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): **July 27, 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 1.01 Entry into a Material Definitive Agreement.

On July 27, 2021, Protagonist Therapeutics, Inc. (the "***Company***") entered into an amended and restated License and Collaboration Agreement ("***Restated Agreement***") with Janssen Biotech, Inc., a Pennsylvania corporation ("***Janssen***"). The Restated Agreement amends and restates the License and Collaboration Agreement, dated May 26, 2017, by and between the Company and Janssen (as amended by the First Amendment thereto, effective May 7, 2019, the "***Original Agreement***").

The Restated Agreement relates to the development, manufacture and commercialization of oral Interleukin ("***IL***")-23 receptor antagonist drug candidates. The candidates currently in development pursuant to the Restated Agreement include PTG-200, PN-232 and PN-235. PTG-200 is an oral Interleukin ("***IL***")-23 receptor antagonist in Phase 2a development for the treatment of Crohn's disease ("***CD***"). PN-235 and PN-232 are second-generation oral IL-23 receptor antagonist candidates currently in Phase 1 studies. Janssen is primarily responsible for the conduct of the PTG-200 trial and the Company is primarily responsible for the conduct of the PN-232 and PN-235 Phase 1 studies.

General. Pursuant to the Restated Agreement, the parties have:

(a) amended development milestones to reflect Janssen's expected development of collaboration compounds for multiple indications in the IL-23 pathway;

(b) limited the Company's further development and related expense obligations under the Restated Agreement to the ongoing PTG-200 Phase 2a study, and the ongoing Phase 1 studies in PN-232 and PN-235 described in the preceding paragraph; Janssen is responsible for all other future development and related expenses under the Restated Agreement;

(c) concluded the parties' two-year research collaboration, while enabling Janssen to continue conducting additional research through July 2024 on compounds developed pursuant to the Original Agreement.

Development Plan. The Restated Agreement enables Janssen to develop collaboration compounds for multiple indications. Janssen's current development plan contemplates parallel development of multiple collaboration compounds against multiple indications in the IL-23 pathway. Under the Restated Agreement, Janssen is required to use commercially reasonable efforts to develop at least one collaboration compound for at least two indications.

Development Expenses. Pursuant to the Original Agreement, the Company was responsible for up to $65 million in costs related to Phase 2 development of PTG-200 and Phase 1 and Phase 2 development of second generation compounds developed during the parties' research collaboration ("***Second Generation Products***"). Under the terms of the Restated Agreement, the Company's development cost obligations have been reduced as described below. The Company estimates its remaining development expense obligation is approximately $6 million.

The Company's development cost obligations in the Original Agreement for the period following the effective date of the Original Agreement were as follows: (a) up to $20 million of costs related to up to three Phase 1 studies of Second Generation Products (100% of the costs up to $10 million for the first Phase 1 study, and 50% of costs for the second and third Phase 1 studies, subject to a $5 million maximum obligation for each study); (b) up to $20 million of costs related to Phase 2a and 2b costs for PTG-200 (i.e., 20% of the first $100 million in costs); (c) up to $25 million in costs related to up to two Phase 2 studies evaluating Second Generation Products.

The Company's continuing development expense obligations under the Restated Agreement are as follows: (a) the Company will continue to fund 20% of the costs related to the ongoing Phase 2a study evaluating PTG-200 for the treatment of CD (subject to the $20 million cap specified in the preceding paragraph); (b) the Company is responsible for 50% of agreed-upon costs related to the ongoing Phase 1 study evaluating PN-235 incurred through January 4, 2021; (c) the Company is responsible for 100% of agreed-upon costs related to the ongoing Phase 1 study evaluating PN-232.

Certain of the Company's previous development expense obligations under the Original Agreement have been limited or eliminated as follows: (a) the Company's previous $25 million obligation for 20% of costs related to Phase 2 studies for Second Generation Products has been eliminated; (b) the Company's previous $5 million obligation for 50% of the costs of a potential third Phase 1 study evaluating a Second Generation Product has been eliminated; and (c) the Company has no obligation to fund any portion of any Phase 2b or other study evaluating PTG-200 beyond the ongoing Phase 2a study.

Development Milestone Payments. The various milestone payment amounts in the Restated Agreement remain substantially the same as in the Original Agreement. Development milestones under the Original Agreement generally corresponded to development milestones for: (a) CD; (b) UC; and (c) any other indication (i.e., any indication other than CD and UC). To reflect parallel development of multiple indications in the IL-23 pathway, milestones under the Restated Agreement generally now correspond to the achievement of specified milestones in: (a) any initial indication (rather than CD, as in the Original Agreement); (b) any second indication (rather than UC, as in the Original Agreement); and (c) any third indication. With respect to Second Generation Products, milestone payments for second and third indications may be triggered by any Second Generation Product (i.e., not necessarily the Second Generation Product that triggered the initial payment for any indication, or the payment for a second indication). In addition, the opt-in payments contemplated by the Original Agreement related to the scope of Janssen's license rights have been converted into development milestones in the Restated Agreement.

Upcoming potential development milestones for Second Generation Products include:

(a) $7.5 million for completion of the first Phase 1 clinical trial of a Second Generation Product;

(b) $25 million for dosing of the 3rd patient in the first Phase 2 clinical trial for any Second Generation Product for any indication;

(c) $10 million for dosing of the 3rd patient in the first Phase 2 clinical trial for any Second Generation Product for a second indication (i.e., an indication different than the indication which triggered the $25 million milestone described in (b) immediately above);

(d) $50 million for dosing of the 3rd patient in a Phase 3 clinical trial for a Second Generation Product for any indication;

(e) $15 million for dosing of the 3rd patient in a Phase 3 clinical trial for a Second Generation Product for a second indication; and

(f) $115 million for a Phase 3 clinical trial for a Second Generation Product for any indication meeting its primary clinical endpoint.

Potential development milestones for PTG-200 are unchanged, except that milestone achievement is generally no longer indication-specific, as described above.

Royalties; Sales Milestones. The mid-single digit to ten percent tiered royalty rates payable pursuant to the Original Agreement remain the same in the Restated Agreement. The sales milestone payments in the Original Agreement also remain the same in the Restated Agreement.

Development; Research; Other. Following completion of the ongoing Phase 2a study for PTG-200 and the ongoing Phase 1 studies for PN-232 and PN-235, the Company has no further collaborative development obligations under the Restated Agreement. Any further research and development will be conducted by Janssen.

Janssen retains exclusive, worldwide rights to develop and commercialize PTG-200 and any second-generation compounds derived from the research collaboration conducted under the Original Agreement, or Janssen's further research under the Restated Agreement.

The Company will have the right to co-detail (for UC and CD indications) up to two of PTG-200 and any Second Generation Products in the U.S. market.

The description of the terms and conditions of the Restated Agreement set forth herein is not complete and is qualified in its entirety by reference to the text of the Restated Agreement, which the Company intends to file as an exhibit to its Quarterly Report on Form 10-Q for the fiscal quarter ending September 30, 2021 and is incorporated herein by reference. For a description of the material terms of the Original Agreement, please see the Company's Current Report on Form 8-K filed on May 8, 2019 and its Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2019.

Cautionary Note on 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. Forward-looking statements include statements regarding the Company's intentions or current expectations concerning, among other things, the development of PTG-200, PN-232 and PN-235, and the Company's anticipated future development expenses. 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, the Company's ability to earn milestone payments under its collaboration agreements, the impact of the current COVID-19 pandemic on discovery and development efforts, and the Company's ability to obtain and adequately protect intellectual property rights for its product candidates. Additional information concerning these and other risk factors affecting the Company's business can be found in its periodic filings with the Securities and Exchange Commission, including under the heading "Risk Factors" contained in the Company's 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 the Company's actual results of operations, financial condition and liquidity, and the development of the industry in which it operates, may differ materially from the forward-looking statements contained in this Form 8-K. Any forward-looking statements that the Company makes in this Form 8-K speak only as of the date of this Form 8-K. The Company assumes no obligation to update its forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this Form 8-K.

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: July 28, 2021

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