

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 12, 2023

CENTESEA PHARMACEUTICALS PLC

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

England and Wales

(State or other jurisdiction of incorporation)

001-04321

(Commission File Number)

98-1612294

(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 2.02 Results of Operations and Financial Condition.

On May 12, 2023, Centessa Pharmaceuticals plc (the “Company”) announced its financial results for the quarter ended March 31, 2023. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (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, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.

99.1	Press Release dated May 12, 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 12, 2023

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

Centessa Pharmaceuticals Reports Financial Results and Business Highlights for the First Quarter of 2023

– Strong clinical momentum and cash runway into 2026 to support multiple clinical readouts across pipeline –

- *Advancing registration program for SerpinPC to treat hemophilia B; Enrolling subjects in PRESent-5, observational feeder study*
- *Dosing subjects in ongoing Phase 1/2a clinical trial for LB101, a PD-L1xCD47 LockBody® to treat solid tumors*
- *Conducting IND enabling activities for ORX750, an orally administered, selective orexin receptor 2 (OX2R) agonist, with the potential to be a best-in-class therapy to treat narcolepsy and other sleep disorders; ORX750 profile to be presented at scientific meeting in 2023*

BOSTON and LONDON, May 12, 2023: [Centessa Pharmaceuticals plc](https://www.centessa-pharm.com) (Nasdaq: CNTA), a clinical-stage pharmaceutical company focused on discovering and developing medicines that are transformational for patients, today reported financial results and business highlights for the first quarter ended March 31, 2023.

“Centessa continued strong clinical momentum in the first quarter with multiple clinical milestones planned for the year,” said Saurabh Saha MD PhD, Chief Executive Officer of Centessa. “We are advancing the registration program for SerpinPC for the treatment of hemophilia B; dosing subjects in the ongoing Phase 1/2a clinical trial for LB101, our first LockBody molecule for the treatment of solid tumors; and, conducting IND enabling activities for our newest product candidate, ORX750, for the treatment of narcolepsy with potential expansion into other sleep disorders.”

Dr. Saha continued, “We expect to rapidly drive our pipeline forward and anticipate a lower cash burn rate for the remainder of the year. We believe we are well positioned with a cash runway into 2026 to support multiple clinical readouts across our programs.”

Recent Highlights

- In March, the first subject was dosed in the Phase 1/2a first-in-human clinical trial of LB101, a conditionally tetravalent PD-L1xCD47 bispecific monoclonal antibody from the Company's LockBody technology platform for the treatment of solid tumors. LB101 is the Company's first

LockBody candidate to enter the clinic. The Company announced clearance of its Investigational New Drug (IND) application by the U.S. Food and Drug Administration (FDA) to initiate the Phase 1/2a trial in January.

- In March, the Company announced ORX750, an orally administered, selective orexin receptor 2 (OX2R) agonist, as a product candidate for the treatment of narcolepsy with potential expansion into other sleep disorders.
- In February, the Company presented additional data from the open-label extension (OLE) of the ongoing Phase 2a study of SerpinPC for the treatment of hemophilia during an oral presentation at the 16th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD). With total exposure of over 40 patient-years across multiple dosing regimens, the Phase 2a data showed a continued favorable safety and tolerability profile for SerpinPC, as well as evidence of sustained efficacy, as measured by a reduction in the all-bleeds annualized bleeding rates (ABR). To date, no thromboembolic events and no treatment-related sustained elevations of D-dimer have been observed across the Phase 2a study.

Anticipated Upcoming Program Milestones

- **Hemophilia (SerpInPC)**- The registrational program for hemophilia B is ongoing. PRESent-5, an observational feeder study, is enrolling subjects and the Company expects to begin dosing in the PRESent-2 and PRESent-3 studies later this year. In addition, the Company plans to share data from Part 5 of the OLE of the Phase 2a study of SerpinPC, subject to completion, at a scientific meeting this year.
- **Solid Tumors (PD-L1xCD47 LockBody LB101)**- The Phase 1/2a first-in-human clinical study is ongoing.
- **Narcolepsy and Other Sleep Disorders (ORX750)**- ORX750 is in preclinical development and undergoing IND-enabling activities. The Company plans to share preclinical data at a scientific meeting later this year.

The Company has multiple earlier-stage programs, including MGX292 and other LockBody molecules such as PD-L1xCD3, and discovery-stage programs. Where applicable, the Company plans to provide updates on preclinical programs as they advance toward clinical studies.

First Quarter 2023 Financial Results

- **Cash, Cash Equivalents and Short-term Investments:** \$346.2 million as of March 31, 2023, which the Company expects will fund operations into 2026, without drawing on the remaining available tranches under the Oberland credit facility.
- **Research & Development Expenses:** \$32.8 million for the first quarter ended March 31, 2023, compared to \$36.9 million for the first quarter ended March 31, 2022.
- **General & Administrative Expenses:** \$16.1 million for the first quarter ended March 31, 2023, compared to \$14.4 million for the first quarter ended March 31, 2022.
- **Net Loss Attributable to Ordinary Shareholders:** \$50.7 million for the first quarter ended March 31, 2023, compared to \$54.5 million for the first quarter ended March 31, 2022.

About Centessa Pharmaceuticals

[Centessa Pharmaceuticals plc](http://www.centessa.com/) 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.

About SerpinPC

SerpinPC is a subcutaneously administered novel inhibitor of activated protein C (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 the LockBody Technology Platform and LB101

Centessa's proprietary LockBody technology platform aims to redefine immuno-oncology treatment for patients with cancer. LockBody drug candidates are designed to selectively drive potent effector function activity, such as CD47 or CD3, to the tumor micro-environment (TME) while avoiding systemic toxicity. The first LockBody candidate is LB101, a conditionally tetravalent PD-L1xCD47 bispecific monoclonal antibody which has two anti-CD47 domains blocked by two anti-PD-L1 domains, with proprietary human IgG-derived hinges linking the anti-CD47 and anti-PD-L1 domains. The cell-killing mechanism of action,

CD47, is designed to be blocked by the PD-L1 tumor targeting domain until the IgG-derived hinges are naturally degraded in the TME, thus unlocking and activating the CD47 effector function activity in the tumor. LB101 is in a Phase 1/2a clinical trial. Additional information on the trial can be accessed at www.clinicaltrials.gov (NCT05821777). LB101 is an investigational agent that has not been approved by the FDA or any other regulatory authority.

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 on rapidly driving and executing the Company’s pipeline and strategy; its strong momentum and expectations on its cash runway into 2026 to support multiple clinical readouts and its anticipation for a lower cash burn rate for remainder of 2023, all of which are based on certain assumptions; the timing of commencement of new studies or clinical trials or clinical and preclinical data related to SerpinPC, LB101, the LockBody technology platform and other LockBody candidates, ORX750, MGX292 and other Company programs (if any); 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 and studies or trials of LB101 and any other LockBody candidates; its expectations on executing its research and clinical development plans and the timing thereof; the Company’s ability to differentiate SerpinPC, LB101 and other LockBody candidates, ORX750, MGX292 and other Company programs (if any) from other treatment options; the development and therapeutic potential of SerpinPC, LB101, the LockBody technology platform and other LockBody candidates, ORX750, MGX292, 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 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, and studies or trials of LB101 or within anticipated timelines; our ability to execute IND-enabling activities in a timely manner or at all, including with respect to ORX750; 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:

Kristen K. Sheppard, Esq.

SVP of Investor Relations

investors@centessa.com

Centessa Pharmaceuticals plc
Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(amounts in thousands except share and per share data)

	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022
Operating expenses:		
Research and development	\$ 32,826	\$ 36,853
General and administrative	16,051	14,385
Change in fair value of contingent value rights	—	1,980
Loss from operations	(48,877)	(53,218)
Interest income	2,531	104
Interest expense	(2,345)	(1,500)
Other (expense) income, net	(1,346)	196
Loss before income taxes	(50,037)	(54,418)
Income tax expense	677	80
Net loss	(50,714)	(54,498)
Other comprehensive income (loss):		
Foreign currency translation adjustment	898	(706)
Total comprehensive loss	\$ (49,816)	\$ (55,204)
Net loss per ordinary share - basic and diluted	\$ (0.53)	\$ (0.60)
Weighted average ordinary shares outstanding - basic and diluted	94,937,904	90,505,345

Centessa Pharmaceuticals plc
Condensed Consolidated Balance Sheets
(unaudited)
(amounts in thousands)

	March 31, 2023	December 31, 2022
Total assets:		
Cash and cash equivalents	\$ 259,988	\$ 393,644
Short-term investments	86,241	—
Other assets	57,631	50,663
Total assets	\$ 403,860	\$ 444,307
Total liabilities		
Other liabilities	\$ 38,999	\$ 38,338
Long term debt	71,600	69,800
Total liabilities	\$ 110,599	\$ 108,138
Total shareholders' equity	\$ 293,261	\$ 336,169
Total liabilities and shareholders' equity	\$ 403,860	\$ 444,307