
**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): **March 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 March 7, 2018, Protagonist Therapeutics, Inc. reported its financial results for the quarter and year ended December 31, 2017. A copy of the press release titled "Protagonist Therapeutics Reports Fourth Quarter and Year-End 2017 Financial Results," is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto and is incorporated herein by reference.

The information in this Item 2.02 and in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K 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 in this Item 2.02 and in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K 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 | Press release, dated March 7, 2018, titled "Protagonist Therapeutics Reports Fourth Quarter and Year-End 2017 Financial Results." |

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: March 7, 2018

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



Protagonist Therapeutics Reports Fourth Quarter and Year-End 2017 Financial Results

Protagonist to host conference call today at 1:30 pm PT/4:30 pm ET

Newark, CA (March 7, 2018): Protagonist Therapeutics, Inc. (NASDAQ: PTGX) today reported its financial results for the fourth quarter and full year ended December 31, 2017 and provided an update on the company's recent achievements.

"2017 was a very successful year for Protagonist wherein we strengthened both our R&D pipeline as well as our financial position," said Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. "During the year, we entered into a major collaboration with Janssen Biotech Inc., raised a net \$64.5 million in a public offering, and ended the year with three products in different stages of clinical development."

"We believe that the company is well positioned for success in 2018," continued Dr. Patel. "We anticipate reporting the interim futility analysis outcome in the first quarter and final top-line results in the fourth quarter from our Phase 2b PROPEL trial of the oral peptide PTG-100. These results, if positive, would demonstrate the potential utility of PTG-100 as an oral targeted therapy for moderate-to-severe ulcerative colitis. During 2018, we also plan to report Phase 1 results from the Janssen collaboration asset PTG-200. Finally, we plan to commence a global clinical trial of PTG-300 in patients with beta-thalassemia and initiate IND enabling studies with our fourth asset, PTG-400."

"We ended the year with approximately \$155.5 million in cash, cash equivalents, and investments and anticipate having enough funds to support our operations through 2019," Dr. Patel concluded.

2017 Research and Development Highlights:

PTG-100

- Protagonist initiated a global Phase 2b trial of alpha-4-beta-7 integrin oral peptide antagonist PTG-100 in approximately 240 patients with moderate-to-severe active ulcerative colitis. An interim futility analysis will be performed in the first quarter of 2018, and final top-line results are anticipated in the fourth quarter of 2018.
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- The company plans to initiate a Phase 2/3 clinical trial in chronic pouchitis, a rare disease indication, in 2018 pending a positive decision from the interim futility analysis in the ulcerative colitis PROPEL study.

PTG-200

- Protagonist entered into a license and collaboration agreement with Janssen Biotech, Inc., a Johnson and Johnson company, to support the clinical development and potential commercialization of PTG-200, a first-in-class oral peptide interleukin-23 receptor (IL-23R) antagonist. Under the terms of the agreement, Protagonist granted Janssen an exclusive worldwide license to PTG-200 and received a \$50 million upfront payment in the third quarter of 2017. Protagonist can also receive up to an additional \$940 million in payments, including potential license option payments of \$125 million at the Phase 2 interim analysis and \$200 million at Phase 2 completion, and \$615 million in other potential clinical development, regulatory approval, and sales milestones.
- Protagonist and Janssen will co-develop and co-fund PTG-200 through Phase 2 clinical development. Janssen will be responsible for funding Phase 3 studies in Crohn's disease and ulcerative colitis. Protagonist will receive double-digit tiered royalties on future net sales and retains the option to co-detail PTG-200 in the United States.
- Protagonist initiated a first-in-human trial of PTG-200 in November 2017. The Phase 1 study is a randomized, double-blind, placebo-controlled, single and multiple dose-escalation trial in normal healthy volunteers. Protagonist and Janssen collaboratively plan to complete this Phase 1 study and anticipate filing a U.S. IND and initiating a global Phase 2 study in Crohn's disease in the second half of 2018.

PTG-300

- Protagonist successfully initiated and completed a Phase 1 randomized, double-blind, placebo-controlled, single dose-escalation and repeat dose study of its hepcidin mimetic PTG-300 in normal healthy volunteers. PTG-300 was found in this study to be safe and well-tolerated at all dose levels. Moreover, in this study, PTG-300 demonstrated its intended dose-related pharmacological effect on serum iron levels, establishing pharmacodynamic clinical proof-of-concept in healthy volunteers. Following our upcoming meetings with the U.S. and European regulatory agencies, the company plans to initiate a global clinical trial of PTG-300 in beta-thalassemia in the second half of 2018.
 - On March 6, 2018, Protagonist announced that the U.S. Food Administration had granted Orphan Drug Designation to PTG-300 for the treatment of beta-thalassemia.
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Corporate Highlights:

- Protagonist completed a public offering of 3,530,000 shares of its common stock at a price to the public of \$17.00 per share in October 2017. The underwriters exercised their option to purchase an additional 529,500 shares at the public offering price in November 2017. Net proceeds from the offering were approximately \$64.5 million.
- The company appointed two new members to the Protagonist Board of Directors during 2017: Rusty Williams, M.D., Ph.D., current Executive Chairman and former President and Chief Executive Officer of Five Prime Therapeutics, and Sarah Noonberg, M.D., Ph.D., previously Chief Medical Officer of Prothena Corporation.

Other Highlights

- 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 in May 2017. This grant provides up to \$1.3 million of funding over two years to support the development of biomarkers useful in the clinical development of IL-23R antagonist agents for the treatment of inflammatory bowel disease (IBD), including PTG-200.
- Several key patents issued to Protagonist during 2017 and January 2018 covering the company's peptide assets. These included U.S. patents No. 9,518,091, covering the company's alpha-4-beta-7 integrin peptide inhibitors, including PTG-100, and No. 9,809,623, providing further specific protection for PTG-100; U.S. patents 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; and No. 9,822,157, covering peptide mimetics of hepcidin, including PTG-300, and related pharmaceutical compositions.

Financial Results

Protagonist reported a net loss of \$37.0 million for the full year 2017, as compared to a net loss of \$37.2 million for the prior year. The company reported a net loss of \$3.1 million for the fourth quarter of 2017, as compared to a net loss of \$11.2 million for the fourth quarter of 2016. The decrease in net loss was driven primarily by license and collaboration revenue recognized during the last half of 2017, which partially offset increased research and development expenses related to PTG-100, PTG-200, and PTG-300 clinical trials and other pre-clinical product candidate studies, and increased general and administrative expenses.

License and collaboration revenue was \$20.1 million for the full year 2017 and \$11.3 million for the fourth quarter of 2017 and consisted of revenue from activities performed under the agreement with Janssen. Protagonist did not recognize any license and collaboration revenue prior to the third quarter of 2017.

Research and development expenses for the full year 2017 were \$46.2 million, as compared to \$25.7 million for the prior year. Research and development expenses for the fourth quarter of 2017 were \$11.7 million, as compared to \$8.8 million for the same period in the prior year. The increase in research and development expense in these periods was due primarily to costs related to contract manufacturing, the preparation for and conduct of PTG-100, PTG-200, and PTG-300 clinical trials, and preclinical development studies for other product candidates.

General and administrative expenses for the full year 2017 were \$11.8 million, as compared to \$7.0 million for the prior year. General and administrative expenses for the fourth quarter of 2017 were \$3.1 million, as compared to \$2.6 million for the same period in the prior year. The increase in G&A expense in these periods was due primarily to increases in employee-related expenses, professional service fees, and other administrative expenses to support the growth of our headcount and operations.

Protagonist ended 2017 with \$155.5 million in cash, cash equivalents and investments.

Conference Call and Web Cast Information

Protagonist executives will host a conference call at 1:30 p.m. PT/4:30 p.m. ET today. To access the live call, dial 1-844-515-9178 (U.S./Canada) or 1-614-999-9313 (international) and refer to conference ID number 4054387. The call will also be webcast and will be accessible from “Events & Presentations” in the Investors section of the company’s website at www.protagonist-inc.com. A replay will be available on the company’s website approximately two hours after the call and will remain available for 90 days.

About Protagonist Therapeutics

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. Two of its clinical stage product candidates, PTG-100 and PTG-200, are oral targeted therapy drugs being developed for inflammatory bowel diseases (IBD). The alpha-4-beta-7 integrin antagonist peptide PTG-100 is currently in a Phase 2b clinical trial for moderate-to-severe ulcerative colitis, and the company’s interleukin-23 receptor antagonist peptide PTG-200 is currently being studied in a Phase 1 clinical trial in healthy volunteers to support further development in Crohn’s disease. Both alpha-4-beta-7 integrin and IL-12/23 pathway blockade are approaches that have been validated through FDA-approved injectable antibody drugs. 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 versatile platform outside of the GI disease areas and is developing an injectable hepcidin mimetic, PTG-300, for the treatment of anemia related to rare blood diseases with an initial focus on beta-thalassemia. PTG-300 recently completed a Phase 1 clinical trial 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.

Protagonist is headquartered in Newark, California with pre-clinical and clinical staff in California, and discovery operations both in 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,” “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 annual report on Form 10-K for the year ended December 31, 2017 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.

Consolidated Statements of Operations
(In thousands, except share and per share data)

| | Three Months Ended December 31, | | Year Ended December 31, | |
|----------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------|----------------------------|--------------------|
| | 2017 | 2016 | 2017 | 2016 |
| | (Unaudited) | | | |
| License and collaboration revenue - related party | \$ 11,282 | \$ — | \$ 20,063 | \$ — |
| Operating expenses: | | | | |
| Research and development | 11,724 | 8,823 | 46,181 | 25,705 |
| General and administrative | 3,071 | 2,574 | 11,779 | 6,961 |
| Total operating expenses | <u>14,795</u> | <u>11,397</u> | <u>57,960</u> | <u>32,666</u> |
| Loss from operations | (3,513) | (11,397) | (37,897) | (32,666) |
| Interest income | 461 | 149 | 940 | 242 |
| Change in fair value of redeemable convertible preferred stock tranche and warrant liabilities | — | — | — | (4,719) |
| Other expense | — | — | — | (34) |
| Net loss | <u>\$ (3,052)</u> | <u>\$ (11,248)</u> | <u>\$ (36,957)</u> | <u>\$ (37,177)</u> |
| Net loss attributable to common stockholders | <u>\$ (3,052)</u> | <u>\$ (11,248)</u> | <u>\$ (36,957)</u> | <u>\$ (37,735)</u> |
| Net loss per share attributable to common stockholders, basic and diluted | <u>\$ (0.15)</u> | <u>\$ (0.67)</u> | <u>\$ (2.09)</u> | <u>\$ (5.80)</u> |
| Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted | <u>20,195,519</u> | <u>16,718,242</u> | <u>17,694,505</u> | <u>6,501,796</u> |

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

| | December 31, 2017 | December 31, 2016 |
|----------------------------------------------------------|----------------------|----------------------|
| Consolidated Balance Sheet Data: | | |
| Cash, cash equivalents and available-for-sale securities | \$ 155,459 | \$ 87,749 |
| Working capital | \$ 108,392 | \$ 76,809 |
| Total assets | \$ 163,734 | \$ 93,990 |
| Deferred revenue — related party | \$ 31,752 | \$ — |
| Accumulated deficit | \$ (101,550) | \$ (64,593) |
| Total stockholders' equity | \$ 120,632 | \$ 87,555 |

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