

## Concert Pharmaceuticals Reports First Quarter 2022 Financial Results

May 5, 2022

**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, Mass.--(BUSINESS WIRE)--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.<sup>1</sup>

### 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](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 –

### 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](#)<sup>®</sup> (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](http://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.

<sup>1</sup>Benigo M. [Clinical, Cosmetic and Investigational Dermatology](#), 2020

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Source: Concert Pharmaceuticals, Inc.