

**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): April 30, 2020

Concert Pharmaceuticals, Inc.

(Exact name of registrant as specified in charter)

**Delaware
(State or Other Jurisdiction
of Incorporation)**

**001-36310
(Commission
File Number)**

**20-4839882
(IRS Employer
Identification No.)**

**65 Hayden Avenue, Suite 3000N
Lexington, MA
(Address of Principal Executive Offices)**

**02421
(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 April 30, 2020, Concert Pharmaceuticals, Inc. announced its financial results for the quarter ended March 31, 2020. 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

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by the Registrant on April 30, 2020

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: April 30, 2020

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



NEWS RELEASE

For additional information contact:

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FOR IMMEDIATE RELEASE**Concert Pharmaceuticals Reports First Quarter 2020 Financial Results and Provides Update on Clinical Programs**

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

Lexington, MA (April 30, 2020) -- Concert Pharmaceuticals, Inc. (NASDAQ:CNCE) today reported financial results for the first quarter of 2020.

“We are continuing to move forward the development of our two clinical drug candidates. Following discussions with the FDA at an End-of-Phase 2 meeting in March, CTP-543 is on the cusp of initiating its Phase 3 clinical program for the treatment of moderate-to-severe alopecia areata later this year. In addition, despite challenges in enrollment due to COVID-19, we have been successful in keeping our Phase 2 trial of CTP-692 up and running and currently expect to complete enrollment by year-end 2020,” stated Roger Tung, Ph.D., President and Chief Executive Officer of Concert Pharmaceuticals. “We are closely monitoring our clinical programs and are actively working with all of the stakeholders involved so that we can attempt to minimize the impact of COVID-19.”

Recent Business Highlights and Upcoming Milestones**CTP-543: An Investigational Treatment for Moderate-to-Severe Alopecia Areata**

- ***CTP-543 Poised to Advance into Phase 3 Testing.*** Following an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) in March 2020, the Company plans to initiate its Phase 3 program of CTP-543 in patients with moderate-to-severe alopecia areata, an autoimmune disorder that results in patchy or complete hair loss. The planned Phase 3 program for CTP-543 will include two randomized, double-blind, placebo-controlled clinical trials at sites in the U.S., Canada and Europe. The Phase 3 study is expected to begin in the fourth quarter of 2020.
 - ***Federal Circuit Granted Concert’s Motion to Vacate and Remand PTAB Decision Involving CTP-543, Effective as of April 16, 2020.*** The U.S. Court of Appeals for the Federal Circuit’s grant of Concert’s motion
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to vacate and remand the Patent Trial and Appeal Board (PTAB) decision relating to Patent No. 9,249,149 took effect on April 16, 2020. The case has been remanded for reconsideration by a new panel of PTAB judges.

- **CTP-543 Phase 2 Results to be Presented as Late-Breaking Research at AAD Virtual Meeting.** Results from the Company's Phase 2 dose-ranging trial of CTP-543 in alopecia areata was selected as an oral presentation at the Late-Breaking Research Program at the American Academy of Dermatology (AAD) Annual Meeting. The in-person meeting, originally scheduled for March 21, 2020, in Denver, will be a virtual meeting that will include dynamic digital content and is expected to take place in the Spring timeframe. This late-breaking presentation will include new analyses from the Company's completed Phase 2 dose-ranging study.

CTP-692: An Investigational Adjunctive Treatment for Schizophrenia

- **CTP-692 Phase 1 Clinical and Nonclinical Findings to be Presented at ASCP Virtual Meeting.** The safety assessments in the single- and multiple-ascending dose Phase 1 trials in healthy volunteers showed that CTP-692 was well tolerated over the dose ranges tested, which included the doses being evaluated in Phase 2 testing. Importantly, key blood and urine markers of kidney function did not indicate any signs of renal impairment. These data are consistent with nonclinical findings showing an improved renal safety profile for CTP-692 compared to non-deuterated D - serine, which is known to produce renal toxicity in rats. In a nonclinical study, CTP-692 was found to produce higher brain exposure compared to D - serine. The clinical results will be presented during the pipeline presentation and the nonclinical results will be presented during the poster session at The American Society of Clinical Psychopharmacology (ASCP) annual meeting, to be held virtually on May 29-30, 2020.
- **CTP-692 Phase 2 Trial Ongoing.** Following the successful completion of the CTP-692 Phase 1 program, the Company advanced CTP-692 into a Phase 2 dose-ranging trial as an adjunctive treatment in patients with schizophrenia in December 2019. The trial is designed to support advancement into pivotal Phase 3 evaluation. Enrollment in the Phase 2 trial is expected to be complete by year-end 2020.

First Quarter 2020 Financial Results

- **Cash and Investment Position.** Cash, cash equivalents and investments as of March 31, 2020 totaled \$159.6 million as compared to \$106.4 million as of December 31, 2019. In the first quarter of 2020, Concert closed a public offering of common stock and pre-funded warrants, raising net proceeds of approximately \$70 million. Under its current operating plan, the Company expects its cash, cash equivalents and investments to fund the Company into the second half of 2021.
 - **R&D Expenses.** Research and development expenses were \$14.0 million for the quarter ended March 31, 2020, compared to \$15.8 million for the same period in 2019. The decrease in research and development expenses relates primarily to the completion of the CTP-543 Phase 2 dose-ranging study as well as related pharmaceutical development for CTP-543. R&D expenses are expected to increase in 2020 as the Company continues to develop CTP-692 and prepares to advance CTP-543 into Phase 3 testing in the fourth quarter of 2020.
 - **G&A Expenses.** General and administrative expenses were \$4.7 million for the quarter ended March 31, 2020, compared to \$5.6 million for the same period in 2019. The decrease in 2020 was primarily related to a decrease in legal expenses.
 - **Net Loss.** For the quarter ended March 31, 2020, net loss applicable to common stockholders was \$20.5 million, or \$0.70 per share, as compared to net loss applicable to common stockholders of \$21.8 million, or \$0.93 per share, for the quarter ended March 31, 2019.
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Conference Call and Webcast

The Company will host a conference call and webcast today, Thursday, April 30, 2020, at 8:30 a.m. ET to provide an update on the Company and discuss first quarter 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 of Concert's presentation 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,	
	2020	2019
Revenue:		
License and research and development revenue	\$ 7	\$ 1,005
Total revenue	<u>7</u>	<u>1,005</u>
Operating expenses:		
Research and development	13,986	15,790
General and administrative	4,672	5,609
Total operating expenses	<u>18,658</u>	<u>21,399</u>
Loss from operations	(18,651)	(20,394)
Interest and other income, net	563	867
Unrealized loss on marketable equity securities	(2,389)	(2,299)
Net loss	<u>\$ (20,477)</u>	<u>\$ (21,826)</u>
Net loss attributable to common stockholders - basic and diluted	(20,477)	(21,826)
Net loss per share applicable to common stockholders - basic and diluted	<u>\$ (0.70)</u>	<u>\$ (0.93)</u>
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	<u>29,110</u>	<u>23,508</u>

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

	March 31, 2020	December 31, 2019
Cash and cash equivalents	\$ 46,079	\$ 53,043
Investments, available for sale	113,515	53,395
Working capital	155,124	99,587
Total assets	187,275	137,471
Total stockholders' equity	154,479	101,457

- more -

About Concert

Concert Pharmaceuticals is a clinical stage biopharmaceutical company focused on applying its DCE Platform® (deuterated chemical entity platform) to create novel medicines designed to treat serious diseases and address unmet patient needs. The Company's approach starts with previously studied compounds, including approved drugs, in which deuterium substitution has the potential to enhance clinical safety, tolerability or efficacy. Concert's pipeline of innovative medicines targets autoimmune diseases and central nervous systems (CNS) disorders. 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 the impact of COVID-19 on our clinical trials, our expectations on the progress of clinical development of CTP-543 and CTP-692, the timing of availability of clinical trial data 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 and timing of future clinical 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

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