

**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 8, 2017

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 8, 2017, Protagonist Therapeutics, Inc. reported its financial results for the quarter ended June 30, 2017. A copy of the press release titled “Protagonist Therapeutics Reports Second Quarter 2017 Financial Results and Business Highlights,” 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.

<u>Exhibit</u>	<u>Description</u>
99.1	Press release, dated August 8, 2017, titled “Protagonist Therapeutics Reports Second Quarter 2017 Financial Results and Business Highlights.”

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.

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 8, 2017

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

INDEX TO EXHIBITS

Exhibit

Description

99.1

Press release, dated August 8, 2017, titled “Protagonist Therapeutics Reports Second Quarter 2017 Financial Results and Business Highlights.”

Protagonist Therapeutics Reports Second Quarter 2017 Financial Results and Business Highlights

Worldwide co-development agreement with Janssen for PTG-200 brings \$50M upfront and potentially up to \$940M in milestones

Q2 cash balance of \$64.5M - Cash to middle of 2019

Newark, California (August 8, 2017): Protagonist Therapeutics, Inc. (Nasdaq: PTGX) today reported its financial results for the second quarter and six months ended June 30, 2017.

“Protagonist achieved several significant milestones during the second quarter, most notably the signing of a major license and collaboration agreement with Janssen for PTG-200, our pre-clinical stage oral interleukin-23 receptor (IL-23R) antagonist for inflammatory bowel diseases (IBD),” said Dinesh V. Patel, Ph.D., President and Chief Executive Officer of Protagonist Therapeutics. “In addition to the strategic advantages this major partnership provides us, it has also extended our financial runway, enabling us to advance our clinical pipeline of innovative peptide drugs and expand the utility of our technology platform.”

Pipeline Highlights:

PTG-200:

- Protagonist granted Janssen exclusive, worldwide rights to PTG-200, a first-in-class oral peptide IL-23R antagonist currently in pre-clinical development and expected to enter phase 1 studies in the second half of 2017. The terms of the agreement included a \$50.0 million upfront payment, which we expect to receive in the third quarter of 2017. Protagonist can also potentially receive up to an additional \$940.0 million in clinical development, regulatory approval, and sales milestones. Protagonist and Janssen will co-develop and co-fund PTG-200 through Phase 2 clinical development. Protagonist will receive double-digit tiered royalties on future net sales and retains the option to co-detail PTG-200 in the United States, if PTG-200 receives regulatory approval.
 - A new U.S. patent, No. 9,624,268, providing composition of matter protection for PTG-200 and covering the use of oral peptide inhibitors of IL-23R to treat IBD, was issued.
 - Protagonist was awarded a Phase 2 Small Business Innovation Research Grant from the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health. This grant provides up to \$1.3 million of funding over two years to support the
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development of biomarkers useful in the clinical development of anti-IL23R agents for the treatment of IBD, including PTG-200.

PTG-100:

- The company is advancing the clinical proof-of-concept and dose optimization global Phase 2b trial in ulcerative colitis (UC) patients with alpha-4-beta-7 integrin specific antagonist peptide PTG-100. PTG-100 is being developed as a potential oral targeted therapy for IBD and related indications. Based on current enrollment rates, the interim analysis is now expected in early 2018; top-line results are still anticipated for the second half of 2018.

PTG-300:

- Protagonist has initiated a Phase 1 clinical study of PTG-300, an injectable hepcidin mimetic peptide discovered using the company's proprietary technology platform, in normal healthy volunteers. PTG-300 is being developed as a potential treatment for patients with chronic iron overload in rare diseases such as beta-thalassemia. The Phase 1 single ascending dose study is evaluating the safety, tolerability, and pharmacokinetics of PTG-300 in normal healthy volunteers. In addition, the effect of PTG-300 on baseline serum iron levels will be analyzed to evaluate pharmacodynamics-based clinical proof-of-concept. The results of this study are anticipated in the second half of 2017.

Corporate Highlights:

- The company appointed Rusty Williams, M.D., Ph.D., current President and Chief Executive Officer of Five Prime Therapeutics, to the Protagonist Board of Directors. Dr. Williams is a member of the National Academy of Sciences and an industry veteran having served in critical roles at various companies such as Chiron Corporation, COR Therapeutics, and Daiichi Research Center.

Financial Results

Protagonist reported a net loss attributable to common stockholders of \$15.0 million and \$29.1 million, respectively, for the second quarter and first six months of 2017, as compared to a net loss attributable to common stockholders of \$7.3 million and \$19.1 million, respectively, for the same periods of 2016. The increase in net loss for both the second quarter and year-to-date periods were driven primarily by research and development (R&D) expenses related to the accelerated progression to Phase 1 initiation of PTG-300; PTG-100 clinical trial and development activities; and other pre-clinical studies and discovery research efforts in support of Protagonist's pipeline; as well as general and administrative (G&A) expenses for operations. The net loss for the second quarter and first six months of 2017 includes non-cash stock-based compensation of \$1.0 million and \$1.8 million, respectively, as compared to \$0.1 million and \$0.2 million, respectively, for the same periods of 2016.

R&D expenses for the second quarter and first six months of 2017 were \$12.0 million and \$23.3 million, respectively, as compared to \$5.7 million and \$11.3 million, respectively, for the same periods of 2016. The increases in R&D expenses were primarily due to increased PTG-100 clinical trial and development activities, which included Phase 2 clinical trial site start-up activities, contract manufacturing costs, and pre-clinical and clinical development studies for other product candidates, including PTG-300. R&D expenses for the second quarter and year-to-date periods also included an increase in employee-related expenses due to an increase in R&D personnel.

G&A expenses for the second quarter and first six months of 2017 were \$3.1 million and \$6.1 million, respectively, as compared to \$1.4 million and \$2.8 million, respectively, for the same periods of 2016. The increases in G&A expenses were primarily due to an increase in employee-related expenses primarily due to an increase in headcount to support the growth of our operations, consulting and professional service fees, and other administrative expenses.

Protagonist ended the second quarter with \$64.5 million in cash, cash equivalents and investments. With the additional funding from the Janssen collaboration, including the \$50.0 million upfront milestone payment the company expects to receive in the third quarter of 2017, the company expects to have sufficient financial resources to fund operations until the middle of 2019.

About Protagonist Therapeutics

Protagonist Therapeutics is a clinical-stage biopharmaceutical company with a proprietary technology platform which is utilized to discover and develop novel peptide-based drugs to address significant unmet medical needs. Its primary focus is on developing potential first-in-class oral targeted therapy-based peptide drugs that work by blocking biological pathways that are currently targeted by marketed injectable antibody drugs. Protagonist's initial lead peptide product candidates, PTG-100 and PTG-200, are based on this approach, and the company believes these candidates have the potential to transform the existing treatment paradigm for inflammatory bowel disease (IBD), consisting primarily of ulcerative colitis and Crohn's disease.

PTG-100, a potential first-in-class oral peptide alpha-4-beta-7 integrin antagonist, is currently in a global Phase 2b clinical trial for treatment of moderate-to-severe ulcerative colitis. PTG-200, a first-in-class oral Interleukin-23 receptor antagonist for potential treatment of IBD, initially Crohn's disease, is currently in pre-clinical development and is expected to enter a Phase 1 clinical study in the second half of 2017. The company recently announced it has entered into a worldwide collaboration with Janssen Biotech to co-develop and commercialize PTG-200 for all indications, including IBD.

In addition to PTG-100 and PTG-200, the company is developing an injectable hepcidin mimetic PTG-300 as a potential orphan drug for the treatment of rare diseases such as beta-thalassemia. PTG-300 is currently being studied in a Phase 1 clinical trial.

Protagonist is headquartered in Newark, California with its pre-clinical and clinical staff in California, and discovery operations both in California and in 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, the initiation and availability of results of our clinical trials, enrollment in our clinical trials, contract manufacturing, capital resources, the possibility of obtaining orphan drug designation, and the potential for eventual regulatory approval of our product candidates. 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 history of net operating losses, our reliance on third parties and uncertainty regarding our ability to achieve profitability, 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 quarter ended June 30, 2017, to be 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.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	\$ 12,007	\$ 5,696	\$ 23,289	\$ 11,321
General and administrative	3,124	1,395	6,115	2,810
Total operating expenses	<u>15,131</u>	<u>7,091</u>	<u>29,404</u>	<u>14,131</u>
Loss from operations	(15,131)	(7,091)	(29,404)	(14,131)
Interest income	152	27	324	39
Change in fair value of redeemable convertible preferred stock tranche and warrant liabilities	—	—	—	(4,719)
Other expense	<u>—</u>	<u>(34)</u>	<u>—</u>	<u>(34)</u>
Net loss	<u>\$ (14,979)</u>	<u>\$ (7,098)</u>	<u>\$ (29,080)</u>	<u>\$ (18,845)</u>
Net loss attributable to common stockholders	<u>\$ (14,979)</u>	<u>\$ (7,323)</u>	<u>\$ (29,080)</u>	<u>\$ (19,110)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.89)</u>	<u>\$ (19.07)</u>	<u>\$ (1.73)</u>	<u>\$ (56.90)</u>
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	<u>16,875,627</u>	<u>383,910</u>	<u>16,821,225</u>	<u>335,855</u>

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

	June 30,	December 31,
	2017	2016
Consolidated Balance Sheet Data:		
Cash, cash equivalents and available-for-sale securities	\$ 64,492	\$ 87,749
Working capital	\$ 59,760	\$ 76,809
Total assets	\$ 70,479	\$ 93,990
Accumulated deficit	\$ (93,673)	\$ (64,593)
Total stockholders' equity	\$ 61,030	\$ 87,555

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