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): November 7, 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 November 7, 2022, Concert Pharmaceuticals, Inc. announced its financial results for the quarter ended September 30, 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 in 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 November 7, 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: November 7, 2022

By: /s/ Jeffrey A. Munsie
Jeffrey A. Munsie
Chief Legal Officer

Exhibit 99.1

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 2022 Financial Results

Company Plans to Submit NDA in First Half of 2023 for Deuruxolitinib in Adults with Moderate to Severe Alopecia Areata

Deuruxolitinib (CTP-543) Phase 3 Data Presented at the EADV Congress Late Breaking News Session

Additional Deuruxolitinib Phase 3 Results to be Presented at the World Congress for Hair Research

Conference Call Scheduled Today at 8:30 a.m. ET; Registration Required to Join Live Call

Lexington, MA (November 7, 2022) -- Concert Pharmaceuticals, Inc. (NASDAQ: CNCE) today reported financial results for the third quarter of 2022.

"With the THRIVE-AA clinical program completed and positive Phase 3 results in hand for deuruxolitinib in alopecia areata, we are well on our way to meeting our goal of submitting the NDA in the first half of 2023," said Roger Tung, Ph.D., President and Chief Executive Officer of Concert Pharmaceuticals. "Given the promising clinical properties and potential best-in-class profile displayed by deuruxolitinib and the great needs of the alopecia areata patient community, we are well-positioned to emerge as a leader in the autoimmune dermatology field. All of our development and precommercial efforts are strongly positioning us to make the transition to being a commercially focused organization."

Recent Highlights and Upcoming Milestones

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

- ***Deuruxolitinib EADV Late Breaking Presentation:*** In September 2022, Brett King, M.D., Department of Dermatology, Yale University School of Medicine, presented THRIVE-AA1 Phase 3 results in alopecia

areata during the 31st European Academy of Dermatology and Venereology (EADV) Congress late breaking news session. To access the full presentation of the safety and efficacy findings from the THRIVE-AA1 study, visit Concert's Scientific Presentation page on its website. Details of the presentation include:

- ***SALT Scores for Scalp Regrowth.*** Data from the THRIVE-AA1 study showed the ability of deuruxolitinib to achieve more stringent criteria for hair regrowth than was measured by the study's primary endpoint of a Severity of Alopecia Tool (SALT) score of 20 or less (meaning 20 percent or less scalp hair loss) at Week 24. Specifically, 21 percent and 35 percent of patients in the deuruxolitinib 8 mg twice-daily and 12 mg twice-daily dose groups, respectively, achieved a SALT score of 10 or less at Week 24, compared to 0 percent of patients in the placebo group ($p<0.0001$). Also, the relative improvement in SALT score from baseline was significantly different for the 12 mg twice-daily dose group compared to placebo ($p<0.001$) as early as Week 4.

- ***Eyebrow or Eyelash Regrowth.*** New data were presented showing that patients in the THRIVE-AA1 study with loss of eyebrow or eyelash hair at baseline who were treated with deuruxolitinib had significant improvement compared to placebo starting as early as 12 weeks, which was the first time point measured, and continuing through the 24-week treatment period ($p<0.001$).

- ***Positive Phase 3 Results Reported for Deuruxolitinib THRIVE-AA2 Study.*** In August 2022, the Company reported positive topline results for its second deuruxolitinib Phase 3 clinical trial, THRIVE-AA2. A statistically significant proportion of patients treated with either 8 mg twice-daily or 12 mg twice-daily of deuruxolitinib in the THRIVE-AA2 study experienced greater scalp regrowth compared to placebo. The proportion of patients achieving a SALT score of 20 or less at Week 24 was 33 percent in the 8 mg twice-daily dose group and 38 percent in the 12 mg twice-daily dose group, compared to 1 percent of patients in the placebo group. The treatment difference for both dose groups relative to placebo was statistically significant ($p<0.0001$). The safety profile seen with deuruxolitinib in THRIVE-AA2 was consistent with previous studies of CTP-543.

- ***Deuruxolitinib Phase 3 Presentation in Alopecia Areata at the World Congress for Hair Research.*** Dr. King will present additional results from the THRIVE-AA1 study during the 12th World Congress for Hair Research being held November 18-21, 2022 in Melbourne, Australia. The presentation will include additional analyses of hair regrowth based on disease severity and time course of disease.

Third Quarter 2022 Financial Results

- ***Cash and Investment Position.*** Cash, cash equivalents and investments as of September 30, 2022 totaled $148.9 million, compared to $141.6 million as of December 31, 2021. Under its current operating plan, the Company expects its cash, cash equivalents and investments to fund the Company through the second quarter of 2023.

- ***R&D Expenses.*** Research and development expenses were $24.4 million for the quarter ended September 30, 2022, compared to $21.9 million for the same period in 2021. The increase in research and development expenses relates primarily to the clinical development program for deuruxolitinib.

- ***G&A Expenses.*** General and administrative expenses were $5.3 million for the quarter ended September 30, 2022, compared to $5.5 million for the same period in 2021. The decrease in general and administrative expenses relates primarily to decreased non-cash stock-based compensation and external professional services.

- ***Net Loss.*** For the quarter ended September 30, 2022, net loss attributable to common stockholders was $28.9 million, or $0.58 per share, compared to net loss attributable to common stockholders of $26.7 million, or $0.78 per share, for the quarter ended September 30, 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 third quarter financial results. To join the live call, please register here. A dial in and unique PIN number will be provided to join the call.

An audio-only webcast of the call may be accessed in the Investors section of the Company's website at www.concertpharma.com. 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 September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenue:				
License and research and development revenue	$ 8	$ 4	$ 29	$ 26
Other revenue	—	539	—	32,539
Total revenue	8	543	29	32,565
Operating expenses:				
Research and development	24,364	21,876	75,708	60,560
General and administrative	5,250	5,462	15,639	16,561
Total operating expenses	29,614	27,338	91,347	77,121
Loss from operations	(29,606)	(26,795)	(91,318)	(44,556)
Investment income	785	4	951	44
Unrealized (loss) gain on marketable equity securities	(164)	113	(788)	590
Unrealized gain on warrant liabilities	81	—	975	—
Net loss	$ (28,904)	$ (26,678)	$ (90,180)	$ (43,922)
Net loss attributable to common stockholders - basic and diluted	(28,904)	(26,678)	(90,553)	(43,922)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.58)	$ (0.78)	$ (2.13)	$ (1.29)
Weighted-average number of common shares used in net loss per share attributable to common stockholders - basic and diluted	49,731	34,090	42,535	33,987

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

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 95,189	$ 141,636
Investments, available for sale	53,669	—
Working capital	139,797	134,209
Total assets	171,134	165,316
Deferred revenue	7,595	7,595
Total stockholders' equity	133,272	112,225

About Concert

Concert Pharmaceuticals is a late-stage clinical biopharmaceutical company that is developing deuruxolitinib (CTP-543), a novel, deuterated, oral JAK1/2 inhibitor. Concert has successfully completed two Phase 3 trials with deuruxolitinib in adults with alopecia areata, a serious autoimmune dermatological disease. The Company is also evaluating the use of deuruxolitinib in other indications and assessing a number of earlier-stage pipeline candidates. For more information, please visit www.concertpharma.com or follow us on Twitter, Instagram or 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 deuruxolitinib, the potential for deuruxolitinib to be a best-in-class treatment for the treatment of alopecia areata, the planned timing for filing a New Drug Application (NDA) for deuruxolitinib 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, including safety profiles, 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 the timing of the submission of an NDA, the availability of regulatory approvals, the 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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