

**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 13, 2023

CENTESEA PHARMACEUTICALS PLC

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

England and Wales

(State or other jurisdiction of incorporation)

001-40445

(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 7391 789784**

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 November 13, 2023, Centessa Pharmaceuticals plc (the “Company”) announced its financial results for the quarter ended September 30, 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 November 13, 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: November 13, 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 Third Quarter of 2023

- *SerpinPC: Ongoing registrational PRESent-2 and PRESent-3 studies for the treatment of hemophilia B; New data from ongoing Phase 2a study accepted for poster presentation at American Society of Hematology (ASH) Annual Meeting in December 2023*
- *ORX750: Preclinical data supporting potential best-in-class profile for the treatment of narcolepsy and other sleep-wake disorders presented at World Sleep Congress; Advancing in IND-enabling studies; Clinical proof of concept data planned for 2024*
- *LockBody® Technology Platform: Ongoing Phase 1/2a study of LB101 (PD-L1xCD47) for the treatment of solid tumors*

BOSTON and LONDON, November 13, 2023: [Centessa Pharmaceuticals plc](#) (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 third quarter ended September 30, 2023.

“We continue to execute and achieve key milestones across our pipeline of potential transformative medicines for patients with unmet needs,” said Saurabh Saha MD PhD, Chief Executive Officer of Centessa. “We’re making good progress enrolling our registrational studies for SerpinPC in hemophilia B, with or without inhibitors, and are excited to share new data from the ongoing Phase 2a study of SerpinPC during a poster presentation at ASH in December. We also continue to advance our novel LockBody technology platform with LB101, a PD-L1xCD47 LockBody, which is in an ongoing Phase 1/2a clinical trial for the treatment of solid tumors.”

Dr. Saha continued, “Momentum continues to build with our orexin agonist development program. The preclinical data we recently shared at the World Sleep Congress show that ORX750 is a highly potent and selective novel orexin receptor 2 (OX2R) agonist that closely mimics the function of the endogenous peptide. We believe these data support a potential best-in-class profile for ORX750 for the treatment of narcolepsy and other sleep-wake disorders. We are focused on rapidly moving ORX750 through IND-enabling studies, obtaining IND clearance and initiating clinical development with the goal of sharing clinical proof of concept data in sleep-deprived healthy volunteers in 2024. In addition, we are exploring follow-up molecules for potential expansion opportunities into a range of sleep-wake disorders and broader neurological indications.”

Recent Highlights

- In October, the Company announced a set of new preclinical data from in vivo and in vitro studies of its investigational, novel OX2R agonist, ORX750, that support a potential best-in-class profile for the treatment of narcolepsy and other sleep-wake disorders. The preclinical data were presented recently at the World Sleep Congress and are also available within a recorded webcast at <https://investors.centessa.com/events-presentations>.
- In November, the Company announced that new data from the third year (Part 5) of the ongoing Phase 2a study of SerpinPC, an investigational subcutaneously administered novel inhibitor of activated protein C (APC), for the treatment of hemophilia, has been accepted for a poster presentation at ASH on December 10, 2023. The presentation will include efficacy and safety data from an additional 52-weeks of continuous treatment with a subcutaneous injection of SerpinPC in subjects with hemophilia.
- In October, the Company announced the dosing of the first subject in its registrational PRESENT-3 clinical study of SerpinPC for the treatment of hemophilia B with inhibitors. The Company initiated dosing in its registrational PRESENT-2 clinical study of SerpinPC for the treatment of hemophilia B without inhibitors in July.
- In August, the Company announced LB206, a PD-L1xCD3 LockBody, as a development candidate and shared preclinical data which demonstrated single agent regressions of large tumors in a difficult-to-treat mouse xenograft model.

Anticipated Upcoming Program Milestones

- **Hemophilia (SerpInPC)** - The registrational PRESENT-2 and PRESENT-3 studies are ongoing. Data from Part 5 of the ongoing Phase 2a study accepted for poster presentation at ASH on December 10, 2023.
- **Solid Tumors (LockBody Technology Platform)**
 - **PD-L1xCD47 LockBody LB101** - Phase 1/2a first-in-human clinical study is ongoing.
 - **PD-L1xCD3 LockBody LB206** - LB206 is a development candidate.
- **Narcolepsy and Other Sleep-Wake Disorders (ORX750)** - The Company is focused on rapidly advancing ORX750 through IND-enabling studies, obtaining IND clearance and initiating clinical development with the goal of sharing clinical proof of concept data in sleep-deprived healthy volunteers in 2024.

Where applicable, the Company plans to provide updates on preclinical programs as they advance toward clinical studies.

Third Quarter 2023 Financial Results

- **Cash, Cash Equivalents and Short-term Investments:** \$281.3 million as of September 30, 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:** \$28.2 million for the third quarter ended September 30, 2023, compared to \$36.7 million for the third quarter ended September 30, 2022.
- **General & Administrative Expenses:** \$12.0 million for the third quarter ended September 30, 2023, compared to \$12.3 million for the third quarter ended September 30, 2022.
- **Net Loss Attributable to Ordinary Shareholders:** \$38.6 million for the third quarter ended September 30, 2023, compared to \$53.9 million for the third quarter ended September 30, 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 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. The ongoing registrational program for SerpinPC in hemophilia B includes a set of clinical studies with multiple components. PRESent-5 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 or without inhibitors) and PRESent-3 (hemophilia B with inhibitors). Additional information on the trials can be accessed at www.clinicaltrials.gov ([NCT05605678](https://clinicaltrials.gov/ct2/show/study/NCT05605678), [NCT05789524](https://clinicaltrials.gov/ct2/show/study/NCT05789524), [NCT05789537](https://clinicaltrials.gov/ct2/show/study/NCT05789537)). The U.S. Food and Drug Administration (FDA) has granted Fast Track designation to SerpinPC for the treatment of hemophilia B, with or without inhibitors. 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.

About ORX750

ORX750 is an investigational, orally administered, highly potent and selective orexin receptor 2 (OX2R) agonist designed to directly target the underlying pathophysiology of orexin neuron loss in narcolepsy type 1 (NT1). ORX750 is Centessa's first orexin product candidate being developed for the treatment of narcolepsy with potential expansion into other sleep-wake disorders. ORX750 is currently undergoing IND-enabling activities and has not been administered as an investigational drug to humans in any jurisdiction.

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 for executing on the Company's pipeline; its expectations on its anticipated cash runway ; the timing of commencement of new studies or clinical trials or clinical and preclinical data related to SerpinPC, LB101, LB206, other LockBody candidates, the LockBody technology platform, ORX750 and other orexin agonist molecules; its ability to identify,

screen, recruit and maintain a sufficient number of or any subjects in its existing and anticipated studies or clinical trials including PRESENT-5, the observational feeder study, PRESENT-2 and PRESENT-3 and studies or trials of LB101, LB206, and any other LockBody candidates, ORX750 and other orexin agonist molecules and its expectations on executing its research and clinical development plans and the timing thereof; the Company's ability to differentiate SerpinPC, LB101, LB206, ORX750, other orexin agonist molecules, and other LockBody candidates from other treatment options; the development and therapeutic potential of SerpinPC, LB101, LB206, other LockBody candidates, the LockBody technology platform, ORX750 and other orexin agonist molecules; 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 existing and 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 and LB206; 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 obtain adequate financing, including through our financing facility with Oberland, to fund our planned clinical trials and other expenses; 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; our operating costs and use of cash, including cash runway, cost of development activities and conducting clinical trials, future expenditures risks; the risk that any one or more of our product candidates will not be successfully developed and/or commercialized; the risk that the historical results of preclinical studies or clinical studies will not be predictive of future results in ongoing or future studies; economic risks to the United States and United Kingdom banking systems; and geo-political risks such as the Russia-Ukraine war or the Israeli-Palestinian conflict. 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 September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Operating expenses:				
Research and development	\$ 28,190	\$ 36,744	\$ 94,689	\$ 127,248
General and administrative	12,019	12,284	41,416	41,432
Change in fair value of contingent value rights	—	—	—	1,980
Loss from operations	(40,209)	(49,028)	(136,105)	(170,660)
Interest income	2,953	77	7,543	205
Interest expense	(2,541)	(1,922)	(7,336)	(5,074)
Other (expense) income, net	(1,677)	(3,143)	(4,550)	2,412
Loss before income taxes	(41,474)	(54,016)	(140,448)	(173,117)
Income tax (benefit) expense	(2,826)	(141)	(26,200)	(83)
Net loss	(38,648)	(53,875)	(114,248)	(173,034)
Other comprehensive income (loss):				
Foreign currency translation adjustment	(419)	(553)	1,241	(2,383)
Unrealized gain on available for sale securities, net of tax	252	—	1,035	—
Other comprehensive income (loss)	(167)	(553)	2,276	(2,383)
Total comprehensive loss	\$ (38,815)	\$ (54,428)	\$ (111,972)	\$ (175,417)
Net loss per ordinary share - basic and diluted	\$ (0.40)	\$ (0.57)	\$ (1.20)	\$ (1.86)
Weighted average ordinary shares outstanding - basic and diluted	96,648,110	94,327,914	95,589,181	92,994,990

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

	September 30, 2023	December 31, 2022
Total assets:		
Cash and cash equivalents	\$ 171,498	\$ 393,644
Short-term investments	109,843	—
Other assets	96,023	50,663
Total assets	\$ 377,364	\$ 444,307
Total liabilities		
Other liabilities	\$ 43,974	\$ 38,338
Long term debt	74,000	69,800
Total liabilities	\$ 117,974	\$ 108,138
Total shareholders' equity	\$ 259,390	\$ 336,169
Total liabilities and shareholders' equity	\$ 377,364	\$ 444,307