
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): **October 18, 2022**

PTC THERAPEUTICS, INC.

(Exact Name of Company as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-35969
(Commission
File Number)

04-3416587
(IRS Employer
Identification No.)

100 Corporate Court
South Plainfield, NJ
(Address of Principal Executive Offices)

07080
(Zip Code)

Registrant's telephone number, including area code: **(908) 222-7000**

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 (*see* General Instruction A.2. below):

- 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, \$0.001 par value per share	PTCT	Nasdaq Global Select Market

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 7.01. Regulation FD Disclosure.

On October 18, 2022, PTC Therapeutics, Inc. (the “Company” or “PTC”) provided an update regarding its ongoing Phase 2 study of PTC518 for the treatment of Huntington’s Disease.

The press release announcing the update is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Report (including Item 7.01 and Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing. All website addresses given in this Report or incorporated herein by reference are for information only and are not intended to be an active link or to incorporate any website information into this Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated October 18, 2022 issued by PTC Therapeutics, Inc.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

Cautionary Statement Concerning Forward Looking Statements

This Current Report on Form 8-K (this “Report”) contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. All statements contained herein, other than statements of historic fact, are forward-looking statements, including statements regarding: the future enrollment, study design, expected timing, availability of data, regulatory submissions and responses and other matters related to PTC’s Phase 2 study of PTC518 for the treatment of Huntington’s disease; PTC’s strategy, future operations, future financial position, future revenues, projected costs; and the objectives of management. Other forward-looking statements may be identified by the words, “guidance”, “plan,” “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions. PTC’s actual results, performance or achievements could differ materially from those expressed or implied by forward-looking statements it makes as a result of a variety of risks and uncertainties, including those related to: the enrollment, conduct and results of studies of PTC518 for Huntington’s disease and events during, or as a result of, the studies that could delay or prevent further development under the program, including with respect to regulatory submissions; the outcome of pricing, coverage and reimbursement negotiations with third party payors for PTC’s products or product candidates that PTC commercializes or may commercialize in the future; significant business effects, including the effects of industry, market, economic, political or regulatory conditions; changes in tax and other laws, regulations, rates and policies; the eligible patient base and commercial potential of PTC’s products and product candidates; PTC’s scientific approach and general development progress; and the factors discussed in the “Risk Factors” section of PTC’s most recent Annual Report on Form 10-K, as well as any updates to these risk factors filed from time to time in PTC’s other filings with the Securities and Exchange Commission. You are urged to carefully consider all such factors. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that any product will receive or maintain regulatory approval in any territory, or prove to be commercially successful. The forward-looking statements contained herein represent PTC’s views only as of the date of this Report and PTC does not undertake or plan to update or revise any such forward-looking statements to reflect actual results or changes in plans, prospects, assumptions, estimates or projections, or other circumstances occurring after the date of this Report except as required by law.

Signature

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.

PTC Therapeutics, Inc.

Date: October 18, 2022

By: /s/ Mark Boulding

Name: Mark Boulding

Title: Executive Vice President and Chief Legal Officer

PTC Provides Update on Ongoing Global PIVOT-HD Trial For PTC518

SOUTH PLAINFIELD, N.J., Oct. 18, 2022 -- PTC Therapeutics, Inc. (NASDAQ: PTCT) confirmed today that enrollment is active and ongoing for its Phase 2 PIVOT-HD trial of PTC518 for the treatment of Huntington's disease at study sites globally. To date, PTC has received approval for conduct of the planned 12-month study in several European countries as well as Australia.

The Phase 2 PIVOT-HD study consists of two parts; an initial 12-week placebo-controlled part focused on PTC518 pharmacology and pharmacodynamic effect, followed by a 9-month placebo-controlled part, during which blood, CSF, and radiographic biomarker data will be collected.

The study will initially include two dose levels, 5 milligrams and 10 milligrams, with the potential to study a third dose leveraging the titratability of the drug. The approvals received to date for the 12-month study include both the 5mg and 10mg dose levels, as well as a potential third dose pending the results of the first two dosing cohorts.

Enrollment in the 12-week portion of the study began first in the United States and continues globally. To date there have been no treatment-related adverse events reported in the US or outside of the US. However, the FDA has requested additional data to allow the study to proceed in the US. Accordingly, enrollment in the US has been paused while discussions with the FDA continue towards resuming US enrollment.

PTC is working towards sharing data from the 12-week portion of PIVOT-HD within the first half of 2023.

About PTC Therapeutics, Inc.

PTC is a science-driven, global biopharmaceutical company focused on the discovery, development and commercialization of clinically differentiated medicines that provide benefits to patients with rare disorders. PTC's ability to innovate to identify new therapies and to globally commercialize products is the foundation that drives investment in a robust and diversified pipeline of transformative medicines. PTC's mission is to provide access to best-in-class treatments for patients who have little to no treatment options. PTC's strategy is to leverage its strong scientific and clinical expertise and global commercial infrastructure to bring therapies to patients. PTC believes this allows it to maximize value for all its stakeholders. To learn more about PTC, please visit us at www.ptcbio.com and follow us on Instagram, Facebook, Twitter, and LinkedIn.

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Forward-Looking Statement

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. All statements contained in this release, other than statements of historic fact, are forward-looking statements, including statements regarding: the future enrollment, study design, expected timing, availability of data, regulatory submissions and responses and other matters related to PTC's Phase 2 trial of PTC518 for the treatment of Huntington's disease; PTC's strategy, future operations, future financial position, future revenues, projected costs; and the objectives of management. Other forward-looking statements may be identified by the words, "guidance", "plan", "anticipate," "believe," "estimate," "expect," "intend," "may," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions.

PTC's actual results, performance or achievements could differ materially from those expressed or implied by forward-looking statements it makes as a result of a variety of risks and uncertainties, including those related to: the enrollment, conduct and results of studies of PTC518 for Huntington's disease and events during, or as a result of, the studies that could delay or prevent further development under the program, including with respect to regulatory submissions; the outcome of pricing, coverage and reimbursement negotiations with third party payors for PTC's products or product candidates that PTC commercializes or may commercialize in the future; significant business effects, including the effects of industry, market, economic, political or regulatory conditions; changes in tax and other laws, regulations, rates and policies; the eligible patient base and commercial potential of PTC's products and product candidates; PTC's scientific approach and general development progress; and the factors discussed in the "Risk Factors" section of PTC's most recent Annual Report on Form 10-K, as well as any updates to these risk factors filed from time to time in PTC's other filings with the SEC. You are urged to carefully consider all such factors.

As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that any product will receive or maintain regulatory approval in any territory, or prove to be commercially successful.

The forward-looking statements contained herein represent PTC's views only as of the date of this press release and PTC does not undertake or plan to update or revise any such forward-looking statements to reflect actual results or changes in plans, prospects, assumptions, estimates or projections, or other circumstances occurring after the date of this press release except as required by law.
