officer

Protagonist Therapeutics Reports Second Quarter 2018 Financial Results

NEWARK, Calif., Aug. 7, 2018 -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today reported its financial results for the second quarter ended June 30, 2018.

“Protagonist continues to advance well-differentiated therapeutic candidates discovered through its novel peptide technology platform,” commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. “We very recently reported results from a comprehensive review of the data from the Phase 2 PROPEL study of PTG-100 for the treatment of moderate to severe active ulcerative colitis. We are pleased to conclude that this drug candidate showed signals of clinical efficacy, has no safety concerns, and warrants further clinical development for potential treatment of ulcerative colitis. We are planning to discuss next steps in the clinical development of PTG-100 with the U.S. Food and Drug Administration (FDA) and other global regulatory authorities in the second half of this year. We are glad to report on the continued progress of the clinical development of PTG-200 in collaboration with our partner Janssen for potential treatment of Crohn’s disease. In addition, we look forward to initiating an open label Phase 2 study in beta-thalassemia patients in the fourth quarter of 2018 with PTG-300, our product candidate for rare blood disorders.”

Product Development Update:

PTG-100

- In March 2018, Protagonist had announced discontinuation of the Phase 2 Propel study following a planned interim analysis conducted by an independent Data Monitoring Committee. The interim data had revealed an unusually high placebo rate of clinical remission (24 percent, approximately four times higher than historical norms for similar UC studies) that led to a futility decision and discontinuation of the trial. A re-read of the endoscopies by the subcontractor of the contract research organization (CRO) and a subsequent fully blinded re-read of the endoscopies by an independent third party, Roberts Clinical Trials, confirmed that a subset of the initial endoscopy reads provided by the CRO were in error. If the re-read of endoscopy results had been utilized for the interim futility analysis, the trial would have continued. Based on this entire analysis, the Company plans to discuss the next steps in advancing the clinical development of PTG-100 with the FDA and other global regulatory authorities in the second half of 2018.
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PTG-200

- In the fourth quarter of 2018, Protagonist expects a U.S. IND filing by its partner Janssen Biotech that will support the initiation of a global Phase 2 study of PTG-200, an oral, gut-restricted interleukin-23 receptor antagonist peptide in Crohn's disease patients. This IND filing would trigger a milestone payment from Janssen of \$25 million under the existing exclusive license and collaboration agreement between Janssen and Protagonist.

PTG-300

- The results of a Phase 1 study in healthy volunteers and supportive pre-clinical data for PTG-300, an injectable hepcidin mimetic peptide, were the subject of oral presentations in June 2018 at the 23rd Congress of the European Hematology Association.
- Protagonist completed discussions with U.S. and global regulatory agencies and filed a U.S. IND in the second quarter of 2018. The Company plans other global regulatory submissions to support the initiation of a global Phase 2 trial in patients with beta-thalassemia in the fourth quarter of 2018.

Preclinical Programs

- The Company presented data related to preclinical product candidates, oral peptide agonists targeting the delta/mu opioid receptors, in a podium presentation at the Digestive Diseases Week conference in June 2018.

Corporate Update – Financing:

- Protagonist recently announced the completion of an equity financing with investors including BVF Partners L.P. and their affiliates for gross proceeds of \$22 million. Proceeds from the financing will be used to advance development of drug candidate PTG-100.

Financial Results

Protagonist reported a net loss of \$8.7 million and \$16.3 million, respectively, for the second quarter and first six months of 2018, as compared to a net loss of \$15.0 million and \$29.1 million, respectively, for the same periods of 2017. The decrease in net loss for both the second quarter and year-to-date periods was driven primarily by license and collaboration revenue recognized during the first and second quarters of 2018, partially offset by increased research

and development (R&D) and general and administrative (G&A) expenses. The net loss for the second quarter and first six months of 2018 includes non-cash stock-based compensation of \$1.6 million and \$2.8 million, respectively, as compared to \$1.0 million and \$1.8 million, respectively, for the same periods of 2017.

License and collaboration revenue was \$11.7 million and \$22.5 million for the second quarter and first six months of 2018, respectively, and consisted of revenue from activities performed under the Janssen Collaboration Agreement. Protagonist did not recognize any license and collaboration revenue for the second quarter or first six months of 2017.

R&D expenses for the second quarter and first six months of 2018 were \$17.7 million and \$33.1 million, respectively, as compared to \$12.0 million and \$23.3 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 quarter also included an increase in salaries and employee-related expenses due to an increase in R&D personnel.

G&A expenses for the second quarter and first six months of 2018 were \$3.2 million and \$6.8 million, respectively, as compared to \$3.1 million and \$6.1 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 primarily due to an increase in headcount to support the growth of our operations, partially offset by a decrease in legal expenses.

Protagonist ended the second quarter with \$125.2 million in cash, cash equivalents and investments. With the financing announced yesterday, the company expects to have sufficient financial resources to fund operations to mid-2020.

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-100 is an oral alpha-4-beta-7 integrin antagonist peptide that is under evaluation for potential treatment of inflammatory bowel diseases. The company's interleukin-23 receptor antagonist peptide, PTG-200, is currently in a Phase 1 clinical trial in healthy volunteers to support a Phase 2 study in Crohn's disease. The IL-12/23 pathway blockade is an approach that has been validated through an FDA-approved injectable antibody drug. The company has entered into a worldwide license and collaboration agreement with Janssen Biotech for the

clinical development of PTG-200. Protagonist has also applied its innovative peptide platform outside of gastrointestinal disease areas and is developing an injectable hepcidin mimetic, PTG-300, for the potential treatment of anemia and iron overload related to rare blood diseases with an initial focus on beta-thalassemia. The company has completed a Phase 1 clinical trial of PTG-300, which established pharmacodynamic-based clinical proof-of-concept in normal healthy volunteers. The U.S. Food and Drug Administration has granted Orphan Drug Designation to PTG-300 for beta-thalassemia. Treatment of patients with myelodysplastic syndromes, hereditary hemochromatosis and polycythemia vera represent additional opportunities for future development of PTG-300.

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 <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 for our programs, our collaborations and milestone payments we may receive under them, the initiation and availability of results of our clinical trials, our research and development plans, the utility of our intellectual property, and the adequacy of our capital resources. In some cases, you can identify these statements by forward-looking words such as “anticipate,” “believe,” “may,” “will,” “would,” or “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 quarterly report on Form 10-Q for the three months ended June 30, 2018 to be 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
License and collaboration revenue - related party	\$ 11,674	\$ —	\$ 22,455	\$ —
Operating expenses:				
Research and development	17,735	12,007	33,103	23,289
General and administrative	3,178	3,124	6,820	6,115
Total operating expenses	20,913	15,131	39,923	29,404
Loss from operations	(9,239)	(15,131)	(17,468)	(29,404)
Interest income	576	152	1,144	324
Net loss	\$ (8,663)	\$ (14,979)	\$ (16,324)	\$ (29,080)
Net loss per share, basic and diluted	\$ (0.41)	\$ (0.89)	\$ (0.77)	\$ (1.73)
Weighted-average shares used to compute net loss per share, basic and diluted	21,207,234	16,875,627	21,160,076	16,821,225

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

	June 30, 2018	December 31, 2017
Consolidated Balance Sheet Data:		
Cash, cash equivalents and available-for-sale securities	\$ 125,167	\$ 155,459
Working capital	\$ 107,093	\$ 108,392
Total assets	\$ 137,473	\$ 163,734
Deferred revenue – related party	\$ 13,202	\$ 31,752
Accumulated deficit	\$ (117,874)	\$ (101,550)
Total stockholders' equity	\$ 107,662	\$ 120,632

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