Concert Pharmaceuticals Reports Second Quarter 2018 Financial Results and Provides Company Update

August 2, 2018

-- Clinical Programs Advance with CTP-543 Phase 2a Topline Data in Alopecia Areata and CTP-692 Phase 1 Trial Initiation Expected in the Fourth Quarter of 2018 --

-- Conference Call Scheduled Today at 8:30 A.M. EDT --

LEXINGTON, Mass.--(BUSINESS WIRE)--Aug. 2, 2018-- Concert Pharmaceuticals, Inc. (NASDAQ: CNCE) today reported financial results for the second quarter of 2018.

“Our focus in the first half of this year has been to execute on advancing our proprietary pipeline candidates to key clinical inflection points. The Phase 2 trial evaluating the 4 and 8 mg twice daily cohorts of CTP-543 for alopecia areata is on track for clinical completion later this year with a topline data readout in the fourth quarter,” said Roger D. Tung, Ph.D., President and Chief Executive Officer of Concert Pharmaceuticals. “In addition, our team is poised to move our next candidate, CTP-692 for schizophrenia, into Phase 1 evaluation by year-end. Importantly, both of these candidates are expected to advance in Phase 2 trials in 2019 in support of their respective registration programs.”

Recent Business Highlights and Upcoming Milestones

- ***CTP-543 Phase 2a Topline Data Expected in the Fourth Quarter of 2018.*** In the second quarter of 2018, Concert completed enrollment of the 8 mg cohort in its Phase 2a trial evaluating CTP-543 for the treatment of moderate-to-severe alopecia areata. The double-blind, randomized, placebo-controlled, sequential dose trial is designed to evaluate the safety and efficacy of 4 mg and 8 mg of CTP-543 twice daily. The primary outcome measure will utilize the severity of alopecia tool (SALT) after 24 weeks of dosing. Topline data from the 4 mg and 8 mg twice daily cohorts is expected in the fourth quarter of 2018.
- ***CTP-543 Protocol Amendment Planned.*** An independent Data Monitoring Committee (DMC) will conduct a planned safety data review of the second cohort of the CTP-543 Phase 2a trial following 12 weeks of dosing with 8 mg of CTP-543 or placebo twice daily. Pending a positive assessment by the DMC, the Company will propose to the U.S. Food and Drug Administration (FDA) a protocol amendment to also evaluate 12 mg of CTP-543 compared to placebo twice daily. Any amendment to the existing protocol will not impact the planned data readout of the 4 mg and 8 mg twice daily cohorts in the fourth quarter of 2018.
- ***CTP-692 Phase 1 Trial Planned to Begin in the Fourth Quarter of 2018.*** The Company intends to advance CTP-692 into Phase 1 clinical testing by year-end 2018. The Phase 1 program will include a crossover pharmacokinetic comparison of CTP-692 to D-serine and single and multiple ascending doses of CTP-692. Initial Phase 1 topline data is expected in the first quarter of 2019.
- ***CTP-692 Preclinical Findings to be Presented at ACT 2018***. Concert’s preclinical studies have demonstrated that selective deuterium modification increased D-serine exposure and resulted in no changes in creatinine and blood urea nitrogen. These results support CTP-692’s potential to improve the safety profile of D-serine. These findings will be presented as a poster at the American College of Toxicology 2018 Annual Meeting being held November 4-7, 2018.
- ***New Corporate Headquarters.*** Concert has leased office and laboratory space located at 65 Hayden Avenue, Lexington, Massachusetts for the Company’s new headquarters. Effective August 13, 2018, Concert will occupy the new space. The Company’s existing lease expires in September 2018.

Second Quarter 2018 Financial Results

- ***Cash and Investment Position.***Cash, cash equivalents and investments as of June 30, 2018, totaled $180.3 million as compared to $203.2 million as of December 31, 2017. Concert expects its cash, cash equivalents and investments as of June 30, 2018 to be sufficient to fund the Company into 2021 under its current operating plan.
- ***Revenues.***Revenue was $2,000 for the quarter ended June 30, 2018, compared to $15,000 for the same period in 2017. For the six months ended June 30, 2018, revenue was $10.5 million, compared to $35,000 for the six months ended June 30, 2017. The increase in revenue in the first half of 2018 relates primarily to non-cash consideration received from Processa Pharmaceuticals in the first quarter of 2018 under a license agreement whereby Processa has worldwide rights to develop and commercialize CTP-499.
- ***R&D Expenses****.* Research and development expenses were $8.9 million for the quarter ended June 30, 2018, compared to $7.3 million for the same period in 2017. For the six months ended June 30, 2018, R&D expenses were $17.5 million compared to $15.5 million for the same period in 2017. The increase in R&D expenses relate primarily to activities associated with the ongoing CTP-543 Phase 2 clinical trial and increased expense associated with the advancement of CTP-692 in 2018 as a new development program.

- ***G&A Expenses.*** General and administrative expenses were $5.5 million for the quarter ended June 30, 2018, compared to $5.7 million for the same period in 2017. For the six months ended June 30, 2018, G&A expenses were $11.1 million compared to $11.0 million for the same period in 2017. The changes in G&A expenses reflect higher stock compensation in 2018 partially offset by lower professional fees in 2018.
- ***Net Loss.*** For the quarter ended June 30, 2018, net loss applicable to common stockholders was $13.3 million, or $0.57 per share, compared with a net loss applicable to common stockholders of $13.0 million, or $0.58 per share, for the quarter ended June 30, 2017.

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 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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Revenue:				
License and research and development revenue	$ 2	$ 15	$ 10,481	$ 35
Operating expenses:				
Research and development	8,862	7,285	17,518	15,522
General and administrative	5,514	5,707	11,144	10,960
Total operating expenses	14,376	12,992	28,662	26,482
Loss from operations	(14,374)	(12,977)	(18,181)	(26,447)
Investment income	660	155	1,300	292
Interest and Other expense	—	(205)	—	(205)
Unrealized gain (loss) on marketable equity securities	669	—	(627)	—
Loss before tax provision	(13,045)	(13,027)	(17,508)	(26,360)
Provision for income taxes	280	—	280	—
Net Loss	$ (13,325)	$ (13,027)	$ (17,788)	$ (26,360)
Net loss per share applicable to common stockholders — basic and diluted	$ (0.57)	$ (0.58)	$ (0.76)	$ (1.17)
Weighted-average number of common shares used in net loss per share applicable to common stockholders— basic and diluted	23,402	22,579	23,313	22,479

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

	June 30, 2018	**December 31, 2017**
Cash and cash equivalents	$ 58,359	$ 27,665
Investments, available for sale	121,988	175,500
Working capital	202,828	199,289
Total assets	220,515	211,736
Deferred revenue	10,533	10,301
Total stockholders' equity	200,283	196,432

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 treat serious diseases and address unmet patient needs. The Company's approach starts with previously studied compounds, including 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 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 statements about our expectations for clinical development of CTP-543 and CTP-692, 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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