

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 1, 2018

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, Massachusetts
(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))
-

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 Condition.

On November 1, 2018, Concert Pharmaceuticals, Inc. announced its financial results for the quarter ended September 30, 2018. 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 contained in Item 2.02 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

Exhibit No.	Description
99.1	Press Release issued by Concert Pharmaceuticals, Inc., dated November 1, 2018.

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.

By: /s/ Roger D. Tung
Roger D. Tung
President and Chief Executive Officer

Date: November 1, 2018



NEWS RELEASE

For additional information contact:

Justine 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 Third Quarter 2018 Financial Results and Provides Company Update
Conference Call Scheduled Today at 8:30 a.m. ET

Lexington, MA (November 1, 2018) -- Concert Pharmaceuticals, Inc. (NASDAQ: CNCE) today reported financial results for the third quarter of 2018.

“This is an exciting time at Concert as we advance multiple pipeline candidates, with our priority directed towards our lead compound, CTP-543 for alopecia areata,” stated Roger Tung, Ph.D., President and Chief Executive Officer of Concert Pharmaceuticals. “The potential of Janus kinase inhibitors to treat alopecia areata is drawing significant interest to this important unmet medical need. Concert is at the forefront of this field, and we are working to bring CTP-543 to market as a new treatment for alopecia areata. We eagerly await our first key data readout later this month.”

Recent Business Highlights and Upcoming Milestones

- **CTP-543 Initial Phase 2a Data Expected in November 2018.** In the second quarter of 2018, Concert completed enrollment of the 8 mg cohort in its Phase 2a trial evaluating CTP-543 for the treatment of moderate-to-severe alopecia areata. Topline data from the 4 mg and 8 mg twice daily cohorts is expected in November 2018. The double-blind, randomized, placebo-controlled, sequential dose trial is designed to evaluate the safety and efficacy of CTP-543 twice daily. The primary outcome measure will be a responder analysis utilizing the severity of alopecia tool (SALT) after 24 weeks of dosing.
- **CTP-543 Protocol Amended to Evaluate 12 mg Twice Daily Dose.** In the third quarter of 2018, an independent Data Monitoring Committee (DMC) conducted a planned interim safety data review after patients in the trial had been dosed with an 8 mg dose of CTP-543 or placebo twice daily for at least 12 weeks. The DMC’s review provided support for an additional cohort to evaluate a 12 mg dose twice daily. Consistent with its previously-stated intent, the Company initiated enrollment in the 12 mg cohort as the final arm of this study in September 2018

-more-

- **CTP-692 Phase 1 Trial Planned to Begin in the Fourth Quarter of 2018.** The Company intends to advance CTP-692 into Phase 1 clinical testing by year-end 2018. The Phase 1 program will include a crossover pharmacokinetic comparison of CTP-692 to D-serine and single and multiple ascending doses of CTP-692. The Company is initially developing CTP-692 as an adjunctive treatment for schizophrenia.
- **Relocation to New Headquarters.** Effective August 13, 2018, Concert relocated its corporate headquarters to 65 Hayden Avenue, Lexington, Massachusetts.

Third Quarter 2018 Financial Results

- **Cash and Investment Position.** Cash, cash equivalents and investments as of September 30, 2018, totaled \$168.5 million as compared to \$203.2 million as of December 31, 2017. Concert expects its cash, cash equivalents and investments to be sufficient to fund the Company into 2021 under its current operating plan.
- **Revenues.** Revenue was \$11,000 for the quarter ended September 30, 2018, compared to \$143.8 million for the same period in 2017. The revenue in 2017 relates primarily to an asset purchase agreement with Vertex Pharmaceuticals, whereby Vertex acquired worldwide rights to CTP-656 and other assets related to the treatment of cystic fibrosis.
- **R&D Expenses.** Research and development expenses were \$11.0 million for the quarter ended September 30, 2018, compared to \$7.1 million for the same period in 2017. The increase in R&D expenses relate primarily to clinical development of CTP-543, including an ongoing Phase 2 clinical trial, and increased expenses associated with the advancement of CTP-692 in 2018 as a new development program.
- **G&A Expenses.** General and administrative expenses were \$6.3 million for the quarter ended September 30, 2018, compared to \$4.9 million for the same period in 2017. The increase in G&A expenses was primarily related to an increase in professional and legal fees in connection with intellectual property matters related to CTP-543.
- **Net Loss.** For the quarter ended September 30, 2018, net loss applicable to common stockholders was \$17.4 million, or \$0.74 per share, compared with a net income applicable to common stockholders of \$128.1 million, or \$5.61 per share, for the quarter ended September 30, 2017.

Conference Call and Webcast

The Company will host a conference call and webcast today at 8:30 a.m. EDT to provide an update on the company and discuss second 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 second 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 -

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue:				
License and research and development revenue	\$ 11	\$ 17	\$ 10,492	\$ 52
Other revenue	—	143,827	—	143,827
Total revenue	11	143,844	10,492	143,879
Operating expenses:				
Research and development	11,031	7,136	28,549	22,658
General and administrative	6,320	4,875	17,464	15,835
Total operating expenses	17,351	12,011	46,013	38,493
(Loss) Income from operations	(17,340)	131,833	(35,521)	105,386
Investment income	703	450	2,003	742
Interest and other expense	—	(609)	—	(814)
Loss on extinguishment of debt	—	(1,432)	—	(1,432)
Unrealized loss on marketable equity securities	(732)	—	(1,359)	—
(Loss) Income before tax provision	(17,369)	130,242	(34,877)	103,882
Provision for income taxes	18	2,177	298	2,177
Net (loss) income	\$ (17,387)	\$ 128,065	\$ (35,175)	\$ 101,705
Net (loss) income attributable to common stockholders - basic	(17,387)	127,324	(35,175)	101,272
Net (loss) income attributable to common stockholders - diluted	(17,387)	127,347	(35,175)	101,284
Net (loss) income per share applicable to common stockholders				
Basic	\$ (0.74)	\$ 5.61	\$ (1.51)	\$ 4.49
Diluted	\$ (0.74)	\$ 5.44	\$ (1.51)	\$ 4.37
Weighted-average number of common shares used in net (loss) income per share applicable to common stockholders:				
Basic	23,421	22,694	23,349	22,551
Diluted	23,421	23,421	23,349	23,195

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

	September 30, 2018	December 31, 2017
Cash and cash equivalents	\$ 39,597	\$ 27,665
Investments, available for sale	128,923	175,500
Working capital	188,716	199,289
Total assets	208,556	211,736
Deferred revenue	10,533	10,301
Total stockholders' equity	185,753	196,432

- 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 has a broad pipeline of innovative medicines targeting autoimmune and inflammatory 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 statements about our expectations on the progress of clinical development of CTP-543 and CTP-692, the sufficiency of our cash, cash equivalents and investments to fund our operations and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "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 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.

Concert Pharmaceuticals Inc., the CoNCERT Pharmaceuticals Inc. logo and DCE Platform are registered trademarks of Concert Pharmaceuticals, Inc.

###