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): August 13, 2024

CENTESSA PHARMACEUTICALS PLC

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

England and Wales	**001-40445**	**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: **+1 (617) 468-5770**

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 August 13, 2024, Centessa Pharmaceuticals plc (the "Company") announced its financial results for the quarter ended June 30, 2024. 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 August 13, 2024
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: August 13, 2024

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

Exhibit 99.1

Centessa Pharmaceuticals Reports Financial Results and Business Highlights for the Second Quarter of 2024

- *Company advancing pipeline of potential best-in-class orexin receptor 2 (OX2R) agonists*
  - *Initiated Phase 1 clinical study with ORX750 being developed for sleep-wake disorders; Safety and efficacy data in acutely sleep-deprived healthy volunteers assessed using Maintenance of Wakefulness Test (MWT) on track for 2H of 2024*
  - *Nominated ORX142 as development candidate; Currently in IND enabling activities for select neurological, neurodegenerative, and psychiatric disorders with excessive daytime sleepiness (EDS)*
- *SerpinPC registrational program for the treatment of hemophilia B progressing; PRESent-2 Part 1 interim analysis planned for 2024*

BOSTON and LONDON, August 13, 2024: Centessa Pharmaceuticals plc (Nasdaq: CNTA), a clinical-stage pharmaceutical company that aims to discover and develop medicines that are transformational for patients, today reported financial results and business highlights for the second quarter ended June 30, 2024.

“Momentum is building across Centessa’s orexin agonist program. During the second quarter, we initiated a Phase 1 clinical study with ORX750, a potential best-in-class OX2R agonist being developed for sleep-wake disorders, including narcolepsy type 1 (NT1), narcolepsy type 2 (NT2) and idiopathic hypersomnia (IH). Today, we are fast approaching a potentially transformative milestone with safety and efficacy data in acutely sleep-deprived healthy volunteers assessed using the MWT, an established registrational and objective endpoint for EDS in sleep-wake disorders, on track for the second half of this year,” said Saurabh Saha MD PhD, Chief Executive Officer of Centessa. “As healthy volunteers have normal orexin tone, data from this study has the potential to enable dose selection for planned clinical studies of ORX750 in subjects with NT1, NT2, and IH. The data also has the potential to open the door to evaluation of our growing pipeline of orexin agonists in clinical studies for a range of disorders where EDS is a significant burden. We are working to advance our pipeline to address these additional areas of high unmet need, and are thrilled to announce ORX142, an orally administered, highly potent and selective OX2R agonist, as our development candidate for potential indication expansion into select neurological, neurodegenerative, and psychiatric disorders with EDS. ORX142 is currently in IND enabling activities and we look forward to sharing preclinical data in the near term.”

Dr. Saha continued, “Additionally, the PRESent registrational program for SerpinPC for the treatment of hemophilia B is progressing, and we will review the planned interim analysis of Part 1 data of the PRESent-2 study this year with the goal of confirming the dose for Part 2 of the study. With our recently extended cash runway, we believe we are well positioned to execute on our clinical plans through multiple clinical readouts that take us one step closer to our goal of bringing transformational medicines to patients.”

Recent Highlights

- In May, the Company announced that it had initiated a Phase 1 first-in-human (FIH) clinical trial to evaluate the safety, tolerability, and pharmacokinetics of single-ascending doses (SAD) and multiple-ascending doses (MAD) of ORX750 in healthy adult subjects. In parallel to the SAD, a cross-over efficacy assessment is being performed utilizing the MWT and Karolinska Sleepiness Scale (KSS) in acutely sleep-deprived healthy adult subjects which is intended to provide data to enable dose selection for planned clinical studies in subjects with NT1, NT2 and IH.
- In April and May, the Company completed an underwritten public offering of 12,390,254 American Depositary Shares (“ADSs”) in the aggregate, at a price to the public of $9.25 per ADS, resulting in net proceeds of approximately $107.3 million, which included the underwriters’ over-allotment option to purchase additional shares.
- In April, the Company announced that the U.S. Food and Drug Administration (FDA) cleared the Investigational New Drug application (IND) to initiate a Phase 1 FIH clinical trial of ORX750.

Anticipated Upcoming Program Milestones

- **Orexin Agonist Program** - The Phase 1 FIH clinical study of ORX750 is ongoing. The Company expects to share Phase 1 proof-of-concept (PoC) safety and efficacy data in acutely sleep-deprived healthy volunteers assessed using the MWT, an established registrational and objective endpoint for EDS in sleep-wake disorders, in the 2H of 2024.
- **Hemophilia Program** - The SerpinPC registrational program in hemophilia B, which includes the 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) studies, is ongoing.
    - For PRESent-2, Part 1 of the study is fully enrolled and all subjects have now been dosed. Part 2 is currently enrolling subjects into the prospective observation period. The Company will review the

planned interim analysis of Part 1 data this year, with the goal of confirming the dose for Part 2 of the study. The primary endpoint for PRESent-2 is measured in Part 2 and is the rate of treated bleeds (expressed as an annualized bleed rate (ABR)) for hemophilia B subjects who previously received on-demand therapy compared to their prospective baseline ABR. The Company plans to present data from Part 1 at a medical conference in late 2024 or early 2025.

- **LockBody Technology Platform** - The Phase 1/2a FIH clinical study of LB101 (PD-L1xCD47 LockBody) for the treatment of solid tumors is ongoing.

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

Second Quarter 2024 Financial Results

- **Cash, Cash Equivalents and Short-term Investments**: $294.8 million as of June 30, 2024. The Company expects its cash, cash equivalents and short-term investments as of June 30, 2024 will fund operations into mid-2026 without drawing on the remaining available tranches under the Oberland credit facility.
- **Research & Development Expenses**: $32.8 million for the second quarter ended June 30, 2024, compared to $33.7 million for the second quarter ended June 30, 2023.
- **General & Administrative Expenses**: $11.2 million for the second quarter ended June 30, 2024, compared to $13.3 million for the second quarter ended June 30, 2023.
- **Net Loss Attributable to Ordinary Shareholders**: $43.8 million for the second quarter ended June 30, 2024, compared to $24.9 million for the second quarter ended June 30, 2023. The net loss for the second quarter of 2023 included a tax benefit of $24.1 million, which primarily related to a release of a valuation allowance on certain U.S. deferred tax assets during the quarter.

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 most advanced programs include a hemophilia program, an orexin agonist program for the treatment of narcolepsy and other sleep-wake disorders, and an immuno-oncology program focused on our LockBody® technology platform. We operate with the conviction that each of our programs has the potential to change the current treatment paradigm and establish a new standard of care. For more information, visit www.centessa.com, which does not form part of this release.

About Centessa's Orexin Agonist Program

Orexin is a neuropeptide that regulates the sleep-wake cycle, leading to arousal and promoting wakefulness. Low levels of orexin result in excessive daytime sleepiness (EDS) and poor regulation of rapid eye movement (REM) sleep and, in narcolepsy type 1 (NT1), cataplexy and other symptoms. Centessa is developing a pipeline of potential best-in-class orexin receptor 2 (OX2R) agonists intended to be orally administered for sleep-wake disorders, including NT1, narcolepsy type 2 (NT2) and idiopathic hypersomnia (IH), with therapeutic potential to alleviate EDS in select neurological, neurodegenerative, and psychiatric conditions. The Company's lead asset, ORX750, is in a Phase 1 clinical study. ORX750 and ORX142 have not been approved by the FDA or any other regulatory authority.

About SerpinPC

SerpinPC is an investigational, 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. The 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, NCT05789524, NCT05789537). The U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation and Fast Track designation to SerpinPC for the treatment of hemophilia B, with or without inhibitors. SerpinPC has not been approved by the FDA or any other regulatory authority for any use.

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. Centessa's first LockBody candidate is LB101, a conditionally tetravalent PD-L1xCD47 bispecific monoclonal antibody. 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 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, other LockBody candidates, the LockBody technology platform, ORX750, ORX142 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 and any other LockBody candidates, ORX750, ORX142 and other orexin agonist molecules; its expectations on executing its research and clinical development plans and the timing thereof; its expectations as to the potential results and impact of each of its clinical programs and trials; the Company’s ability to differentiate SerpinPC, LB101, other LockBody candidates, ORX750, ORX142 and other orexin agonist molecules from other treatment options; the development, design and therapeutic potential of SerpinPC, LB101, other LockBody candidates, the LockBody technology platform, ORX750, ORX142 and other orexin agonist molecules; and regulatory matters, including the timing and likelihood of success of obtaining regulatory clearance, 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, ORX750 or ORX142 or within anticipated timelines; our expectations relating to the Phase 1 first-in-human, clinical trial of ORX750, including the predicted timing of enrollment, the predicted efficacious doses of ORX750 and our ability to successfully conduct our clinical development of 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 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 Middle East conflicts. 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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Centessa Pharmaceuticals plc
Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(amounts in thousands except share and per share data)

	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023
Operating expenses:				
Research and development	$ 32,815	$ 33,673	$ 55,467	$ 66,499
General and administrative	11,165	13,346	24,603	29,397
Loss from operations	(43,980)	(47,019)	(80,070)	(95,896)
Interest income	3,240	2,059	5,831	4,590
Interest expense	(2,525)	(2,450)	(5,054)	(4,795)
Other (expense) income, net	154	(1,527)	(1,383)	(2,873)
Loss before income taxes	(43,111)	(48,937)	(80,676)	(98,974)
Income tax expense (benefit)	705	(24,051)	1,186	(23,374)
Net loss	(43,816)	(24,886)	(81,862)	(75,600)
Other comprehensive (loss) income:				
Foreign currency translation adjustment	(61)	762	(86)	1,660
Unrealized gain on available for sale marketable securities, net of tax	33	783	188	783
Other comprehensive (loss) income	(28)	1,545	102	2,443
Total comprehensive loss	$ (43,844)	$ (23,341)	$ (81,760)	$ (73,157)
Net loss per ordinary share - basic and diluted	$ (0.40)	$ (0.26)	$ (0.78)	$ (0.80)
Weighted average ordinary shares outstanding - basic and diluted	109,489,184	95,162,734	104,688,452	95,050,940

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

	June 30, 2024	December 31, 2023
Total assets:		
Cash and cash equivalents	$ 127,372	$ 128,030
Short-term investments	167,461	128,519
Other assets	104,012	103,697
Total assets	$ 398,845	$ 360,246
Total liabilities		
Other liabilities	$ 35,380	$ 48,302
Long term debt	76,500	75,700
Total liabilities	111,880	124,002
Total shareholders’ equity	286,965	236,244
Total liabilities and shareholders' equity	$ 398,845	$ 360,246