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 5, 2020

Concert Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in 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 November 5, 2020, Concert Pharmaceuticals, Inc. announced its financial results for the quarter ended September 30, 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:

Exhibit No.	Description
99.1	Press release issued by the Registrant on November 5, 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: November 5, 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 Third Quarter 2020 Financial Results and Provides Company Update

CTP-543 THRIVE-AA1 Phase 3 Trial Initiated in Patients with Moderate to Severe Alopecia Areata

CTP-543 Treatment Shows Maintenance of Hair Regrowth in Open Label Extension Trial; Data Presented at EADV Virtual Meeting

CTP-692 Phase 2 Trial Fully Enrolled; Topline Data Expected in First Quarter of 2021

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

Lexington, MA (November 5, 2020) -- Concert Pharmaceuticals, Inc. (NASDAQ:CNCE) today reported financial results for the third quarter of 2020.

"Our focus this year has been to advance our proprietary pipeline. Our team has diligently and effectively executed on our plan, and I'm pleased that we have achieved our stated 2020 pipeline milestones. CTP-543 for moderate to severe alopecia areata, which received U.S. Food and Drug Administration (FDA) Breakthrough Therapy and Fast Track Designations, is now in pivotal testing, and CTP-692 for schizophrenia is currently on track for topline data readout in the first quarter of 2021," said Roger Tung, Ph.D., President and Chief Executive Officer of Concert Pharmaceuticals. "Both of our clinical candidates represent important opportunities for new medicines that we hope will have a meaningful impact on the lives of patients."

Recent Business Highlights and Upcoming Milestones

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

- ***Initiated CTP-543 THRIVE-AA1 Phase 3 Trial in November 2020.*** The THRIVE-AA1 Phase 3 trial is a randomized, double-blind, placebo-controlled clinical trial of CTP-543 to evaluate hair regrowth using the

Severity of Alopecia Tool (SALT) after 24 weeks of dosing in approximately 700 adult patients 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. The initiation of the THRIVE-AA1 trial follows an end-of-phase 2 meeting where Concert discussed key aspects of its Phase 3 program and registration strategy with the FDA. The Company expects to report topline results from the THRIVE-AA1 trial in 2022.

- ***CTP-543 THRIVE-AA2 Phase 3 Trial Planned for First Half of 2021.*** A second Phase 3 trial of CTP-543, THRIVE-AA2, is expected to begin in the first half of 2021.

- ***New CTP-543 Data Presented in Late-Breaking News Session at EADV 2020.*** Initial data from an ongoing long-term, open label extension study with CTP-543 were presented in the late-breaking news session at the European Academy of Dermatology and Venereology (EADV) Virtual Congress on October 29, 2020. The presentation highlighted that in the open label extension study, treatment with CTP-543 shows continued maintenance of hair regrowth relative to the hair growth shown in the Company's previously conducted Phase 2 trials in patients with alopecia areata. The 8 mg and 12 mg twice-daily doses continued to be generally well tolerated and adverse events were consistent with those reported in the Phase 2 trials.

- ***Published Findings on Alopecia Areata Burden of Disease in Journal of Investigative Dermatology.*** In October 2020, the Journal of Investigative Dermatology published results from a Concert-sponsored survey designed to understand the burden and everyday experience of patients living with moderate-to-severe alopecia areata. Key findings of the research showed that patients with alopecia areata suffer significantly increased burden of illness, including a negative impact on many aspects of daily life, extending considerably beyond the cosmetic concerns of hair loss. The article, entitled "Burden of Illness in Alopecia Areata: A Cross-Sectional Online Survey Study," is available online at: https://www.jidsponline.org/article/S1087-0024(20)30017-4/fulltext

CTP-692: An Investigational Adjunctive Treatment for Schizophrenia

- ***CTP-692 Phase 2 Enrollment Complete.*** In September 2020, the Company announced that the CTP-692 Phase 2 trial was fully enrolled. The CTP-692 Phase 2 trial is assessing three doses of CTP-692 as an adjunctive treatment for schizophrenia. A total of 325 patients already on a stable course of an antipsychotic medication were randomized to receive 1, 2 or 4-gram doses of CTP-692 or placebo once-daily. The primary outcome measure is the change in the Positive and Negative Syndrome Scale (PANSS) total score at 12 weeks, compared to baseline.

- ***CTP-692 Topline Data Expected First Quarter of 2021.*** The treatment duration of the CTP-692 Phase 2 trial is 12 weeks. The Company expects to report topline data in the first quarter of 2021 and believes that positive results would support advancement directly into Phase 3 testing.

Third Quarter 2020 Financial Results

- ***Cash and Investment Position.*** Cash, cash equivalents and investments as of September 30, 2020 totaled $124.2 million as compared to $106.4 million as of December 31, 2019. Under its current operating plan, the Company expects its cash, cash equivalents and investments to fund the Company into the second half of 2021.

- ***Revenues.*** For the quarter ended September 30, 2020, revenue was $1.5 million. Revenue during this period resulted from the non-cash recognition of deferred revenue relating to a previous agreement with Celgene Corporation.

- ***R&D Expenses.*** Research and development expenses were $16.3 million for the quarter ended September 30, 2020, compared to $13.5 million for the same period in 2019. The increase in research and development expenses relates primarily to the ongoing Phase 2 clinical trial of CTP-692. R&D expenses are expected to

continue to increase in 2020 as the Company continues its Phase 2 clinical trial of CTP-692 and conducts its Phase 3 clinical trial of CTP-543.

- ***G&A Expenses.*** General and administrative expenses were $4.5 million for the quarter ended September 30, 2020, compared to $4.7 million for the same period in 2019.

- ***Net Loss.*** Net loss applicable to common stockholders was $18.9 million, or $0.60 per share, for the quarter ended September 30, 2020, as compared to net loss applicable to common stockholders of $17.2 million, or $0.72 per share, for the quarter ended September 30, 2019.

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 third 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 the third quarter financial results 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 September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Revenue:				
License and research and development revenue	$ 1,501	$ 10	$ 7,895	$ 1,064
Operating expenses:				
Research and development	16,347	13,511	45,121	43,797
General and administrative	4,514	4,742	13,917	15,329
Total operating expenses	20,861	18,253	59,038	59,126
Loss from operations	(19,360)	(18,243)	(51,143)	(58,062)
Investment income	183	724	1,101	2,474
Unrealized gain (loss) on marketable equity securities	269	334	(2,419)	(2,091)
Loss before income taxes	(18,908)	(17,185)	(52,461)	(57,679)
Income tax benefit	—	—	(85)	—
Net loss	$ (18,908)	$ (17,185)	$ (52,376)	$ (57,679)
Net loss per share applicable to common stockholders - basic and diluted	$ (0.60)	$ (0.72)	$ (1.71)	$ (2.43)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	31,547	23,807	30,707	23,703

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

	September 30, 2020	**December 31, 2019**
Cash and cash equivalents	$ 33,675	$ 53,043
Investments, available for sale	90,496	53,395
Working capital	129,000	99,587
Total assets	153,373	137,471
Deferred revenue	2,750	10,533
Total stockholders' equity	127,944	101,457

– 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 pipeline consists of clinical stage candidates targeting autoimmune and central nervous systems (CNS) disorders, and a number of preclinical compounds that it is currently assessing. 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, the timing of initiation and design of future clinical trials 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 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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