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): May 26, 2017

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))

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 1.01. Entry into a Material Definitive Agreement.

On May 26, 2017, Protagonist Therapeutics, Inc. ("Protagonist" or "the Company") and Janssen Biotech, Inc., a Pennsylvania corporation ("Janssen"), entered into an exclusive license and collaboration agreement (the "Collaboration Agreement") for the development, manufacture and commercialization of PTG-200 worldwide for the treatment of Crohn's disease ("CD") and ulcerative colitis ("UC"). PTG-200 is the Company's oral Interleukin ("IL")-23 receptor antagonist drug candidate currently in pre-clinical development. The effectiveness of the Collaboration Agreement is subject to the expiration or termination of all applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

Under the Collaboration Agreement, Protagonist would grant to Janssen an exclusive worldwide license to develop, manufacture and commercialize PTG-200 and related IL-23 receptor inhibitor compounds for all indications, including CD and UC. The Company will be responsible, at its own expense, for the conduct of the Phase 1 clinical trial for PTG-200, and Janssen will be responsible for the conduct of a Phase 2 clinical trial for PTG-200 in CD. All such clinical trials would be conducted in accordance with a mutually agreed upon clinical development plan and budget. Development costs for the Phase 2 clinical trial would be shared between the parties on an 80% Janssen and 20% Protagonist basis. Should Janssen elect to retain its license following completion of the Phase 2 clinical trial, it would be responsible for the manufacture, continued development of, seeking regulatory approval for, and commercialization of PTG-200 worldwide. The parties' development activities under the Collaboration Agreement through the Phase 2 clinical trial will be overseen by a joint governance structure which will have equal representation by both parties.

Upon the effectiveness of the Collaboration Agreement, Janssen would pay Protagonist $50 million as an initial payment. Following the conclusion of the planned Phase 2A portion of the Phase 2 clinical trial, if Janssen elects to maintain its license rights and continue the development of PTG-200 in the Phase 2B portion of such clinical trial (the "First Opt-in"), Protagonist would receive a $125 million payment. Following the conclusion of the planned Phase 2B portion of the Phase 2 clinical trial, if Janssen elects again to maintain its license rights (the "Second Opt-in"), Protagonist would receive a $200 million payment. Protagonist is eligible to receive additional potential regulatory and sales milestone payments of up to an aggregate of $615 million and tiered royalties paid as a percentage of Janssen's worldwide net sales at rates ranging from ten to the mid-teens, with certain customary reductions in certain circumstances. If Janssen does not make either the First Opt-in or the Second Opt-in election, the Collaboration Agreement would terminate.

Protagonist would also have an option to provide up to 30% of the required U.S. details for PTG-200 to prescribers, using its own sales force personnel, upon commercial launch in the United States. If such right is exercised, the Company's detailing costs would be reimbursed by Janssen.

The Collaboration Agreement contains customary representations, warranties and covenants by Protagonist and Janssen and includes an obligation by Protagonist not to develop or commercialize other compounds which also target the IL-23 receptor outside of the Collaboration Agreement until completion of the Phase 2B portion of the Phase 2 clinical trial. Each of Protagonist and Janssen is required to indemnify the other party against all losses and expenses relating to breaches of its representations, warranties and covenants.

The Collaboration Agreement would remain in effect until the royalty obligations cease following patent and regulatory expiry, unless terminated earlier. Either Protagonist or Janssen may terminate the Collaboration Agreement for uncured material breach. Janssen retains the right to terminate the Collaboration Agreement for convenience and without cause on written notice of a certain period. Upon a termination of the Collaboration Agreement, all rights revert back to Protagonist, and in certain circumstances, if such termination occurs during ongoing clinical trials, Janssen would, if requested, provide certain financial and operational support to Protagonist for the completion of such trials.

The foregoing description of the Collaboration Agreement and the transactions contemplated thereby does not purport to be complete and is subject to, and qualified in its entirety by reference to, the complete text of the Collaboration Agreement, which will be filed with the Securities and Exchange Commission (the "SEC").

With the additional funding from this collaboration, Protagonist believes it has the financial resources to fund all ongoing and planned research and development activities until the middle of 2019.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements for purposes of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include statements regarding Protagonist's intentions or current expectations concerning, among other things, the potential for its programs, the timing of its clinical trials, the potential for eventual regulatory approval and commercialization of its product candidates, its potential receipt of milestone payments and royalties under its collaboration agreement with Janssen and the adequacy of its financial resources. In some cases you can identify these statements by forward-looking words such as "may," "will," "continues," "expects," "believes," "potential," 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, Protagonist's history of net operating losses, its reliance on third parties and uncertainty regarding its ability to achieve profitability, its ability to develop and commercialize its product candidates, its ability to use and expand its programs to build a pipeline of product candidates, its ability to obtain and maintain regulatory approval of its product candidates, its ability to operate in a competitive industry and compete successfully against competitors that have greater resources, and its ability to obtain and adequately protect intellectual property rights for its product candidates. The Company discusses many of these risks in greater detail under the heading "Risk Factors" contained in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, filed with the SEC on May 10, 2017. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made, and the facts and assumptions underlying the forward-looking statements may change. Except as required by law, Protagonist disclaims any obligation to update these forward-looking statements to reflect future information, events or circumstances.

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: May 30, 2017

By: /s/ Dinesh V. Patel, Ph.D.
Dinesh V. Patel, Ph.D.
President and Chief Executive Officer