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): August 5, 2021

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, 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 August 5, 2021, Concert Pharmaceuticals, Inc. announced its financial results for the quarter ended June 30, 2021. 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 and Exhibit 99.1 attached hereto is intended to be furnished and 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 the Registrant on August 5, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: August 5, 2021

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 Second Quarter 2021 Financial Results

CTP-543 Phase 3 Program On Track to Support NDA Filing in Early 2023

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

Lexington, MA (August 5, 2021) -- Concert Pharmaceuticals, Inc. (NASDAQ: CNCE) today reported financial results for the second quarter of 2021.

“Our development priority is to advance CTP-543 through its pivotal trials for alopecia areata in support of a planned early 2023 New Drug Application. We remain on track with our clinical progression of CTP-543, a drug candidate with the potential to address an important unmet medical need and sizeable market opportunity,” said Roger Tung, Ph.D., President and Chief Executive Officer of Concert Pharmaceuticals. “Alopecia areata is a chronic autoimmune disease with no approved treatment that causes significant emotional and psychological distress in many patients. There's an enormous need for an FDA-approved treatment, and we're proud that Concert was one of the first in the industry to act on this important disease by advancing CTP-543, which has the potential to be a best in class treatment.”

Recent Highlights and Upcoming Milestones

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

- ***Initiated CTP-543 THRIVE-AA2 Phase 3 Trial in May 2021.*** THRIVE-AA2, the second study in the CTP-543 pivotal program, is a randomized, double-blind, placebo-controlled Phase 3 clinical trial of CTP-543 to evaluate hair regrowth using the Severity of Alopecia Tool (SALT) after 24 weeks of dosing in approximately 440 adults 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 Company expects to report topline results from the THRIVE-AA2 trial in the second half of 2022.

- ***CTP-543 THRIVE-AA1 Phase 3 Trial Progressing.*** THRIVE-AA1, the first study in the CTP-543 pivotal program, is a randomized, double-blind, placebo-controlled Phase 3 clinical trial of CTP-543 to evaluate

hair regrowth using the Severity of Alopecia Tool (SALT) after 24 weeks of dosing in approximately 700 adults 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 Company expects to report topline results from the THRIVE-AA1 trial in the first half of 2022.

- ***CTP-543 Long-term Data Presented at JAK Inhibitors Drug Development Summit.*** Data from an ongoing open label, long-term extension study with CTP-543 were presented at the 2nd JAK Inhibitors Drug Development Summit on July 1, 2021. The presentation highlighted that in the extension study, treatment with CTP-543 showed 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. Approximately 57% of participants receiving 12 mg of CTP-543 twice-daily following 52 weeks of dosing achieved a clinically-meaningful SALT score of 20 or less. A SALT score ≤ 20 corresponds to 80% or more hair coverage on the scalp. CTP-543 has been generally well tolerated in the extension study, and adverse events are consistent with those reported in the Phase 2 trials.

- ***September is Alopecia Areata Awareness Month.*** Throughout the month of September, Concert, along with the alopecia areata community, will raise awareness and recognize the importance of alopecia areata, a serious autoimmune disorder that affects approximately 1 million individuals in the U.S. and which often results in poor health-related quality of life as well as high levels of anxiety and depression. Follow our #LightItUpBlue4AlopeciaAreata campaign on Twitter at @ConcertPharma.

Second Quarter 2021 Financial Results

- ***Cash and Investment Position.*** Cash, cash equivalents and investments as of June 30, 2021 totaled $122.4 million as compared to $130.0 million as of December 31, 2020. Under its current operating plan, the Company expects its cash and cash equivalents to fund the Company into the second quarter of 2022. In May 2021, Vertex purchased the potential future milestones under the companies' 2017 asset purchase agreement relating to VX-561 for $32.0 million.

- ***Revenues.*** For the quarter ended June 30, 2021, revenue was $32.0 million, compared to $6.4 million for the same period in 2020. Revenue recognized in 2021 was the result of the $32.0 million of proceeds received from Vertex. Revenue recognized in 2020 was the result of the expiration of licensing options under a previous collaboration with Celgene Corporation.

- ***R&D Expenses.*** Research and development expenses were $20.2 million for the quarter ended June 30, 2021, compared to $14.8 million for the same period in 2020. The increase in research and development expenses relates primarily to the clinical development program for CTP-543.

- ***G&A Expenses.*** General and administrative expenses were $5.6 million for the quarter ended June 30, 2021, compared to $4.7 million for the same period in 2020. The increase in general and administrative expenses relates primarily to increased external professional service expenses and non-cash stock-based compensation.

- ***Net Income (Loss).*** For the quarter ended June 30, 2021, net income applicable to common stockholders was $5.4 million, or $0.16 per share, as compared to net loss applicable to common stockholders of $13.0 million, or $0.41 per share, for the quarter ended June 30, 2020.

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 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 –

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
License and research and development revenue	$ 17	$ 6,387	$ 22	$ 6,394
Other revenue	32,000	—	32,000	—
Total revenue	32,017	6,387	32,022	6,394
Operating expenses:				
Research and development	20,184	14,788	38,684	28,774
General and administrative	5,614	4,731	11,099	9,403
Total operating expenses	25,798	19,519	49,783	38,177
Income (loss) from operations	6,219	(13,132)	(17,761)	(31,783)
Investment income	15	355	40	918
Unrealized (loss) gain on marketable equity securities	(809)	(299)	477	(2,688)
Income (loss) before income taxes	5,425	(13,076)	(17,244)	(33,553)
Income tax benefit	—	(85)	—	(85)
Net income (loss)	$ 5,425	$ (12,991)	$ (17,244)	$ (33,468)
Net income (loss) attributable to common stockholders - basic and diluted	5,415	(12,991)	(17,244)	(33,468)
Net income (loss) per share applicable to common stockholders - basic and diluted	$ 0.16	$ (0.41)	$ (0.51)	$ (1.11)
Weighted-average number of common shares used in net income (loss) per share applicable to common stockholders:				
Basic	33,974	31,455	33,934	30,283
Diluted	34,083	31,455	33,934	30,283

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

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 122,399	$ 77,202
Investments, available for sale	—	52,766
Working capital	124,313	132,546
Total assets	148,705	159,263
Deferred revenue	2,750	2,750
Total stockholders’ equity	122,716	131,162

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 lead product candidate is in late-stage development for the treatment of alopecia areata, a serious autoimmune dermatological condition. Concert is also assessing a number of earlier-stage pipeline candidates. 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 regarding the development of CTP-543, the timing of availability of clinical trial data, the timing of regulatory filings 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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