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 4, 2021

Concert Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-36310**	**20-4839882**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
65 Hayden Avenue, Suite 3000N Lexington, Massachusetts		**02421**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's telephone number, including area code: (781) 860-0045

(Former Name or Former 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
Common stock, $0.001 par value per share	CNCE	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR 240.12b-2).

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 4, 2021, Concert Pharmaceuticals, Inc. announced its financial results for the quarter ended March 31, 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 Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and 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.	Description
99.1	Press release issued by the Registrant on May 4, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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.

CONCERT PHARMACEUTICALS, INC.

Date: May 4, 2021

By: /s/ Jeffrey A. Munsie
Jeffrey A. Munsie
Chief Legal Officer

Exhibit 99.1

NEWS RELEASE

For additional information contact:
Justine E. Koenigsberg (Investors)
Concert Pharmaceuticals, Inc.
(781) 674-5284
ir@concertpharma.com

Kathryn Morris (media)
The Yates Network
(914) 204-6412
kathryn@theyatesnetwork.com

FOR IMMEDIATE RELEASE

Concert Pharmaceuticals Reports First Quarter 2021 Financial Results

CTP-543 Phase 3 Program for Alopecia Areata Advancing as Planned to Support NDA Filing in Early 2023

Conference Call Scheduled Today at 8:30 a.m. ET

Lexington, MA (May 4, 2021) -- Concert Pharmaceuticals, Inc. (NASDAQ: CNCE) today reported financial results for the first quarter of 2021.

"We are committed to advancing CTP-543, our breakthrough therapy candidate for moderate to severe alopecia areata. Patients currently lack effective, approved treatment options. We believe we have the potential to provide patients with a new, clinically meaningful and best-in-class treatment option," stated Roger Tung, Ph.D., President and Chief Executive Officer of Concert Pharmaceuticals. "We remain on track with our THRIVE-AA Phase 3 clinical program with CTP-543, in support of our New Drug Application that we anticipate filing in early 2023."

Recent Business Highlights and Upcoming Milestones

CTP-543: An Investigational Treatment for Moderate to Severe Alopecia Areata

- ***THRIVE-AA1 Phase 3 Trial in Alopecia Areata On Track to Report Topline Data in 2022.*** The THRIVE-AA1 Phase 3 trial is a randomized, double-blind, placebo-controlled clinical trial of CTP-543 to evaluate hair regrowth after 24 weeks of dosing in approximately 700 adults with moderate to severe alopecia areata. The trial is evaluating 8 mg and 12 mg twice-daily doses of CTP-543 compared to placebo at sites in the U.S., Canada and Europe. The Company expects to report topline results from the THRIVE-AA1 trial in 2022. Additional information about the THRIVE-AA1 trial (NCT04518995) is available at clinicaltrials.gov.

- ***Initiation of THRIVE-AA2 Phase 3 Trial in Alopecia Areata Expected in May 2021.*** The Company expects to initiate a second pivotal Phase 3 trial of CTP-543, THRIVE-AA2, later this month. The planned

THRIVE-AA2 Phase 3 trial is a randomized, double-blind, placebo-controlled clinical trial of CTP-543 to evaluate hair regrowth after 24 weeks of dosing in approximately 440 adults with moderate to severe alopecia areata. The trial will evaluate 8 mg and 12 mg twice-daily doses of CTP-543 compared to placebo at sites in the U.S., Canada and Europe. Additional information about the THRIVE-AA2 trial (NCT04797650) is available at clinicaltrials.gov.

- ***Update on CTP-543 Open Label, Long-Term Extension Study to be Presented at JAK Summit.*** Concert's Chief Development Officer, James V. Cassella, Ph.D., will present an update on the ongoing open label, long-term extension study of CTP-543 at the 2nd JAK Inhibitors Drug Development Summit scheduled for July 1, 2021. The presentation will provide an update on the extension study, building on the data presented at the late-breaking news session at the European Academy of Dermatology and Venereology (EADV) in October 2020, during which the Company showed the maintenance of hair regrowth in patients on treatment for at least one year. Details about the upcoming meeting are available at https://jak-drugdevelopment.com/.

First Quarter 2021 Financial Results

- ***Cash and Investment Position.*** Cash, cash equivalents and investments as of March 31, 2021 totaled $111.8 million as compared to $130.0 million as of December 31, 2020. Under its current operating plan, the Company expects its cash, cash equivalents and investments to fund the Company through 2021.

- ***R&D Expenses.*** Research and development expenses were $18.5 million for the quarter ended March 31, 2021, compared to $14.0 million for the same period in 2020. The increase in research and development expenses relates primarily to the ongoing CTP-543 Phase 3 THRIVE-AA clinical program.

- ***G&A Expenses.*** General and administrative expenses were $5.5 million for the quarter ended March 31, 2021, compared to $4.7 million for the same period in 2020, an increase of $0.8 million due to an increase in external professional service expenses and non-cash stock-based compensation expense.

- ***Net Loss.*** Net loss applicable to common stockholders was $22.7 million, or $0.67 per share, for the quarter ended March 31, 2021, as compared to net loss applicable to common stockholders of $20.5 million, or $0.70 per share, for the quarter ended March 31, 2020.

Conference Call and Webcast

The Company will host a conference call and webcast today at 8:30 a.m. ET to provide an update on the Company and discuss its first quarter 2021 financial results. To access the conference call, please dial (855) 354-1855 (U.S. and Canada) or (484) 365-2865 (International) five minutes prior to the start time.

A live webcast may be accessed in the Investors section of the Company's website at www.concertpharma.com. Please log on to the Concert website approximately 15 minutes prior to the scheduled webcast to ensure adequate time for any software downloads that may be required. A replay of the webcast will be available on Concert's website for three months.

– Financial Tables to Follow –

Concert Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Revenue:		
License and research and development revenue	$ 5	$ 7
Operating expenses:		
Research and development	18,500	13,986
General and administrative	5,485	4,672
Total operating expenses	23,985	18,658
Loss from operations	(23,980)	(18,651)
Investment income	25	563
Unrealized gain (loss) on marketable equity securities	1,286	(2,389)
Net loss	$ (22,669)	$ (20,477)
Net loss per share applicable to common stockholders - basic and diluted	$ (0.67)	$ (0.70)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	33,894	29,110

Concert Pharmaceuticals, Inc.
Summary Balance Sheet Data
(in thousands)
(unaudited)

	March 31, 2021	**December 31, 2020**
Cash and cash equivalents	$ 89,772	$ 77,202
Investments, available for sale	22,009	52,766
Working capital	115,552	132,546
Total assets	139,991	159,263
Deferred revenue	2,750	2,750
Total stockholders’ equity	114,039	131,162

– more –

About Concert

Concert Pharmaceuticals is a clinical stage biopharmaceutical company that is developing small molecule drugs that it discovered through the application of its DCE Platform® (deuterated chemical entity platform). Selective incorporation of deuterium into known molecules has the potential, on a case-by-case basis, to provide better pharmacokinetic or metabolic properties, thereby enhancing their clinical safety, tolerability or efficacy. Concert's lead product candidate is in late-stage development for the treatment of alopecia areata, a serious autoimmune dermatological condition. Concert is also assessing a number of earlier-stage pipeline candidates. For more information please visit www.concertpharma.com or follow us on Twitter at @ConcertPharma or on LinkedIn.

Cautionary Note on Forward Looking Statements

Any statements in this press release about our future expectations, plans and prospects, including, among others, statements about our expectations regarding the development of CTP-543, the timing of availability of clinical trial data, the timing of initiation and design of future clinical trials, the timing of regulatory filings and the sufficiency of our cash, cash equivalents and investments to fund our operations, and any other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation, timing and design of future clinical trials, the availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a clinical trial will be predictive of the final results of that trial or whether results of early clinical trials will be indicative of the results of later clinical trials, expectations for regulatory approvals, availability of funding sufficient for our foreseeable and unforeseeable operating expenses and capital expenditure requirements, expectations with respect to the protection of our intellectual property afforded by our patents and other factors discussed in the "Risk Factors" section of our most recent Annual Report on Form 10-K or Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission and in other filings that we make with the Securities and Exchange Commission. In addition, any forward-looking statements included in this press release represent our views only as of the date of this release and should not be relied upon as representing our views as of any subsequent date. We specifically disclaim any obligation to update any forward-looking statements included in this press release.

###