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 27, 2020

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, MA	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 February 27, 2020, Concert Pharmaceuticals, Inc. announced its financial results for the quarter and year ended December 31, 2019. 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:

Exhibit No.	Description
99.1	Press release issued by the Registrant on February 27, 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: February 27, 2020

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

Exhibit 99.1

NEWS RELEASE

For additional information contact:
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FOR IMMEDIATE RELEASE

Concert Pharmaceuticals Reports 2019 Financial Results and Provides Update on Clinical Programs

CTP-543 Phase 3 Program for Treatment of Alopecia Areata Expected to Begin in 2020

New CTP-543 Patent Covers Pharmaceutical Compositions of CTP-543 and Methods of Treating Alopecia Areata with CTP-543

CTP-692 Phase 2 Topline Results as Adjunctive Treatment for Schizophrenia Expected by Year End 2020

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

Lexington, MA (February 27, 2020) -- Concert Pharmaceuticals, Inc. (NASDAQ:CNCE) today reported financial results for the year ended December 31, 2019 and provided an update on its product pipeline and corporate activities. “Our 2019 accomplishments provide a strong foundation for an exciting year at Concert in 2020. Both of our proprietary programs, CTP-543 for alopecia areata and CTP-692 for schizophrenia, exemplify great examples of innovative clinical compounds that originated from Concert’s technology and that have the potential to create meaningful impact for patients,” stated Roger Tung, Ph.D., President and Chief Executive Officer of Concert Pharmaceuticals. “The robust results from our Phase 2 dose-ranging trial of CTP-543 for the treatment of alopecia areata support advancing the drug candidate into pivotal testing with a potential best-in-class product profile for this serious disease. With the recent initiation of the Phase 2 dose-ranging trial of CTP-692 in patients with schizophrenia, we expect to report topline data by year end that may enable us to advance the program directly into pivotal evaluation in 2021.”

Recent Business Highlights and Upcoming Milestones

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

- ***New CTP-543 Patent Provides Protection until 2037.*** In February 2020, the U.S. Patent and Trademark Office issued U.S. Patent No. 10,561,659 (’659 patent) related to CTP-543. The patent, which will expire in 2037,

covers pharmaceutical compositions of CTP-543 and methods of treating alopecia areata with CTP-543. Importantly, this patent covers the clinical doses of CTP-543 that produced the robust results observed in the Company's Phase 2 dose-ranging trial for the treatment of alopecia areata and will be Orange Book eligible on approval of CTP-543.

- ***Federal Circuit Granted Concert's Motion to Vacate and Remand PTAB Decision Involving CTP-543.*** The U.S. Court of Appeals for the Federal Circuit (CAFC) granted the Company's motion to vacate and remand the Patent Trial and Appeal Board (PTAB) decision to invalidate U.S. Patent No. 9,249,149 ('149 patent). Concert's motion was made in light of the recent CAFC ruling on the Constitution's Appointments Clause (*Arthrex, Inc. v. Smith & Nephew, Inc., No. 18-2140*). The case will now be remanded for reconsideration by a new panel of PTAB judges. The PTAB proceeding is limited to the '149 patent and has no bearing on the '659 patent, which provides independent protection of CTP-543.

- ***CTP-543 Dose Regimen Trial Successfully Completed.*** In the fourth quarter of 2019, the Company completed an open label trial evaluating 8 mg twice-daily compared to 16 mg once-daily dosing of CTP-543 in patients with moderate-to-severe alopecia areata. Results in the 8 mg twice-daily arm were consistent with the previously-reported 8 mg twice-daily results from the Company's Phase 2 dose-ranging trial of CTP-543. Treatment with CTP-543 was generally well tolerated in both arms of the study. All but one of the patients who completed this trial elected to continue in an open-label long-term extension study. Based on the results observed, the twice-daily regimen is preferred and will be utilized in the future efficacy trials in the CTP-543 clinical development program.

- ***CTP-543 Phase 2 Data Presented in Late-Breaking News Session at EADV 2019.*** In October 2019, Phase 2 dose-ranging data of CTP-543 in patients with moderate-to-severe alopecia areata were presented in the late-breaking news session at the European Academy of Dermatology and Venereology (EADV) Annual Congress. The presentation highlighted the Phase 2 results in which CTP-543 met the primary efficacy endpoint for the 8 mg twice-daily and 12 mg twice-daily doses with greater hair regrowth on the scalp compared to placebo. In the study, treatment with CTP-543 was generally well tolerated.

- ***CTP-543 Phase 2 Results Selected for Late-Breaking Oral Presentation at AAD.*** Results from the Company's Phase 2 dose-ranging trial of CTP-543 in alopecia areata will be presented during an oral presentation at the Late-Breaking Research Program at the American Academy of Dermatology (AAD) Annual Meeting on March 21, 2020, in Denver, CO. This late-breaking presentation will include new analyses from the Company's completed Phase 2 dose-ranging study.

- ***End of Phase 2 Meeting and Phase 3 Initiation Expected in 2020.*** Data from the Company's Phase 2 trials will support an end of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) to review and discuss the Company's registration pathway for CTP-543 for the treatment of alopecia areata. The Company expects to meet with the FDA in the first quarter of 2020 and initiate Phase 3 testing of CTP-543 in the second half of 2020.

CTP-692: An Investigational Adjunctive Treatment for Schizophrenia

- ***CTP-692 Phase 2 Trial Initiation.*** 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 evaluation. The Company expects to report topline Phase 2 data by year end 2020.

- ***CTP-692 W**ebcast with Key Opinion Leader.* In November 2019, the Company hosted a webcast for investors to highlight the CTP-692 program. The event included a presentation on mechanism and the need for new treatments in schizophrenia by Dr. Joseph Coyle, Director, Laboratory for Psychiatric and Molecular Neuroscience at McLean Hospital and Harvard Medical School. The replay of the event, with slides, can be accessed on the Events & Presentations page of the Investors section of Concert's corporate website.

Full Year 2019 Financial Results

- ***Cash and Investment Position.*** Cash, cash equivalents and investments as of December 31, 2019 totaled $106.4 million as compared to $153.3 million as of December 31, 2018. In the first quarter of 2020, Concert announced the closing of a public offering of common stock and pre-funded warrants, raising net proceeds of $70.3 million, before offering expenses. Under its current operating plan, the Company expects its cash, cash equivalents and investments to fund the Company into the second half of 2021.

- ***Revenue.*** Revenue was $1.1 million for the year ended December 31, 2019, compared to $10.5 million for the year ended December 31, 2018. Revenue recognized in 2019 was primarily from an upfront payment from a license agreement with Cipla Technologies regarding CTP-354, a novel $GABA_A$ receptor subtype-selective modulator. Revenue recognized in 2018 consisted of non-cash consideration received from Processa Pharmaceuticals under a licensing agreement whereby Processa has worldwide rights to develop and commercialize CTP-499, a deuterated analog of an active metabolite of pentoxifylline.

- ***R&D Expenses.*** Research and development expenses were $59.8 million for the year ended December 31, 2019, compared to $43.1 million for the year ended December 31, 2018, an increase of $16.7 million. The increase in expenses in 2019 primarily related to external expenses to support Phase 2 development of CTP-543 as well as Phase 1 clinical trials and manufacturing costs to support the continued development of CTP-692 into Phase 2 testing.

- ***G&A Expenses.*** General and administrative expenses were $20.3 million for the year ended December 31, 2019, compared to $22.9 million for the year ended December 31, 2018, a decrease of $2.6 million. Decreases in legal and employee-related expenses were partially offset by an increase in audit fees.

- ***Net Loss.*** For the year ended December 31, 2019, net loss attributable to stockholders was $78.2 million, or $3.29 per share, as compared to net loss attributable to stockholders of $56.0 million, or $2.40 per share, for the year ended December 31, 2018.

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 full year 2019 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 December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Revenue:				
License and research and development revenue	$ 13	$ 13	$ 1,077	$ 10,505
Total revenue	13	13	1,077	10,505
Operating expenses:				
Research and development	16,019	14,560	59,816	43,149
General and administrative	4,947	5,516	20,276	22,940
Total operating expenses	20,966	20,076	80,092	66,089
Loss from operations	(20,953)	(20,063)	(79,015)	(55,584)
Interest and other income (expense), net	466	(771)	849	(127)
Loss before income taxes	(20,487)	(20,834)	(78,166)	(55,711)
Provision for income taxes	—	15	—	313
Net loss	$ (20,487)	$ (20,849)	$ (78,166)	$ (56,024)
Net loss attributable to common stockholders - basic and diluted	(20,487)	(20,849)	(78,166)	(56,024)
Net loss per share applicable to common stockholders - basic and diluted	$ (0.86)	$ (0.89)	$ (3.29)	$ (2.40)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	23,848	23,432	23,740	23,370

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

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 53,043	$ 17,770
Investments, available for sale	53,395	135,544
Working capital	99,587	171,400
Total assets	137,471	192,547
Total stockholders' equity	101,457	167,740

- 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 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 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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