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 29, 2020**

PTC THERAPEUTICS, INC.

(Exact Name of Company as Specified in Charter)

Delaware	**001-35969**	**04-3416587**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

100 Corporate Court	
South Plainfield, NJ	**07080**
(Address of Principal Executive Offices)	(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. o

Introductory Note.

On May 29, 2020, PTC Therapeutics, Inc. (the "Company") completed the previously announced acquisition of Censa Pharmaceuticals, Inc. ("Censa"), a Delaware corporation (the "Merger"). The Merger was effected pursuant to an agreement and plan of merger, dated as of May 5, 2020 (the "Merger Agreement"), by and among the Company, Hydro Merger Sub, Inc., a Delaware corporation and a wholly owned, indirect subsidiary of the Company ("Merger Sub"), and, solely in its capacity as the representative, agent and attorney-in-fact of the securityholders of Censa, Shareholder Representative Services LLC, a Colorado limited liability company.

Item 1.01 Entry into a Material Definitive Agreement.

As a result of the Merger, the Company became a party to a license agreement dated as of February 8, 2015, as amended (the "License Agreement") between Shiratori Pharmaceutical Co., Ltd. ("Shiratori") and Censa. Pursuant to the License Agreement, Shiratori granted to Censa the sole and exclusive worldwide right and license, with the right to sublicense, under certain licensed know-how (the "Licensed Know-How") and licensed patents (the "Licensed Patents") relating to manufacturing processes and technology for sepiapterin, to research, have researched, develop, have developed, use, import, export, market, have marketed, offer for sale, sell and have sold, and otherwise commercialize any final pharmaceutical product in finished form containing sepiapterin as an active pharmaceutical ingredient (the "Product") covered by the Licensed Patents or using the Licensed Know-How in all countries and territories of the world outside of Japan (the "Territory"). Shiratori is also responsible for supplying sepiapterin to the Company for manufacturing pre-clinical and clinical supplies of the Product.

Under the License Agreement, the Company is obligated to pay to Shiratori a low single digit percentage of annual net sales of the Product in each country in the Territory until the expiration of the last-to-expire Licensed Patent controlled by Shiratori covering the relevant country. The Company is also obligated to pay to Shiratori certain regulatory and development milestones.

Unless earlier terminated, the License Agreement will continue in full force and effect on a country-by-country and Product-by-Product basis until the obligation to pay royalties with respect to the sale of such Product in such country expires. The parties may agree to mutually terminate the License Agreement. Shiratori may elect to terminate the License Agreement upon sixty days' prior written notice to the Company in the event that the Company fails to (i) achieve regulatory approval for the Product in either the United States or European Union by February 8, 2026 or (ii) commercially launch the Product in the United States or European Union by February 8, 2027. The Company may elect to terminate the License Agreement upon sixty days' prior written notice to Shiratori.

The foregoing description of the License Agreement is a summary only and is qualified in its entirety by reference to the terms of the License Agreement, a copy of which will be filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020.

Item 3.02. Unregistered Sales of Equity Securities.

The description of the common stock consideration under the terms of the Merger Agreement set forth in Item 8.01 is incorporated herein by reference. In connection with the closing of the Merger, the Company issued to the Censa securityholders the common stock consideration, and if the $30 million initial development milestone payment becomes payable and the Company elects to pay such payment in shares of its common stock, the Company will issue such shares of common stock to Censa securityholders in connection therewith, pursuant to an exemption from registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), and/or Regulation D promulgated thereunder.

Item 7.01. Regulation FD Disclosure.

On June 1, 2020, the Company issued a press release in which it announced the closing of the Merger. A copy of the press release is attached to this Current Report on Form 8-K (this "Report") as Exhibit 99.1 and is incorporated by reference into this Item 7.01.

The information set forth in or incorporated by reference into this Item 7.01, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On May 29, 2020, the Company completed the previously announced acquisition of Censa pursuant to the Merger Agreement. The Merger Agreement provided for the acquisition of Censa by the Company through the merger of Merger Sub into Censa, with Censa surviving as a wholly owned, indirect subsidiary of the Company.

Upon the closing of the Merger, the Company paid to the Censa securityholders total upfront consideration of approximately $50 million. The total upfront consideration was composed of (i) approximately $10.0 million, funded with cash on hand, subject to certain other pre- and post-closing adjustments, and (ii) 845,365 shares of the Company's common stock. As previously disclosed, and subject to the terms and conditions of the Merger Agreement, Censa securityholders may become entitled to receive contingent payments from the Company based on the achievement of certain development, regulatory and net sales milestones as well as based upon a percentage of net sales of PTC923 (formerly known as CNSA-001) and sublicense fees paid to the Company in consideration of any sublicense of Censa's intellectual property to commercialize PTC923. Pursuant to the Merger Agreement, the Company has the option to pay the initial $30 million development milestone, if achieved, in cash or shares of the Company's common stock.

The above description of the Merger Agreement is a summary only and is qualified in its entirety by reference to the terms of the Merger Agreement. A copy of the Merger Agreement was previously filed as Exhibit 2.1 to the Company's Current Report on Form 8-K filed on May 6, 2020.

The representations, warranties and covenants contained in the Merger Agreement were made only for the purposes of the Merger Agreement, were made as of specific dates, were made solely for the benefit of the parties to the Merger Agreement and may not have been intended to be statements of fact but, rather, as a method of allocating risk and governing the contractual rights and relationships among the parties thereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated June 1, 2020, 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 Report contains forward-looking statements addressing the Merger and the other transactions contemplated in the Merger Agreement and any other statements about future expectations, prospects, estimates and other matters that are dependent upon future events or developments. All statements, other than those of historical fact, contained in this Report are forward-looking statements, including statements related to the potential financial impact and benefits to the Company of the Merger, including with respect to the business of Censa and the Company's expectations with respect to contingent payments to the Censa securityholders based on net sales and sublicense fees and the potential achievement of development, regulatory and sales milestones and contingent payments to the Censa securityholders with respect thereto; the future expectations, plans and prospects for the Company; the Company's strategy, future operations, future financial position, future revenues or projected costs; the integration of Censa's operations; and the objectives of management. Other forward-looking statements may be identified by the words "look forward", "plan," "anticipate," "believe," "estimate," "expect," "intend," "may," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. The Company'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 Company's ability to realize the anticipated benefits of the Merger, including the possibility that the expected benefits from the Merger will not be realized or will not be realized within the expected time period; significant transaction costs; unknown liabilities; the risk of litigation and/or regulatory actions related to the Merger; other 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 CNSA-001; and the factors discussed in the "Risk Factors" section of the Company's most recent Quarterly Report on Form 10-Q and Annual Report on Form 10-K as well as any updates to these risk factors filed from time to time in the Company's other filings with the SEC. 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 or product candidate will receive or maintain regulatory approval in any territory, or prove to be commercially successful. The forward-

looking statements contained herein represent the Company's views only as of the date of this Report and the Company 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. 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.

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: June 4, 2020

By: /s/ Mark Boulding

Name: Mark Boulding

Title: Executive Vice President and Chief Legal Officer

PTC Therapeutics Successfully Completes Acquisition of Censa Pharmaceuticals

SOUTH PLAINFIELD, N.J., June 1, 2020 – PTC Therapeutics, Inc. (NASDAQ: PTCT) today announced that it has successfully completed the acquisition of Censa Pharmaceuticals, Inc., a biopharmaceutical company focused on the development of CNSA-001 (sepiapterin), a clinical-stage investigational therapy for orphan metabolic diseases, including phenylketonuria (PKU) and other diseases associated with defects in the tetrahydrobiopterin (BH4) biochemical pathways diagnosed at birth.

"We're thrilled to complete the acquisition of Censa," said Stuart W. Peltz, Ph.D., Chief Executive Officer, PTC Therapeutics, Inc. "This acquisition adds a well established late-stage PKU clinical program to our growing rare disease portfolio. Given PTC's established development and commercial capabilities, we're well-positioned to bring this therapy to patients with unmet medical need expeditiously."

With the acquisition, PTC adds CNSA-001 to its robust pipeline of treatments for rare disorders. CNSA-001 has been pursued as a possible treatment for orphan metabolic diseases associated with defects in the tetrahydrobiopterin biochemical pathways. CNSA-001 is an oral formulation of synthetic sepiapterin, a precursor to intracellular tetrahydrobiopterin, which is a critical enzymatic cofactor involved in the metabolism and synthesis of numerous metabolic products. The Phase 2 trial evaluating CNSA-001 for PKU met its primary and secondary endpoints in December 2019[1], and the program is Phase 3 ready.

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1 - Bratkovic et al., A Phase 2 Randomized, Double Crossover, Open-label, Active Controlled Study Of CNSA-001 In Patients With Phenylketonuria, American College of Medical Genetics and Genomics (ACMG) Annual Meeting 2020.

About Phenylketonuria (PKU)

Phenylketonuria (PKU) is an inborn error of metabolism caused predominantly by mutations in the phenylalanine hydroxylase (PAH) gene resulting in toxic buildup of the amino acid phenylalanine (Phe) in the brain. Gene mutations of PAH result in inefficient Phe metabolism leading to hyperphenylalaninemia. There are at least 1,000 unique mutations in the PAH gene, resulting in phenotypic variation in the amount of enzyme produced and/or enzyme activity. With the near universal adoption of newborn screening for high plasma phenylalanine PKU is typically diagnosed at birth. PKU has been described in all ethnic groups, and its incidence worldwide varies widely, but is estimated that there are 16,500 patients in the U.S. If left untreated, severe and irreversible disability can occur to include permanent intellectual disability, seizures, delayed development, behavioral problems, and possibly psychiatric disorders. It has been shown that administration of tetrahydrobiopterin improves the function of PAH resulting in reduction in phenylalanine plasma concentration. CNSA-001 has the potential to address the metabolic and neurological signs and symptoms of a broad range of PKU patients.

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 globally commercialize products is the foundation that drives investment in a robust and diversified pipeline of transformative medicines and our mission to provide access to best-in-class treatments for patients who have an unmet medical need. To learn more about PTC, please visit us at www.ptcbio.com and follow us on Facebook, on Twitter at @PTCBio, and on LinkedIn.

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Forward-Looking Statements:
This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. All statements, other than those of historical fact, contained in this release are forward-looking statements, including statements related to the potential financial impact and benefits to PTC of its acquisition of Censa, including with respect to the business of Censa and PTC's expectations with respect to contingent payments to the Censa securityholders based on net sales and sublicense fees and the potential achievement of development, regulatory and sales milestones and contingent payments to the Censa securityholders with respect thereto; the future expectations, plans and prospects for PTC; PTC's strategy, future operations, future financial position, future revenues or projected costs; the integration of Censa's operations; and the objectives of management. Other forward-looking statements may be identified by the words "look forward", "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: PTC's ability to realize the anticipated benefits of the acquisition, including the possibility that the expected benefits from the acquisition will not be realized or will not be realized within the expected time period; significant transaction costs; unknown liabilities; the risk of litigation and/or regulatory actions related to the acquisition; other 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 CNSA-001; the integration of Censa's operations and the factors discussed in the "Risk Factors" section of PTC's most recent Quarterly Report on Form 10-Q and 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.

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 or product candidate 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.