

Concert Pharmaceuticals Reports Third Quarter 2016 Financial Results and Provides Company Update

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

LEXINGTON, Mass.--(BUSINESS WIRE)-- [Concert Pharmaceuticals, Inc.](#) (NASDAQ: CNCE) today reported financial results for the third quarter of 2016.

"As we approach the end of the year, our team continues to make progress in advancing the drug candidates in our proprietary pipeline. Concert is well positioned to achieve our goal of having two efficacy studies underway with our proprietary compounds in 2017," said Roger Tung, PhD, Chief Executive Officer of Concert Pharmaceuticals. "We are excited by the emerging profile of CTP-656, which may provide significant advantages over the current standard of care. We believe these advantages may enable CTP-656 to provide a therapeutic benefit in cystic fibrosis patients with gating mutations. We are also excited to be advancing CTP-543, which has the potential to be the first FDA-approved oral medicine for the treatment of alopecia areata, a significant unmet need."

Recent Business Highlights and Upcoming Milestones

- | **CTP-543 Investigational New Drug Filing.** In October 2016, Concert filed an investigational new drug application (IND) for CTP-543 (deuterated ruxolitinib). Under the IND, the Company intends to conduct a Phase 2 efficacy trial in patients with moderate to severe alopecia areata that is expected to begin in the first quarter of 2017. We expect to report topline 6-month data by the end of 2017. The first study to be conducted under the IND will be a single-dose crossover trial in healthy volunteers comparing metabolism and pharmacokinetics of CTP-543 and ruxolitinib, and is expected to begin in the fourth quarter of 2016.
- | **CTP-543 Phase 1 Clinical Evaluation.** In the second quarter of 2016, Concert initiated its Phase 1 program to evaluate single and multiple ascending doses of CTP-543 in healthy volunteers. The Company expects to report the CTP-543 Phase 1 pharmacokinetic results from the single and multiple ascending dose trials in the fourth quarter of 2016. Pharmacodynamic topline results from the multiple ascending dose trial are expected in the first quarter of 2017.
- | **CTP-656 Simplified Dosing To Support Improved Patient Benefit.** In October 2016, Concert presented CTP-656 (deuterated ivacaftor) Phase 1 food effect clinical trial results at the North American Cystic Fibrosis Conference. The food effect results showed that the exposure of CTP-656 was the same regardless of the fat content of a meal. In addition, the safety, tolerability and pharmacokinetic profile of CTP-656 observed to date supports its development as a once-daily CFTR potentiator for the treatment of cystic fibrosis. Concert expects to open an IND with the U.S. Food and Drug Administration in the fourth quarter of 2016 to advance CTP-656 into a Phase 2 trial in patients with cystic fibrosis. The Company expects to report Phase 2 topline data by year-end 2017.
- | **Expansion of Management Team.** In September, the Company announced the expansion of its senior management team with the appointment of executives in regulatory affairs and commercial strategy to serve in leadership roles as the Company advances its clinical pipeline. Christine Boisclair has been appointed as Vice President, Regulatory Affairs and Scott Weintraub has joined Concert in the newly created position of Vice President, Commercial and Product Strategy.

Third Quarter 2016 Financial Results

- | **Cash and Investments Position.** Cash, cash equivalents and investments as of September 30, 2016, totaled \$108.0 million as compared to \$118.4 million as of June 30, 2016. Concert expects its cash, cash equivalents and investments as of September 30, 2016, to be sufficient to fund the Company through the second quarter of 2018.
- | **Revenues.** Revenue was \$26,000 for the quarter ended September 30, 2016, compared to \$1.7 million for the corresponding quarter in 2015. The decrease in revenue relates to the completion of the Phase 1 clinical evaluation under our strategic collaboration with Celgene Corporation in 2015.
- | **R&D Expenses.** Research and development expenses were \$8.1 million for the quarter ended September 30, 2016, compared to \$7.1 million for the same period in 2015, an increase of \$1.0 million. The increase was primarily due to expenses associated with the development of the Company's proprietary programs CTP-656 and CTP-543.

- 1 **G&A Expenses.** General and administrative expenses were \$3.4 million for the quarter ended September 30, 2016, compared to \$3.3 million for the same period in 2015, an increase of \$0.1 million.
- 1 **Net Loss.** For the quarter ended September 30, 2016, net loss was \$11.4 million, or \$0.51 per share, as compared to a net loss of \$8.6 million, or \$0.39 per share for the quarter ended September 30, 2015.

Conference Call and Webcast

The Company will host a conference call and webcast today at 8:30 a.m. EST to provide an update on the company and discuss third 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 Concert's presentation 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue:				
License and research and development revenue	\$ 26	\$ 1,709	\$ 153	\$ 6,269
Other revenue	—	—	—	50,155
Total revenue	<u>26</u>	<u>1,709</u>	<u>153</u>	<u>56,424</u>
Operating expenses:				
Research and development	8,054	7,135	28,323	22,499
General and administrative	3,440	3,268	10,845	9,800
Total operating expenses	<u>11,494</u>	<u>10,403</u>	<u>39,168</u>	<u>32,299</u>
(Loss) Income from operations	(11,468)	(8,694)	(39,015)	24,125
Interest and other income (expense), net	112	(21)	338	(229)
(Loss) Income before income taxes	(11,356)	(8,715)	(38,677)	23,896
(Benefit) Provision for income taxes	—	(161)	—	406
Net (loss) income	<u>\$ (11,356)</u>	<u>\$ (8,554)</u>	<u>\$ (38,677)</u>	<u>\$ 23,490</u>
Net (loss) income per share applicable to common stockholders - basic	<u>\$ (0.51)</u>	<u>\$ (0.39)</u>	<u>\$ (1.74)</u>	<u>\$ 1.13</u>
Net (loss) income per share applicable to common stockholders - diluted	<u>\$ (0.51)</u>	<u>\$ (0.39)</u>	<u>\$ (1.74)</u>	<u>\$ 1.07</u>
Weighted-average number of common shares used in net (loss) income per share applicable to common stockholders - basic	<u>22,229</u>	<u>21,949</u>	<u>22,215</u>	<u>20,824</u>
Weighted-average number of common shares used in net (loss) income per share applicable to common stockholders - diluted	<u>22,229</u>	<u>21,949</u>	<u>22,215</u>	<u>21,918</u>

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

	September 30, 2016	December 31, 2015
Cash and cash equivalents	\$ 29,803	\$ 92,510
Investments, available for sale	78,189	49,680
Working capital	102,870	137,481

Total assets		112,362		146,932
Deferred revenue		10,067		10,170
Total stockholders' equity	\$	96,140	\$	130,635

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 address unmet patient needs. The Company's approach starts with 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 pulmonary diseases, including cystic fibrosis, central nervous systems (CNS) disorders, as well as autoimmune and inflammatory diseases. For more information please visit www.concertpharma.com.

Cautionary Note on Forward Looking Statements

Any statements in this press release about our future expectations, plans and prospects, including statements about our expectations on the progress of clinical development of our therapeutic candidates, including CTP-656 and CTP-543, 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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