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): May 5, 2022

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 May 5, 2022, Concert Pharmaceuticals, Inc. announced its financial results for the quarter ended March 31, 2022. 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 May 5, 2022
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: May 5, 2022

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 First Quarter 2022 Financial Results

Phase 3 Data Readout in Alopecia Areata Expected Second Quarter of 2022

Alopecia Areata Represents Significant Market Opportunity with Important Medical Need

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

Lexington, MA (May 5, 2022) -- Concert Pharmaceuticals, Inc. (NASDAQ: CNCE) today reported financial results for the first quarter of 2022.

"We are at an exciting point in our progress with CTP-543, our drug candidate for alopecia areata, a serious autoimmune disorder with significant unmet medical need. Our pivotal trials, THRIVE-AA1 and THRIVE-AA2, have collectively enrolled over 1,200 patients in the U.S., Canada and Europe. We're grateful to the many individuals who chose to participate in our studies to advance research for this important autoimmune disorder and, in the event of positive data, provide us with the information we need to support filing our New Drug Application with the FDA, which is planned for the first half of next year," stated Roger Tung, Ph.D., President and Chief Executive Officer of Concert Pharmaceuticals. "We continue to expect to report topline results from the THRIVE-AA1 trial this quarter. The THRIVE-AA2 topline results are expected to follow soon thereafter, in the third quarter of 2022."

Recent Business Highlights and Upcoming Milestones

CTP-543: An Investigational Treatment in Phase 3 Trials for Moderate to Severe Alopecia Areata

- ***Topline Data for THRIVE-AA1 Expected in the Second Quarter of 2022.*** The Company expects to report topline results from the first CTP-543 Phase 3 trial, THRIVE-AA1, in the second quarter of 2022. THRIVE-AA1 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. The trial is

evaluating 8 mg and 12 mg twice-daily oral doses of CTP-543 compared to placebo. The trial enrolled 708 adult patients with moderate to severe alopecia areata at sites in the U.S., Canada and Europe.

- ***Topline Data for THRIVE-AA2 Expected in the Third Quarter of 2022.*** The Company expects to report topline results from the THRIVE-AA2 trial in the third quarter of 2022. THRIVE-AA2 is a randomized, double-blind, placebo-controlled Phase 3 clinical trial of CTP-543 to evaluate hair regrowth using SALT after 24 weeks of dosing. The trial is evaluating 8 mg and 12 mg twice-daily oral doses of CTP-543 compared to placebo. The trial enrolled 517 adult patients with moderate to severe alopecia areata at sites in the U.S., Canada and Europe.

- ***New Drug Application (NDA) Filing for Alopecia Areata Expected in the First Half of 2023.*** If the CTP-543 clinical program is successful, the Company intends to file an NDA with the U.S. Food and Drug Administration (FDA) in the first half of 2023. If approved, the Company expects that CTP-543 would be one of the first FDA-approved treatments for alopecia areata. The FDA has granted CTP-543 Breakthrough Therapy designation for the treatment of adult patients with moderate to severe alopecia areata and Fast Track designation for the treatment of alopecia areata. Alopecia areata is an autoimmune disease that may affect up to approximately 1.5 million Americans at any given time.[1]

First Quarter 2022 Financial Results

- ***Cash and Investment Position.*** Cash, cash equivalents and investments as of March 31, 2022 totaled $109.0 million as compared to $141.6 million as of December 31, 2021. Under its current operating plan, the Company expects its current cash, cash equivalents and investments to fund the Company into the fourth quarter of 2022. In addition, Concert has the potential to receive an additional $103.1 million upon the full exercise of the warrants issued in connection with its November 2021 financing.

- ***R&D Expenses.*** Research and development expenses were $30.5 million for the quarter ended March 31, 2022, compared to $18.5 million for the same period in 2021. The increase in research and development expenses relates primarily to the clinical development for CTP-543.

- ***G&A Expenses.*** General and administrative expenses were $5.5 million for each of the quarters ended March 31, 2022 and 2021. General and administrative expenses primarily consist of employee benefits and compensation and external professional services.

- ***Net Loss.*** Net loss applicable to common stockholders was $37.7 million, or $1.03 per share, for the quarter ended March 31, 2022, as compared to net loss applicable to common stockholders of $22.7 million, or $0.67 per share, for the quarter ended March 31, 2021.

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 its first quarter 2022 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 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 March 31,	
	2022	**2021**
Revenue:		
License and research and development revenue	$ —	$ 5
Operating expenses:		
Research and development	30,489	18,500
General and administrative	5,539	5,485
Total operating expenses	36,028	23,985
Loss from operations	(36,028)	(23,980)
Investment income	20	25
Unrealized (loss) gain on marketable equity securities	(564)	1,286
Unrealized loss on warrant liabilities	(1,156)	—
Net loss	$ (37,728)	$ (22,669)
Net loss per share applicable to common stockholders - basic and diluted	$ (1.03)	$ (0.67)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	36,687	33,894

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

	March 31, 2022	**December 31, 2021**
Cash and cash equivalents	$ 59,363	$ 141,636
Investments, available for sale	49,643	—
Working capital	99,686	134,209
Total assets	129,411	165,316
Deferred revenue	7,595	7,595
Total stockholders' equity	76,566	112,225

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 Annual Report on Form 10-K or 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.

[1]Benigo M. Clinical, Cosmetic and Investigational Dermatology, 2020

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