

# CONCERT PHARMACEUTICALS, INC.

## **FORM 8-K** (Current report filing)

Filed 11/09/17 for the Period Ending 11/09/17

Address	99 HAYDEN AVENUE SUITE 500 LEXINGTON, MA, 02421
Telephone	781-860-0045
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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

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**FORM 8-K**

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**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 9, 2017**

**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.)**

**99 Hayden Avenue, Suite 500  
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))
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**Item 2.02. Results of Operations and Financial Condition.**

On November 9, 2017, Concert Pharmaceuticals, Inc. announced its financial results for the quarter ended September 30, 2017. The full text of the press release 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

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release issued by Concert Pharmaceuticals, Inc., dated November 9, 2017</a>

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**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 9, 2017

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



## NEWS RELEASE

**For additional information contact:**

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**FOR IMMEDIATE RELEASE**

## **Concert Pharmaceuticals Reports Third Quarter 2017 Financial Results and Provides Company Update** *Conference Call Scheduled Today at 8:30 a.m. EST*

**Lexington, MA (November 9, 2017)** -- Concert Pharmaceuticals, Inc. (NASDAQ: CNCE) today reported financial results for the third quarter of 2017.

“This is an exciting time for our deuterium-based chemistry as we continue to demonstrate our technology’s ability to meaningfully improve the clinical properties of existing medicines. The CTP-656 program and subsequent asset purchase agreement with Vertex Pharmaceuticals is a great example of leveraging our platform to rapidly create significant value,” said Roger Tung, Ph.D., President and CEO of Concert Pharmaceuticals. “Our priorities now include advancing CTP-543 through its Phase 2 program for alopecia areata while assessing indication expansion opportunities and broadening our pipeline with new proprietary candidates.”

**Recent Business Highlights and Upcoming Milestones**

- **CTP-543 Phase 2a Trial Underway.** The Company began dosing patients in the Phase 2a trial in the third quarter of 2017. The Phase 2a trial is designed to assess two doses (4 mg and 8 mg twice daily) of CTP-543 compared to placebo in patients with moderate-to-severe alopecia areata over 24 weeks of dosing. Dosing in the 8 mg arm of the trial is expected to begin after an independent Data Monitoring Committee completes a planned interim review of the safety data from the first dosing cohort in the first quarter of 2018. Concert expects to complete the trial in the second half of 2018.
  - **CTP-543 Patent Proceedings.** In October 2017, the Patent Trial and Appeal Board (PTAB) denied Incyte’s petition to institute inter partes review (IPR) of U.S. Patent No. 9,249,149. The denial of Incyte’s IPR petition upholds the validity of Concert’s composition of matter patent claims covering CTP-543.
  - **CTP-656 Asset Purchase Agreement Closed.** In July 2017, Concert received a \$160 million cash payment from Vertex Pharmaceuticals under an asset purchase agreement whereby Vertex acquired worldwide development and commercialization rights to CTP-656 and other assets related to the treatment of cystic fibrosis. CTP-656 is an investigational cystic fibrosis transmembrane conductance regulator (CFTR)
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potentiator that has the potential to be used as part of future once-daily combination regimens of CFTR modulators that treat the underlying cause of cystic fibrosis. Concert is eligible to receive up to \$90 million in additional milestones based on regulatory approval in the U.S. and reimbursement in the U.K., Germany or France.

- **Alopecia Areata Patient Focused Drug Development Meeting.** In September 2017, the U.S. Food and Drug Administration (FDA) hosted a patient-focused meeting for alopecia areata as part of its Patient-Focused Drug Development Initiative. The meeting's goal was to obtain patient input on the impact of alopecia areata, including on daily life, patient views and experiences regarding current treatments, and decision factors taken into account when selecting a treatment. The meeting materials are available on the FDA's website at: <https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm554443.htm>
- **Repayment of Venture Debt.** In September 2017, Concert paid \$30.8 million to Hercules Capital in repayment of the Company's outstanding obligations under a Loan Agreement. All outstanding obligations under the Loan Agreement were paid in full, and the agreement has been terminated.

### Third Quarter 2017 Financial Results

- **Cash and Investments Position.** Cash, cash equivalents and investments as of September 30, 2017, totaled \$207.1 million as compared to \$103.4 million as of June 30, 2017. Concert expects its cash, cash equivalents and investments as of September 30, 2017 to be sufficient to fund the Company into 2021.
- **Revenues.** Revenue was \$143.8 million for the quarter ended September 30, 2017, compared to \$26,000 for the corresponding quarter in 2016. The increase in revenue relates to the close of the CTP-656 asset purchase agreement with Vertex.
- **R&D Expenses.** Research and development expenses were \$7.1 million for the quarter ended September 30, 2017, compared to \$8.1 million for the same period in 2016, a decrease of \$1.0 million. The decrease was primarily due to the discontinuation of development related to CTP-656 resulting from the asset purchase agreement.
- **G&A Expenses.** General and administrative expenses were \$4.9 million for the quarter ended September 30, 2017, compared to \$3.4 million for the same period in 2016, an increase of \$1.5 million. The increase in general and administrative expenses was primarily related to an increase in stock compensation, professional and legal fees in connection with the CTP-656 asset purchase agreement and intellectual property matters related to CTP-543.
- **Net Income (Loss).** For the quarter ended September 30, 2017, net income was \$128.1 million, or \$5.61 per share, as compared to a net loss of \$11.4 million, or \$0.51 per share for the quarter ended September 30, 2016.

### Conference Call and Webcast

The Company will host a conference call and webcast today at 8:30 a.m. EST 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 Concert's presentation may be accessed in the Investors section of the Company's website at [www.concertpharma.com](http://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 -

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
<b>Revenue:</b>				
License and research and development revenue	\$ 17	\$ 26	\$ 52	\$ 153
Other Revenue	143,827	—	143,827	—
Total revenue	143,844	26	143,879	153
<b>Operating expenses:</b>				
Research and development	7,136	8,054	22,658	28,323
General and administrative	4,875	3,440	15,835	10,845
Total operating expenses	12,011	11,494	38,493	39,168
Income (loss) from operations	131,833	(11,468)	105,386	(39,015)
Interest and other income (expense), net	(1,591)	112	(1,504)	338
Income (loss) before tax provision	130,242	(11,356)	103,882	(38,677)
Provision for income taxes	2,177	—	2,177	—
Net income (loss)	\$ 128,065	\$ (11,356)	\$ 101,705	\$ (38,677)
Net income (loss) attributable to common stockholders - basic	127,324	(11,356)	101,272	(38,677)
Net income (loss) attributable to common stockholders - diluted	127,347	(11,356)	101,284	(38,677)
<b>Net income (loss) per share applicable to common stockholders:</b>				
Basic	\$ 5.61	\$ (0.51)	\$ 4.49	\$ (1.74)
Diluted	\$ 5.44	\$ (0.51)	\$ 4.37	\$ (1.74)
<b>Weighted-average number of common shares used in net income (loss) per share applicable to common stockholders:</b>				
Basic	22,694	22,229	22,551	22,215
Diluted	23,421	22,229	23,195	22,215

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

	September 30, 2017	December 31, 2016
Cash and cash equivalents	\$ 32,119	\$ 40,555
Investments, available for sale	174,993	55,630
Working capital	202,229	92,159
Total assets	212,229	100,395
Deferred revenue	10,309	10,050
Total stockholders' equity	\$ 195,860	\$ 85,594

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## **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 address unmet patient needs. The Company's approach starts with 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](http://www.concertpharma.com).

## **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, 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.

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