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): September 17 , 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 8.01 Other Events.

On September 17, 2021, Protagonist Therapeutics, Inc. (the "Company") issued a press release announcing that the Company's clinical studies for rusfertide, an investigational product candidate currently in development, have been placed on a clinical hold. A copy of the press release titled "Protagonist Therapeutics Reports FDA Clinical Hold on Rusfertide Clinical Development Program" is attached hereto as Exhibit 99.1 and incorporated by reference herein. The Company has begun to provide the FDA with the information requested, including additional information related to four cases of cancer observed to date across all rusfertide clinical trials. These four cases relate to distinct forms of cancer and were assessed to be unrelated to rusfertide due to a preexisting condition or natural disease progression.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 8.01, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits.*

Exhibit	Description
99.1	Press release, dated September 17, 2021, titled "Protagonist Therapeutics Reports FDA Clinical Hold on Rusfertide Clinical Development Program"
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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.

Date: September 17, 2021

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

Exhibit 99.1

Protagonist Therapeutics Reports FDA Clinical Hold on Rusfertide Clinical Development Program

NEWARK, Calif., September 17, 2021—Protagonist Therapeutics, Inc. (Nasdaq: PTGX) ("Protagonist" or "the Company") today announced the receipt of a verbal communication from the U.S. Food and Drug Administration (FDA) that Protagonist's clinical studies for rusfertide, an investigational product candidate currently in development, have been placed on a clinical hold.

The clinical hold follows Protagonist's notification to the FDA of a recent non-clinical finding in a 26-week rasH2 transgenic mouse model study. The rasH2 model is designed to detect signals related to tumorigenicity, and benign and malignant subcutaneous skin tumors were observed in this study.

The Company is working with the FDA and will be prepared to make all appropriate updates to clinical study documents and determine the next steps in consultation with the FDA. In particular, we will provide additional clinical safety reports, update the investigator brochures and patient informed consent forms, and make necessary modifications to study protocols. Dosing of patients in all ongoing clinical trials with rusfertide will be put on hold, and study investigators have been contacted to facilitate patient notification.

"Patient safety is our absolute top priority," said Dinesh Patel, President and Chief Executive Officer of Protagonist. "We are fully committed to working closely with the FDA in understanding and evaluating potential clinical risks and determining next steps for the development of rusfertide."

About Protagonist Therapeutics

Protagonist Therapeutics is a biopharmaceutical company with multiple peptide-based investigational new chemical entities in different stages of development, all derived from the Company's proprietary technology platform. Protagonist's pipeline includes rusfertide (PTG-300), an investigational, injectable hepcidin mimetic in a Phase 2 proof-of-concept clinical trial for polycythemia vera (PV), a Phase 2 study in PV subjects with high hematocrit levels, and a Phase 2 study for hereditary hemochromatosis.

The Company is also evaluating an orally delivered, gut-restricted alpha-4-beta-7 integrin specific antagonist peptide (PN-943) currently in a Phase 2 study in adults with moderate to severe active ulcerative colitis (UC). The Company is targeting ulcerative colitis as the initial indication.

The Company has a worldwide license and collaboration agreement with Janssen Biotech, Inc., for the development of oral peptide IL-23 receptor antagonists. Compounds included in this agreement are PTG-200, PN-235 and PN-232. PTG-200 is an orally delivered interleukin-23 receptor specific antagonist peptide in a Phase 2 clinical trial for Crohn's disease. PN-235 and PN-232, both second-generation oral interleukin-23 receptor antagonist candidates, are currently in Phase 1 studies.

Protagonist is headquartered in Newark, California. For further information, please visit 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 Company's clinical development program for rusfertide. 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 ability to develop and commercialize our product candidates, our ability to earn milestone payments under our collaboration agreements, the impact of the current COVID-19 pandemic on our discovery and development efforts, 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. Additional information concerning these and other risk factors affecting our business can be found in our periodic filings with the Securities and Exchange Commission, including under the heading "Risk Factors" contained in our 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 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.

Contacts

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