
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): **November 26, 2024**

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.)

500 Warren Corporate Center Drive
Warren, NJ
(Address of Principal Executive Offices)

07059
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 1.01. Entry Into a Material Definitive Agreement.

On November 26, 2024, PTC Therapeutics, Inc. (the “Company”) entered into an asset purchase agreement (the “PRV Transfer Agreement”) with an affiliate of a large pharmaceutical company (the “Buyer”), pursuant to which the Company agreed to sell to the Buyer a Rare Pediatric Disease Priority Review Voucher (“PRV”) for a purchase price equal to \$150.0 million, payable in cash, upon the closing of the sale.

The Company was awarded the PRV on November 13, 2024, under a U.S. Food and Drug Administration (“FDA”) program intended to encourage the development of certain rare pediatric disease product applications, when its gene therapy for the treatment of aromatic l-amino acid decarboxylase deficiency was approved by the FDA.

The sale of the PRV as contemplated by the PRV Transfer Agreement remains subject to customary closing conditions, including the expiration or termination of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. The PRV Transfer Agreement contains customary representations, warranties, covenants and indemnification provisions subject to certain limitations.

The foregoing description of the PRV Transfer Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the PRV Transfer Agreement, which the Company intends to file as an exhibit to the Company’s Annual Report on Form 10-K for the fiscal year ending December 31, 2024.

Item 7.01. Regulation FD Disclosure.

On November 27, 2024, the Company issued a press release announcing that it had entered into the PRV Transfer Agreement, furnished as Exhibit 99.1 to this Current Report on Form 8-K (this “Report”).

The information in this Item 7.01 of this Report, including 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 (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

Exhibit No.	Description
99.1	Press Release, dated November 27, 2024 issued by PTC Therapeutics, Inc.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

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: November 27, 2024

By: /s/ Pierre Gravier
Name: Pierre Gravier
Title: Chief Financial Officer

PTC Therapeutics Enters into Agreement to Sell Priority Review Voucher for \$150 Million

WARREN, N.J., Nov. 27, 2024 -- PTC Therapeutics, Inc. (NASDAQ: PTCT) announced today that it has entered into an agreement to sell its Rare Pediatric Priority Review Voucher (PRV) for \$150 million upon the closing of the transaction.

PTC was granted the PRV on November 13, 2024 along with the U.S. Food and Drug Administration (FDA) approval of KEBILIDI™ (eladocagene exuparvovec-tneq) for the treatment of children and adults with AADC deficiency, including the full spectrum of disease severity.

The transaction is subject to customary closing conditions, including expiration of the applicable waiting period under the Hart-Scott Rodino (HSR) Antitrust Improvements Act.

About the Rare Pediatric Disease Priority Review Voucher Program

The FDA awards priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. The program is intended to encourage development of new drugs and biologics for the prevention and treatment of rare pediatric diseases. A PRV can be redeemed to receive priority review of a subsequent marketing application for a different product, or it can be sold or transferred.

About PTC Therapeutics, Inc.

PTC is a global biopharmaceutical company focused on the discovery, development and commercialization of clinically differentiated medicines that provide benefits to children and adults living 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 Facebook, Instagram, LinkedIn and X.

For More Information:

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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 expectations, plans and prospects for PTC, including with respect to the expected closing of the transaction and any expectations with respect to the timing for such closing and HSR clearance of the transaction and the timing of any such clearance; 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 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.
