

CONCERT PHARMACEUTICALS, INC.

FORM 8-K (Current report filing)

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Address	99 HAYDEN AVENUE SUITE 500 LEXINGTON, MA 02421
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**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): August 8, 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 August 8, 2017, Concert Pharmaceuticals, Inc. announced its financial results for the quarter ended June 30, 2017. 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**

The Exhibits to this Current Report on Form 8-K are listed in the Exhibit Index attached hereto.

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: August 8, 2017

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by Concert Pharmaceuticals, Inc., dated August 8, 2017



NEWS RELEASE

For additional information contact:

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FOR IMMEDIATE RELEASE

Concert Pharmaceuticals Reports Second Quarter 2017 Financial Results and Provides Company Update

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

Lexington, MA (August 8, 2017) -- [Concert Pharmaceuticals, Inc.](#) (NASDAQ: CNCE) today reported financial results for the second quarter of 2017.

“We are very pleased that we have closed the CTP-656 asset purchase agreement with Vertex, which resulted in a payment to Concert of \$160 million in July. We believe our transaction with Vertex provides the optimal pathway to rapidly advance the development of CTP-656 for the benefit of cystic fibrosis patients,” said Roger Tung, Ph.D., President and Chief Executive Officer of Concert Pharmaceuticals, Inc. “The Vertex transaction significantly extends our cash runway and we expect the proceeds will allow us to advance CTP-543 into pivotal testing as well as broaden our proprietary development pipeline. We are excited about Concert’s prospects, with our near-term focus on rapidly advancing CTP-543 through the Phase 2a trial for the treatment of alopecia areata. We are also assessing the potential to address additional autoimmune indications with CTP-543.”

Recent Business Highlights and Upcoming Milestones

- ***CTP-656 Asset Purchase Agreement with Vertex.*** In July 2017, the U.S. Federal Trade Commission (FTC) terminated the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR Act) which represented the final regulatory closing condition required to complete the asset purchase agreement under which [Vertex Pharmaceuticals, Inc.](#) (NASDAQ: VRTX) agreed to acquire CTP-656 and other assets related to the treatment of cystic fibrosis. On May 24, 2017, Concert shareholders approved the authorization of the CTP-656 asset purchase agreement. As a result, in July 2017 the companies closed the transaction and Vertex paid \$160 million in cash for worldwide development and commercialization rights to CTP-656.
 - ***CTP-543 Phase 2 for Alopecia Areata.*** In July 2017 the U.S. Food and Drug Administration (FDA) lifted the clinical hold on Concert’s CTP-543 Phase 2a clinical trial for alopecia areata. Concert has resumed enrollment in a modified Phase 2a trial and expects to complete the trial in the second half of 2018.
 - ***Alopecia Areata Patient-Focused Drug Development Initiative.*** On September 11, 2017, the FDA will host a patient-focused meeting for alopecia areata as part of its Patient-Focused Drug Development Initiative. These
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meetings, which are open to the public, are intended to take into account the current state of drug development, specific interests of the FDA review division, and needs of the patient population. Additional information is available on the FDA's website at: <https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm347317.htm>.

- **PGR Petition Against Incyte.** In June 2017, Concert filed a Post Grant Review (PGR) petition with the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office against Incyte Corporation. The PGR petition challenges the validity of all claims in Incyte's U.S. Patent No. 9,662,335, which includes claims relating to deuterated ruxolitinib analogs. The Company expects the PTAB will make a decision whether to institute a review in the first quarter of 2018.
- **Venture Debt Financing.** In June 2017, Concert secured \$30 million in venture debt from Hercules Capital, Inc. The Company intends to pay off the loan in September 2017 which will enable a 50 percent reduction in the end of term charge and waiver of the prepayment penalty.

Second Quarter 2017 Financial Results

- **Cash and Investment Position.** Cash, cash equivalents and investments as of June 30, 2017, totaled \$103.4 million as compared to \$83.9 million as of March 31, 2017. The increase was driven by a \$30 million term loan facility entered into on June 8, 2017 with Hercules. In July 2017, upon the closing of the Asset Purchase Agreement, Vertex paid to the Company \$160 million in cash, with \$16 million to initially be held in escrow for a period of 18 months. Including proceeds from the CTP-656 asset purchase agreement, the Company believes pro forma cash will be sufficient to fund the Company into 2021.
- **Revenues.** Revenue was \$15,000 for the quarter ended June 30, 2017, compared to \$71,000 for the corresponding quarter in 2016. Revenue recognized in 2017 and 2016 is comprised of services performed by Concert in connection with its strategic collaborations with Celgene Corporation and Jazz Pharmaceuticals.
- **R&D Expenses.** Research and development expenses were \$7.3 million for the quarter ended June 30, 2017, compared to \$9.8 million for the same period in 2016, a decrease of \$2.5 million. The decrease was primarily due to the timing to initiate the CTP-543 Phase 2a trial in 2017 as well as scale-up manufacturing expenses in 2016 to support the CTP-656 and CTP-543 Phase 2 trials.
- **G&A Expenses.** General and administrative expenses were \$5.7 million for the quarter ended June 30, 2017, compared to \$3.8 million for the same period in 2016, an increase of \$1.9 million. The increase in general and administrative expenses was primarily related to professional fees in connection with the CTP-656 asset purchase agreement and intellectual property matters related to CTP-543.
- **Net Loss.** For the quarter ended June 30, 2017, net loss was \$13.0 million, or \$0.58 per share, as compared to a net loss of \$13.4 million, or \$0.60 per share for the quarter ended June 30, 2016.

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 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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue:				
License and research and development revenue	\$ 15	\$ 71	\$ 35	\$ 127
Total revenue	15	71	35	127
Operating expenses:				
Research and development	7,285	9,816	15,522	20,269
General and administrative	5,707	3,828	10,960	7,405
Total operating expenses	12,992	13,644	26,482	27,674
Loss from operations	(12,977)	(13,573)	(26,447)	(27,547)
Interest and other income (expense), net	(50)	132	87	226
Net loss	(13,027)	(13,441)	(26,360)	(27,321)
Net loss per share applicable to common stockholders - basic and diluted	\$ (0.58)	\$ (0.60)	\$ (1.17)	\$ (1.23)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	22,579	22,217	22,479	22,208

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

	June 30, 2017	December 31, 2016
Cash and cash equivalents	\$ 27,591	\$ 40,555
Investments, available for sale	75,829	55,630
Working capital	100,152	92,159
Total assets	108,622	100,395
Deferred revenue	10,025	10,050
Loan payable, net of discount	29,188	—
Total stockholders' equity	\$ 64,381	\$ 85,594

- 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 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.

Cautionary Note on Forward Looking Statements

Any statements in this press release about our future expectations, plans and prospects, including statements about our expectations for 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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