

Healthcare: BioPharmaceuticals

Concert Pharmaceuticals, Inc. | CNCE - \$8.79 - NASDAQ | Buy

Company Update

Stock Data

52-Week Low - High	\$7.12 - \$16.26
Shares Out. (mil)	18.01
Mkt. Cap.(mil)	\$158.3
3-Mo. Avg. Vol.	155,614
12-Mo.Price Target	\$28.00
Cash (mil)	\$98.3
Tot. Debt (mil)	\$13.0

EPS \$

Yr Dec	—2013—	—2014E—	—2015E—
		Curr	Curr
1Q	-	(0.76)A	(0.47)E
2Q	-	(0.45)A	(0.45)E
3Q	-	(0.42)E	(0.28)E
4Q	-	(0.48)E	(0.01)E
YEAR	(4.99)A	(1.62)E	(1.21)E
P/E	NM	NM	NM

Concert's IPO was on February 9, 2014

Quarterly EPS may not add to full year due to increases in share count and rounding

Revenue (\$ millions)

Yr Dec	—2013—	—2014E—	—2015E—
		Curr	Curr
1Q	-	1.6A	1.2E
2Q	-	1.2A	1.7E
3Q	-	2.0E	5.2E
4Q	-	1.5E	10.5E
YEAR	25.4A	8.3E	18.6E

CNCE One-Year Price and Volume History



CNCE: A \$2 Million Anti-Depressant Milestone as AVP-786 Phase II Starts

CNCE received a \$2 million milestone payment from Avanir (AVNR-NC), which initiated a Phase II study of AVP-786 in patients with major depressive disorder (MDD). This is the second development milestone received under the licensing agreement for AVP-786. This 10-week randomized, double-blind, placebo-controlled study is designed to reduce placebo effects and give relatively quick response as to the drug's efficacy. Reiterate Buy.

Event

CNCE received a \$2 million milestone payment from Avanir (AVNR-NC) which initiated a Phase II study of AVP-786 in patients with major depressive disorder (MDD). This is the second development milestone received under the licensing agreement for AVP-786. CNCE is entitled for additional milestone contingent on successful achievements of regulatory, clinical and commercial targets, as well as tiered royalties on worldwide sales. The current study is a randomized, double-blind, placebo-controlled multi-center Phase II study that will follow 200 patients for 10 weeks and serve as a proof-of-concept study assessing the efficacy and safety of AVP-786 in MDD patients.

Impact

We view this Phase II study initiation as another incremental positive in the clinical progress of CNCE. We also believe that the study design taken by Avanir, a 10-week trial that will assess efficacy using sequential parallel comparison design, will allow for a reliable (with minimum rate of false positive) and relatively fast readout of data. CNCE has a busy schedule ahead of it as it prepares to initiate multiple clinical studies in 2H14. CNCE expects to initiate the PhII study of CTP-354 in patients with spasticity associated with spinal cord injury later this year. We look forward to top-line data from the PhI portion of this study in October. CNCE is leaning towards a single Phase III study with two doses of CTP-499 and intends on initiating discussion with the FDA later this year, including talks of the possibility to conduct the PhIII under SPA. Regarding the partnered programs, JZP-386 PhI study was initiated in a first-in-human study and the PhI study of CTP-730 is expected to initiate in the fall.

Action

With a 1) proprietary platform in modifying drugs with deuterium, 2) growing internal pipeline, 3) three partnerships in hand, to date and 4) a strong IP portfolio, we believe Concert is poised for success, which should be supported by upcoming catalysts

Intraday Price: \$9.05 at 11:26am ET, 8/26/14

VALUATION

Our valuation of Concert is based on our probability-weighted clinical net present value (NPV) valuation model. We believe that this method is appropriate in capturing the value of the clinical stage pipeline. It allows for the flexing of assumptions based on key factors such as chance of success, peak sales estimates, and year of commercial launch.

Factors that could impede shares from reaching our price target include negative clinical data flow from Concert's clinical stage programs as well as any potential delays or issues on the regulatory front and financing risk.

RISKS

- **Pipeline product risk** - Concert's pipeline consists of earlier stage developmental candidates. With this stage of development comes increased risk from negative trial readouts. Additionally, CPT-499 and CTP-354 represent major contributors to our valuation and any negative readouts, clinical or regulatory delays could negatively impact the stock. We believe Concert looks to mitigate some of this risk by having a platform technology which can generate a broad set of drug candidates for its pipeline.
- **Partnering risk** - Concert currently has signed partnerships and is continually engaging in business development activities. Because these programs are under the direction of other companies, there is no guarantee those programs will progress to meaningful catalysts, including potential commercialization. Any delays or terminated partnerships in the future, could have a negative impact on Concert's valuation.
- **Regulatory** - Should Concert's products successfully complete pivotal registrational studies, there is no guarantee that regulatory agencies would approve these products. Unforeseen issues may arise during clinical development which could impact the approvability of a therapeutic candidate.
- **Financing risk**- As with all non-profitable biotechnology companies, funding is continuously necessary to fund operations and ongoing clinical studies. Should Concert encounter problems in raising sufficient funds to continue its operations, this could significantly impact that stock's valuation

COMPANY DESCRIPTION

Concert Pharmaceuticals create novel medicines that address medically important needs by applying its DCE Platform (Deuterated Chemical Entity Platform) to compounds with well-characterized pharmacological activity. This approach may enable drug discovery and clinical development that is more efficient and less expensive than conventional small molecule drug research and development. The company was co-founded in 2006 by Richard Aldrich, Roger Tung and Christoph Westphal, and is located in the historic town of Lexington, Massachusetts.

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Disclosures:

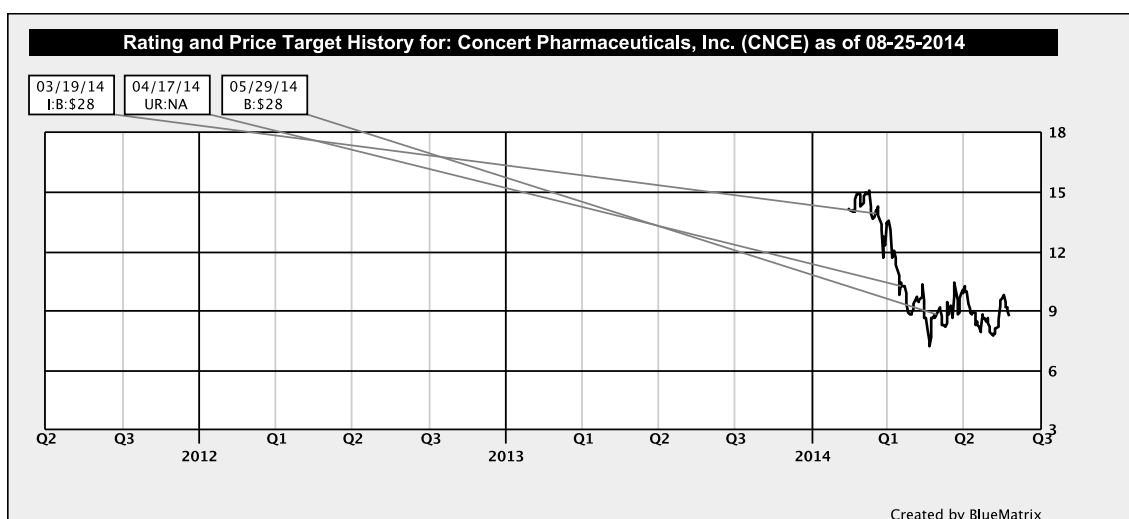
Within the last twelve months, ROTH has received compensation for investment banking services from Concert Pharmaceuticals, Inc..

ROTH makes a market in shares of Concert Pharmaceuticals, Inc. and as such, buys and sells from customers on a principal basis.

Within the last twelve months, ROTH has managed or co-managed a public offering for Concert Pharmaceuticals, Inc..

On September 28, 2010, ROTH changed its rating system in order to replace the Hold rating with Neutral.

On May 26, 2011, ROTH changed its rating system in order to incorporate coverage that is Under Review.



Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years.

Distribution Ratings/IB Services shows the number of companies in each rating category from which Roth or an affiliate received compensation for investment banking services in the past 12 month.

Distribution of IB Services Firmwide

Rating	Count	Percent	IB Serv./Past 12 Mos. as of 08/26/14	
			Count	Percent
Buy [B]	191	80.93	109	57.07
Neutral [N]	23	9.75	9	39.13
Sell [S]	1	0.42	0	0
Under Review [UR]	20	8.47	11	55.00

Ratings System Definitions - ROTH employs a rating system based on the following:

Buy: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return of at least 10% over the next 12 months.

Neutral: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return between negative 10% and 10% over the next 12 months.

Sell: A rating, which at the time it is instituted and or reiterated, that indicates an expectation that the price will depreciate by more than 10% over the next 12 months.

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