# 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): February 24, 2022 (February 18, 2022)

# CENTESSA PHARMACEUTICALS PLC

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

| **England and Wales** | **001-04321** | **Not applicable** |
|---|---|---|
| (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 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 3.02 Unregistered Sales of Equity Securities.**

Centessa Pharmaceuticals plc (the “Company” or “Centessa”) commenced dosing in its pivotal Phase 3 clinical trial evaluating lixivaptan as a potential treatment for Autosomal Dominant Polycystic Kidney Disease (ADPKD) on February 18, 2022. Such event is the milestone trigger for payment of contingent value rights originally issued to the former shareholders and option holders of the Company’s subsidiary, Palladio Biosciences, Inc., in connection with its acquisition by Centessa in January 2021. The contingent value rights entitle such holders to a number of ordinary shares of the Company (including in the form of American Depositary Shares or ADSs) in an aggregate amount of approximately $39.7 million based on the Volume Weighted Average Price (VWAP) of the Company's ADSs over the five day trading period ending on the date of the milestone trigger. The ordinary shares (including in the form of ADSs) will be issued in exchange for the previously-issued contingent value rights.

**Item 7.01 Regulation FD Disclosure.**

On February 24, 2022, the Company issued a press release titled “Centessa Pharmaceuticals Doses First Subject in Global Phase 3 ACTION Study of Lixivaptan in Autosomal Dominant Polycystic Kidney Disease.” 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, 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.**

| Exhibit No. | |
|---|---|
| 99.1 | Press Release of the Company dated February 24, 2022 |

**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: February 24, 2022

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

***Centessa Pharmaceuticals Doses First Subject in***
***Global Phase 3 ACTION Study of Lixivaptan in Autosomal Dominant Polycystic Kidney Disease***

BOSTON and LONDON, February 24, 2022 – Centessa Pharmaceuticals plc (Nasdaq: CNTA) (the "Company"), together with its subsidiary Palladio Biosciences, Inc. ("Palladio"), today announced it has started dosing of the first subject in its pivotal Phase 3 clinical trial ("ACTION Study") evaluating lixivaptan as a potential treatment for Autosomal Dominant Polycystic Kidney Disease ("ADPKD"). The trial is expected to enroll approximately 1,350 subjects across more than 200 sites in over 20 countries. The Company anticipates completing enrollment in the second half of 2023 and, if results are supportive, plans to submit a New Drug Application ("NDA") after completion of the one-year double-blind portion of the study.

"The start of dosing in the ACTION Study marks a major clinical milestone for Centessa, as we work towards providing ADPKD patients a new treatment option with a differentiated tolerability profile," said Saurabh Saha, MD, PhD, Chief Executive Officer of Centessa. "With its unique structure and metabolite profile, lixivaptan has the potential to avoid the liver toxicity associated with the only FDA-approved ADPKD therapy. The ACTION Study has been designed to serve as a single registration trial and will evaluate the efficacy and safety of lixivaptan in a broad group of ADPKD patients."

Dosing of the first subject in the ACTION Study is the trigger for payment of the contingent value rights ("CVR") originally issued to former shareholders and option holders of Palladio in January 2021 in connection with Centessa's acquisition of Palladio. The CVR will be settled in newly issued ADSs of Centessa.

**About the ACTION Study**

The ACTION Study is a Phase 3 trial consisting of a two-arm, double-blind, placebo-controlled, randomized phase ("Part 1") followed by a single-arm, open-label phase ("Part 2"). The ACTION Study will evaluate the efficacy and safety of lixivaptan that has been titrated to a maximum tolerated dose between 100-200 mg BID in subjects with ADPKD and a Mayo Clinic MRI imaging classification of 1C, 1D or 1E and an estimated glomerular filtration rate ("eGFR") ≥25 and ≤90 mL/min/1.73 $m^2$. The primary analysis of the ACTION Study will be performed at the end of Part 1 of the trial, which will have a 2:1 randomization (lixivaptan:placebo) and is designed to assess lixivaptan in slowing the decline in renal function as measured at 52 weeks by the difference in eGFR between the lixivaptan-treated and placebo-treated subjects. Final efficacy measurements at the end of the double-blind period will be conducted while subjects are off study drug during three clinic visits over a 28 day period. The trial is expected to enroll approximately 1,350 subjects across more than 200 sites in over 20 countries. All subjects successfully completing Part 1 are expected to continue into Part 2 of the study and will be treated with lixivaptan for an additional year to further assess the sustainability of the potential benefit on eGFR change over a two-year period. Consistent with Part 1, final efficacy measurements will be conducted off study drug. Both parts of the study will contribute to

further evaluating the safety profile of lixivaptan. An independent data monitoring committee will periodically review all safety data, including the liver chemistry data for all subjects, throughout the study. The Company anticipates completing enrollment in the second half of 2023 and, if results are supportive, plans to submit an NDA after completion of the one-year double-blind portion of the study (“Part 1”).

Further information on the ACTION Study can be found at www.clinicaltrials.gov at the following link: https://clinicaltrials.gov/ct2/show/NCT04064346

**About Centessa Pharmaceuticals**
Centessa Pharmaceuticals plc (“Centessa”) aims to bring impactful new medicines to patients by combining the strengths of an asset-centric model with the benefits of scale and diversification typical of larger R&D organizations. Centessa’s programs range from discovery-stage to late-stage development and include diverse therapeutic areas such as oncology, hematology, immunology/inflammation, neuroscience, hepatology, pulmonology and nephrology. For more information, visit www.centessa.com.

**About Palladio Biosciences**
Palladio Biosciences, Inc. (“Palladio”) aims to develop transformative medicines for rare diseases of the kidney. Palladio is actively investigating the potential of its lead product candidate, lixivaptan, in subjects with Autosomal Dominant Polycystic Kidney Disease (“ADPKD”).

**About Lixivaptan**
Lixivaptan is an investigational, oral, nonpeptide selective vasopressin V2 receptor antagonist in development for the potential treatment of ADPKD. The development program is designed to show that lixivaptan can slow the decline in renal function that is typically observed in ADPKD patients while avoiding the liver safety issues associated with JYNARQUE®, a form of branded tolvaptan indicated for ADPKD, which is the only drug currently approved for ADPKD. Lixivaptan has been granted Orphan Drug Designation from the FDA.

**About ADPKD**
ADPKD is a rare hereditary disorder characterized by the formation and enlargement of cysts in the kidney, liver, and other organs. It is the fourth leading cause of kidney failure in the U.S. and one of the most common inherited genetic diseases in humans, occurring equally in women and men, in all races, globally. There are an estimated 140,000 diagnosed ADPKD patients in the U.S.

**Forward Looking Statements**
This press release contains forward-looking statements. These statements may be identified by words such as “aims,” “anticipates,” “believes,” “could,” “estimates,” “expects,” “forecasts,” “goal,” “intends,” “may,” “plans,” “possible,” “potential,” “seeks,” “will,” 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 enrollment,

timing and conduct of the Company's ACTION study; timing of a New Drug Application for lixivaptan as a as a potential treatment for Autosomal Dominant Polycystic Kidney Disease; the Company's ability to deliver impactful medicines to patients; the ability of our key executives and subject-matter experts to drive execution of the Company's portfolio of programs; our asset-centric business model and the intended advantages and benefits thereof; research and clinical development plans; the scope, progress, results and costs of developing our product candidates or any other future product candidates; the design, scope and purpose of our ongoing ACTION Study; the development and therapeutic potential of our product candidates, including lixivaptan; strategy; regulatory matters, including the timing and likelihood of success of obtaining approvals to initiate or continue clinical trials or market any products; and market size and opportunity for our product candidates. Any forward-looking statements in this press release are based on our current expectations, estimates 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 our ability to protect and maintain our intellectual property position; business, regulatory, economic and competitive risks, uncertainties, contingencies and assumptions about the Company; risks inherent in developing products and technologies; future results from our ongoing and planned clinical trials; our ability to obtain adequate financing to fund our planned clinical trials and other expenses; our ability to recruit and retain subjects in our trials; 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 or the acceptance and approval of a New Drug Application; 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 commercialized; the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies; and risks related to the COVID-19 pandemic including the effects of the Delta, Omicron and any other variants. These and other risks concerning our programs and operations are described in additional detail in our most recent Form 10-Q, which is on file with the SEC. We explicitly disclaim any obligation to update any forward-looking statements except to the extent required by law.

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