

**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 15, 2021

CENTESEA 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 Conditions

On November 15, 2021, Centessa Pharmaceuticals plc announced its financial results for the quarter ended September 30, 2021. 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 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 15, 2021](#)

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 15, 2021

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

Centessa Pharmaceuticals Announces Third Quarter 2021 Financial Results and Business Updates

- ~ Announced positive topline data from proof-of-concept study of SerpinPC in severe hemophilia A and B subjects not on prophylaxis, demonstrating 88% reduction in median Annualized Bleeding Rate (“ABR”) for all bleeds and 94% reduction in median ABR for spontaneous joint bleeds in highest dose tested ~
- ~ Announced proof-of-mechanism data from first three PiMZ subjects dosed in Phase 1 Part B study evaluating ZF874 for the treatment of Alpha-1 Antitrypsin Deficiency (“AATD”) ~
 - ~ Announced collaboration between Orexia Therapeutics and Schrödinger to discover novel orexin receptor agonists ~
- ~ Successful entry into a \$300 million financing facility with Oberland Capital to enable further scale-up of development activities and pursuit of strategic business development opportunities ~
- ~ Centessa leadership team strengthened through appointment of David Grainger, PhD, a leading biotech entrepreneur, as Chief Innovation Officer ~
- ~ Programs across Centessa portfolio continue to progress, with multiple INDs/CTAs expected in 2022 ~

BOSTON & LONDON, November 15, 2021 – Centessa Pharmaceuticals plc (Nasdaq: CNTA), a clinical-stage company (“Centessa” or “Company”) leveraging its innovative asset-centric business model to discover, develop and ultimately deliver impactful medicines to patients, today reported financial results for the quarter ended September 30, 2021, and provided a review of recent accomplishments and anticipated upcoming milestones.

“This has been a very productive quarter, as we continued to build our team and shared the first two data updates since the formation of Centessa earlier this year. We announced positive topline data from our proof-of-concept study evaluating SerpinPC in severe hemophilia subjects and seek to move this program into registrational studies in 2022. More recently, in our Phase 1 Part B study evaluating ZF874 for the treatment of AATD, we reported encouraging proof-of-mechanism data from three initial PiMZ subjects and plan to provide an update in 2022 once we have data on PiZZ subjects at multiple doses. In addition to these exciting early results, we are continuing to progress programs across our entire portfolio,” said Saurabh Saha, MD, PhD, Chief Executive Officer of Centessa.

Dr. Saha continued, “Our recent \$300 million financing facility with Oberland Capital will provide additional financial flexibility to help further advance our portfolio and better enable the Company to pursue strategic business development opportunities.”

Recent Business Highlights

- **Announced Positive Topline Data from Proof-of-Concept Study of SerpinPC in Severe Hemophilia A and B Subjects Not on Prophylaxis:** In September, the Company, together with subsidiary ApcinteX Limited (“ApcinteX”), announced positive topline results from the Phase 2a part of AP-0101, the six-month repeat dose portion of the ongoing first-in-human proof-of-concept study evaluating SerpinPC in severe hemophilia A and B subjects. In the highest dose cohort, SerpinPC reduced the self-reported all bleeds Annualized Bleeding Rate (“ABR”) by 88% during the last 12 weeks of treatment (pre-specified primary assessment period) as compared to

the all bleeds ABR prospectively measured during the pre-exposure observation period. In this cohort, five out of eight subjects had zero or one bleed during the 12-week pre-specified primary assessment period and self-reported spontaneous joint bleeds ABR was reduced by 94%. SerpinPC was well-tolerated with no sustained elevations in D-dimer.

- **Demonstrated Proof-of-Mechanism in First Three PiMZ Subjects Dosed in Part B of Phase 1 Study Evaluating ZF874:** In November, the Company, together with subsidiary Z Factor Limited (“Z Factor”), announced proof-of-mechanism data from the first three PiMZ subjects dosed in the ongoing repeat dose Phase 1 Part B study of ZF874 in subjects carrying at least one Z-mutated alpha-1-antitrypsin allele (PiXZ). These are the first clinical data that suggest a pharmacological chaperone may be able to sufficiently increase functional Z-A1AT to levels greater than 11 micromolar in individuals with the PiZZ genotype, levels that have been the basis for approval of the existing A1AT augmentation therapies. Because one subject showed a delayed, reversible increase in ALT and AST, the Company will be exploring lower doses and different dosing regimens. The Company is taking steps to increase enrollment by adding sites in the United Kingdom and intends to expand the study to the European Union.
- **Secured \$300 Million Financing Facility with Oberland Capital Management LLC:** In October, the Company entered into a \$300 million financing facility (“Oberland Agreement”). Under the terms of the agreement, Oberland Capital Management LLC (“Oberland Capital”) will purchase up to \$300 million of 6-year, interest-only, senior secured notes from the Company, including \$75 million funded in October, a total of \$125 million available within 24 months at the option of the Company, and \$100 million available to fund M&A, in-licensing, or other strategic transactions, at the option of the Company and Oberland Capital. The Company’s pro forma cash position as of September 30, 2021, following receipt of the net proceeds from the first tranche of notes in October, was \$653.4 million.
- **Centessa Subsidiary, Orexia Therapeutics, Initiated Collaboration with Schrödinger to Discover Novel Orexin Receptor Agonists:** In October, Orexia entered into an exclusive collaboration with Schrödinger focused on the discovery of novel therapeutics targeting the orexin-2 receptor (“OX2R”), which is known to play a role in a broad spectrum of sleep disorders including narcolepsy. The collaboration provides Orexia with substantial access to Schrödinger’s entire computational platform as well as Schrödinger’s extensive expertise in ultra-large-scale deployment of its technology.
- **Leadership Team Strengthened by Appointment of Chief Innovation Officer:** In October, the Company announced the appointment of David Grainger, PhD, as Chief Innovation Officer. Dr. Grainger will be a member of the Company’s executive leadership team and will be responsible for the overall management of the scientific and research activities.

Upcoming Milestones

- **ApcinteX’s SerpinPC, an activated protein C inhibitor for Hemophilia:** During 2022, the Company expects to launch a global full development plan aimed at one or more registrations to maximize the broad potential for SerpinPC in the hemophilia space. The Company also expects to provide an update in 2022 on the ongoing Phase 2a open-label extension study.

- **Palladio Biosciences' lixivaptan, a vasopressin V2 receptor for Autosomal Dominant Polycystic Kidney Disease ("ADPKD"):** By the end of 2021, the Company expects to report initial safety data from the ongoing open-label ALERT Study of subjects who previously discontinued JYNARQUE® (tolvaptan) due to liver toxicity. The Company expects to dose the first subject in the registrational Phase 3 ACTION Study by 1Q 2022.
- **Z Factor's ZF874, a Z-A1AT folding corrector for AATD:** During 2022, the Company expects to report on additional PiMZ as well as PiZZ subjects from the expanded Phase 1 Part B. The Company anticipates starting a global Phase 2 study in 2Q 2022, with 6-month dosing to commence in 2H 2022 once a dose and regimen are established and chronic animal toxicology is completed.
- **Pega-One's imgatuzumab, a non-fucosylated anti-epidermal growth factor receptor ("EGFR") monoclonal antibody ("mAb") for Advanced Cutaneous Squamous Cell Carcinoma ("CSCC"):** The Company expects to initiate an open-label, single arm, Phase 2 trial of imgatuzumab in advanced CSCC by the end of 2021 and dose the first subject in 1Q 2022.
- **Capella Bioscience's CBS001, an anti-LIGHT mAb for Idiopathic Pulmonary Fibrosis ("IPF"):** In 1H 2022, the Company expects to submit a Clinical Trial Authorisation ("CTA") application with the UK Medicines and Healthcare products Regulatory Agency ("MHRA") for CBS001 and commence a Phase 1 study shortly thereafter.
- **Capella Bioscience's CBS004, an anti-BDCA2 mAb for Systemic & Cutaneous Lupus Erythematosus ("SLE/CLE") and Systemic Sclerosis ("SSc"):** In 2H 2022, the Company expects to submit an Investigational New Drug ("IND") application with the U.S. Food and Drug Administration ("FDA") for CBS004 and commence a Phase 1 study shortly thereafter.
- **Orexia Therapeutics' oral orexin receptor agonist for Narcolepsy Type 1 ("NT1"), and other neurological disorders characterized by excessive daytime sleepiness:** The Company is on track to select a candidate for its oral program and commence IND enabling activities in 2022
- **Janpix Limited's dual degrader of Signal Transducer and Activator of Transcription proteins 3 and 5 ("STAT3" and "STAT5") for Acute Myeloid Leukemia:** By the end of 2021, the Company expects to select a candidate for the STAT3/5 program.
- **PearlRiver Bio's small molecule kinase inhibitors for EGFR mutations in Non-Small Cell Lung Cancer ("NSCLC"):** The Company is progressing an EGFR-C797S mutation inhibitor for the treatment of NSCLC and expects to report on ongoing candidate selection in 2022. The Company will not select a candidate for its exon20 mutation program in 2021 and is presently reviewing this program.

Third Quarter 2021 Financial Results

Cash Position: Cash and cash equivalents were \$578.8 million as of September 30, 2021, compared to \$613.8 million as of June 30, 2021, a reduction of \$35 million. On a pro forma basis as of September 30, 2021, cash and cash equivalents were \$653.4 million, inclusive of the net proceeds of \$74.6 million from the first tranche received under the Oberland Agreement on October 4, 2021. Based on the current, non-risk-adjusted operating plan, the Company expects the cash and cash equivalents as of September 30,

2021, plus the net proceeds of the first tranche, supplemented by the additional funds available under the Oberland Agreement, if drawn, to fund its operations into mid-2024.

Research & Development (“R&D”) Expenses: R&D expenses for the Company for the three months ended September 30, 2021, were \$25.9 million, compared to \$1.9 million for the Centessa Predecessor Group (comprised of Z Factor Limited, LockBody Therapeutics Ltd, and Morphogen-IX Limited, three of the Centessa Subsidiaries acquired in January 2021) for the three months ended September 30, 2020. The \$23.9 million increase is primarily attributable to the growth in the portfolio of product candidates under development following the acquisition of the Centessa Subsidiaries in January 2021, as well as increased spending in the Centessa Predecessor Group.

General & Administrative (“G&A”) Expenses: G&A expenses for the Company for the three months ended September 30, 2021, were \$12.5 million, compared to \$0.2 million for the Centessa Predecessor Group during the three months ended September 30, 2020. The \$12.2 million increase is primarily attributable to public company costs, the operating costs of Centessa Pharmaceuticals plc and Centessa Pharmaceutical Inc., including professional fees and personnel costs, and the increase in operating costs resulting from the acquired Centessa subsidiaries. In addition, the increase in personnel related expenses includes an increase in headcount and an increase in share-based compensation expense of \$2.6 million which is primarily attributable to the equity awards issued at the time of the acquisition and the subsequent issuances of awards through September 30, 2021.

Net Loss: Net Loss attributable to common stockholders for the quarter ended September 30, 2021, was \$40.2 million, or \$0.45 per share, compared to a net loss of \$2.1 million for the Centessa Predecessor Group for the quarter ended September 30, 2020.

About Centessa Pharmaceuticals

Centessa Pharmaceuticals plc 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. The asset-centric model refers to a highly specialized, singular-focused company that is led by a team of well-recognized subject matter experts. Centessa’s asset-centric companies’ 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.

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 Company’s ability to deliver impactful medicines to patients; the ability of our key executives 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; our collaborations and the intended benefits thereof; strategy; regulatory matters, including the timing and likelihood of success of obtaining approvals to initiate or continue clinical trials or market any products; market size and opportunity; our ability to complete certain milestones; the availability of funding to operate our business and pursue our objectives; and our cash position and runway.

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, 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; 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 and any other variants. These and other risks concerning our programs and operations are described in additional detail in our reports that we 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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Centessa Pharmaceuticals plc (Successor) and Centessa Predecessor Group (Predecessor)
Consolidated and Combined Statements of Operations and Comprehensive Loss
(unaudited)
(amounts in thousands except share and per share data)

	Successor		Predecessor		
	Three months ended September 30, 2021	Period from January 30, 2021 through September 30, 2021	Period from January 1, 2021 through January 29, 2021	Three months ended September 30, 2020	Nine months ended September 30, 2020
Operating expenses:					
Research and development	25,850	54,126	600	1,923	6,604
General and administrative	12,464	29,900	121	193	831
Change in fair value of contingent value rights	—	11,312	—	—	—
Acquired in-process research and development	—	220,454	—	—	—
Loss from operations	(38,314)	(315,792)	(721)	(2,116)	(7,435)
Interest income (expense), net	65	100	(9)	(22)	(56)
Amortization of debt discount	—	—	(37)	(78)	(220)
Other income (expense), net	(1,906)	(4,605)	—	6	(5)
Gain on extinguishment of debt	—	—	—	72	339
Net loss	(40,155)	(320,297)	(767)	(2,138)	(7,377)
Other comprehensive loss:					
Foreign currency translation adjustment	(487)	2,828	45	372	(359)
Total comprehensive loss	\$ (40,642)	\$ (317,469)	\$ (722)	\$ (1,766)	\$ (7,736)
Net loss per ordinary share - basic and diluted	\$ (0.45)	\$ (4.60)			
Weighted average ordinary shares outstanding - basic and diluted	89,899,454	69,597,648			

Centessa Pharmaceuticals plc (Successor) and Centessa Predecessor Group (Predecessor)
Condensed Consolidated and Combined Balance Sheets
(unaudited)
(amounts in thousands except share and per share data)

	<u>Successor</u>	<u>Predecessor</u>
	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Total Assets		
Cash and cash equivalents	\$ 578,815	\$ 7,227
Other assets	33,392	4,490
Total assets	<u>\$ 612,207</u>	<u>\$ 11,717</u>
Total Liabilities		
Liabilities	\$ 29,144	\$ 8,619
Contingent value rights	33,930	—
Total liabilities	<u>63,074</u>	<u>8,619</u>
Total combined deficit and shareholders' equity	<u>549,133</u>	<u>3,098</u>
Total liabilities, combined deficit and shareholders' equity	<u>\$ 612,207</u>	<u>\$ 11,717</u>