

Healthcare: BioPharmaceuticals

Concert Pharmaceuticals, Inc. | CNCE - \$8.29 - NASDAQ | Buy

Company Update

Stock Data

52-Week Low - High	\$7.12 - \$16.26
Shares Out. (mil)	17.90
Mkt. Cap.(mil)	\$148.4
3-Mo. Avg. Vol.	149,338
12-Mo.Price Target	\$28.00
Cash (mil)	\$108.0
Tot. Debt (mil)	\$13.0

EPS \$

Yr Dec	—2013—	—2014E—	—2015E—
		Curr	Curr
1Q	-	(0.76)A	(0.52)E
2Q	-	(0.47)E	(0.53)E
3Q	-	(0.48)E	(0.33)E
4Q	-	(0.58)E	(0.12)E
YEAR	(4.99)A	(1.71)E	(1.51)E
P/E	NM	NM	NM

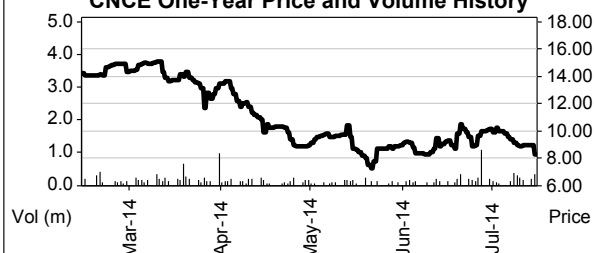
Concert's IPO was on February 9, 2014

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	0.0E
2Q	-	0.3E	0.0E
3Q	-	0.3E	4.0E
4Q	-	0.9E	8.0E
YEAR	25.4A	5.0E	12.0E

CNCE One-Year Price and Volume History



CNCE: Partial Clinical Hold Lifted, CTP-354 Ascending Dose Study To Expand

CNCE received notice from the FDA that it has removed the partial clinical hold on its CTP-354 drug candidate for spasticity. The FDA required added preclinical toxicology studies of repeated CTP-354 doses over 6 mg per day and has now notified that the studies were completed as required. Following this notice, CNCE will initiate a 12 mg CTP-354 dosing cohort as part of its Phase I ascending dose study. Reiterate Buy.

Event

CNCE received notice from the FDA that it has removed the partial clinical hold on its CTP-354 drug candidate for spasticity resulting from spinal cord injury or multiple sclerosis. The FDA required additional preclinical toxicology studies of repeated CTP-354 doses over 6 mg per day and has now notified that CNCE has completed these studies as required. Following this notice, CNCE will initiate a 12mg CTP-354 dosing cohort as part of its Phase I multiple ascending dose study.

Impact

We are encouraged by the removal of the partial clinical hold on the study and view positively CNCE's determination to proceed onward with the ascending dose study, initiating a higher dose cohort. We look forwards to the next step in CTP-354 development with the expected Phase II study to be initiated in 2H14.

Recall also that the company's most advanced product, CTP-499, has generated positive Phase II data in diabetic kidney disease, including data supporting the drug's mechanism of action in reducing markers of fibrosis in the kidneys. CNCE had a successful end of Phase II meeting with the FDA and we believe the company is on the right track to proceed to the next stage. The company plans on submitting a SPA application for the Phase III study of CTP-499 and if approved, it can help speed up the approval process. We view this application as a sign of confidence of CNCE in CTP-499 and its potential benefit to diabetic kidney disease patients. We believe that the visibility garnered through this successful FDA meeting could serve as a potential trigger for partnership interest in further developing CTP-499.

Action

We reiterate our Buy rating and \$28 price target. 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

VALUATION

We reiterate our Buy rating and \$28 price target. 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.

Regulation Analyst Certification ("Reg AC"): The research analyst primarily responsible for the content of this report certifies the following under Reg AC: I hereby certify that all views expressed in this report accurately reflect my personal views about the subject company or companies and its or their securities. I also certify that no part of my compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

Disclosures:

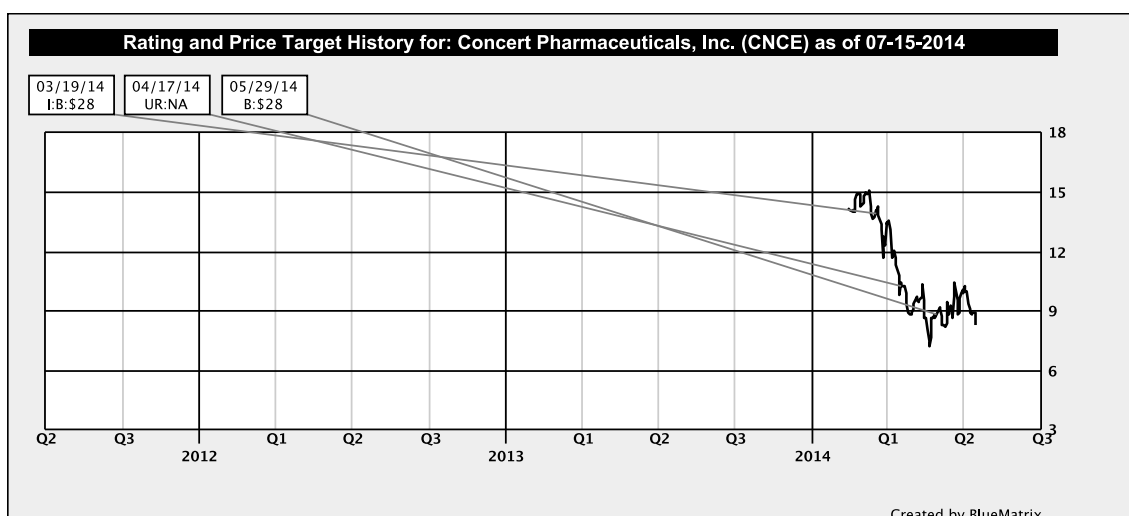
Within the last twelve months, ROTH has received compensation for investment banking services from Concert Pharmaceuticals, Inc..

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 07/16/14	
			Count	Percent
Buy [B]	181	79.04	101	55.80
Neutral [N]	24	10.48	9	37.50
Sell [S]	1	0.44	0	0
Under Review [UR]	22	9.61	13	59.09

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.

Under Review [UR]: A rating, which at the time it is instituted and or reiterated, indicates the temporary removal of the prior rating, price target and estimates for the security. Prior rating, price target and estimates should no longer be relied upon for UR-rated securities.

Not Covered [NC]: ROTH does not publish research or have an opinion about this security.

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