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 22, 2023

CENTESSA PHARMACEUTICALS PLC

(Exact name of Registrant, as specified in its charter)

England and Wales	**001-04321**	**98-1612294**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

Mailing address:
3rd Floor
1 Ashley Road
Altrincham
Cheshire WA14 2DT
United Kingdom
(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: **+44 (0) 203 920 6789, ext. 9999**

Former name or 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**
Ordinary shares, nominal value £0.002 per share	CNTA	Nasdaq Stock Market, LLC*
American Depositary Shares, each representing one ordinary share, nominal value £0.002 per share	CNTA	Nasdaq Stock Market, LLC

*Not for trading, but only in connection with the listing of the American Depositary Shares on 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 7.01 Regulation FD Disclosure.

On May 22, 2023, the Company issued a press release titled "Centessa Pharmaceuticals Receives Fast Track Designation from the U.S. FDA for SerpinPC for Hemophilia B." A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information under this Item 7.01, including Exhibit 99.1 hereto, is being furnished and 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.

Item 8.01 Other Events.

On May 22, 2023, the Company announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to SerpinPC, an investigational novel inhibitor of activated protein C (APC) being developed for the treatment of hemophilia B, with or without inhibitors.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	
99.1	Press Release dated May 22, 2023
104	Cover Page Interactive Data (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.

Date: May 22, 2023

By:	/s/ Saurabh Saha
Name:	Saurabh Saha, M.D., Ph.D.
Title:	Chief Executive Officer

Centessa Pharmaceuticals Receives Fast Track Designation from the U.S. FDA for SerpinPC for Hemophilia B

BOSTON & LONDON, May 22, 2023 – Centessa Pharmaceuticals plc (Nasdaq: CNTA), a clinical-stage pharmaceutical company that aims to discover and develop medicines that are transformational for patients, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to SerpinPC, an investigational novel inhibitor of activated protein C (APC) being developed for the treatment of hemophilia B, with or without inhibitors.

"We are pleased with the FDA's decision to grant Fast Track designation for SerpinPC as we continue to advance the PRESent registrational studies for SerpinPC in hemophilia B," said Saurabh Saha MD PhD, Chief Executive Officer of Centessa. "This designation is important recognition of SerpinPC's novel mechanism of action and underscores the critical need for new treatment options for persons with hemophilia B. We believe SerpinPC has the potential to be a first-in-class subcutaneously administered therapy with a differentiated safety profile for persons with hemophilia B, subject to review and approval."

According to the FDA, Fast Track is a process designed to facilitate the development and expedite the review of drug candidates to treat serious conditions and fulfill an unmet medical need. A therapeutic candidate that receives Fast Track designation may be eligible for more frequent interactions with the FDA to discuss the candidate's development plan and, if relevant criteria are met, eligibility for Accelerated Approval, Priority Review, or Rolling Review.

About SerpinPC

SerpinPC is a subcutaneously administered novel inhibitor of APC being developed as a potential treatment for hemophilia, regardless of severity or inhibitor status, and which may also be developed to prevent bleeding associated with other bleeding disorders. Centessa is advancing the registrational program for SerpinPC in hemophilia B, which includes a set of clinical studies with multiple components. PRESent-5, initiated in late 2022, is an observational feeder study to collect prospective observational data for minimum defined periods before switching to dosing subjects in the interventional studies. The interventional studies include PRESent-2 (moderately severe to severe hemophilia B without inhibitors, and severe hemophilia A with and without inhibitors) and PRESent-3 (hemophilia B with inhibitors). Additional information on the trials can be accessed at www.clinicaltrials.gov

(NCT05605678, NCT05789524, NCT05789537). SerpinPC is an investigational agent that has not been approved by the FDA or any other regulatory authority.

About Centessa Pharmaceuticals

Centessa Pharmaceuticals plc is a clinical-stage pharmaceutical company that aims to discover and develop medicines that are transformational for patients. Our programs span discovery-stage to late-stage development and cover a range of high-value indications. We operate with the conviction that each one of our programs has the potential to change the current treatment paradigm and establish a new standard of care. For more information, visit http://www.centessa.com/, which does not form part of this release.

Forward Looking Statements

This press release contains forward-looking statements. These statements may be identified by words such as “may,” “might,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “objective,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “continue,” “ongoing,” “aim,” “seek,” and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements, including statements related to the Company’s ability to discover and develop transformational medicines for patients; its expectations regarding the implications of Fast Track designation; its expectations regarding the timing of commencement of new studies or clinical trials or clinical and preclinical data related to SerpinPC, and other Company programs (if any); its ability to continue to meet the criteria for Fast Track designation; its ability to be eligible for Accelerated Approval, Priority Review, or Rolling Review; its ability to identify, screen, recruit and register a sufficient number of or any subjects in its anticipated new studies or clinical trials including PRESent-5, the observational feeder study, PRESent-2 and PRESent-3; its expectations on executing its research and clinical development plans and the timing thereof; the Company’s ability to differentiate SerpinPC and other Company programs (if any) from other treatment options; the development and therapeutic potential of SerpinPC and other Company programs (if any); the Company's ability to present profiles or data of any of the Company's products at scientific meetings and conferences and regulatory matters, including the timing and likelihood of success of obtaining authorizations to initiate or continue clinical trials. Any forward-looking statements in this press release are based on our current expectations, estimates, assumptions and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties

include, but are not limited to, risks related to the safety and tolerability profile of our product candidates; our ability to maintain Fast Track designation; our ability to identify, screen and recruit a sufficient number of or any subjects in our anticipated new studies or clinical trials including PRESent-2, PRESent-3, PRESent-5; our ability to execute IND-enabling activities in a timely manner or at all; our ability to protect and maintain our intellectual property position; business (including commercial viability), regulatory, economic and competitive risks, uncertainties, contingencies and assumptions about the Company; risks inherent in developing product candidates and technologies; future results from our ongoing and planned clinical trials; our ability to maintain our cash runway and obtain adequate financing, including through our financing facility with Oberland, to fund our planned clinical trials and other expenses into 2026; trends in the industry; the legal and regulatory framework for the industry, including the receipt and maintenance of clearances to conduct or continue clinical testing; future expenditures risks related to our asset-centric corporate model; the risk that any one or more of our product candidates will not be successfully developed and/or commercialized; the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies; economic risks to the United States and United Kingdom banking systems; and geo-political risks such as the Russia-Ukraine war. These and other risks concerning our programs and operations are described in additional detail in our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and our other reports, which are on file with the U.S. Securities and Exchange Commission (SEC). We explicitly disclaim any obligation to update any forward-looking statements except to the extent required by law.

Contact:
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