

Healthcare: BioPharmaceuticals

Concert Pharmaceuticals, Inc. | CNCE - \$9.34 - NASDAQ | Buy

Company Update

Stock Data

52-Week Low - High	\$7.12 - \$16.26
Shares Out. (mil)	17.90
Mkt. Cap.(mil)	\$167.2
3-Mo. Avg. Vol.	141,935
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

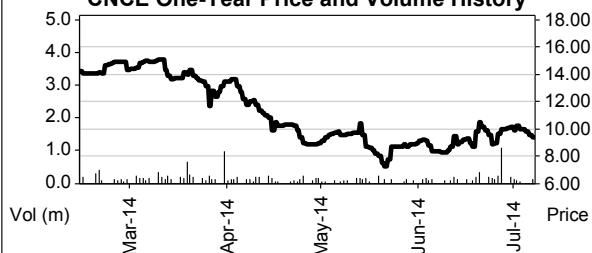
Concert's IPO was on February 9, 2014

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: Visibility Important for Investors and Potential Partners Alike

CNCE announced that it had a successful end-of-phase II meeting with the FDA regarding its product CTP-499 intended for diabetic kidney disease. CNCE was given general agreement with their proposed Phase III study design and primary endpoint. CNCE plans on submitting a SPA request later in the year. We believe this is important visibility for both investors and potential partners alike. Reiterate Buy.

Event

CNCE announced that it had a successful end-of-phase II meeting with the FDA regarding its product CTP-499 intended for diabetic kidney disease. CNCE was given general agreement regarding their proposed Phase III study design, which could be a single study evaluating two doses of CTP-499 compared to placebo or two separate studies of single dose CTP-499 compared to placebo. An acceptable primary endpoint that can support NDA filing was also agreed upon in the meeting, in the form of reduction in the rate of progression of renal disease. This endpoint will be measured by analyzing the time-to-event of the composite of serum creatinine increases (at least 50% increase) or end-stage renal disease. CNCE plans on submitting a SPA request later in the year. Importantly, we believe important precedent has been set with NephroGenex (NRX-NC) receiving an SPA for the same endpoint.

Impact

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. Following this successful meeting, we believe the company is on the right track to proceed to the next stage. The SPA application, if approved, can help speed up the approval process and 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.

CNCE is also focusing on another product, CTP-354, developed for spasticity associated with multiple sclerosis and spinal cord injury; a Phase II program is expected to begin in 2H14.

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

Intraday price: \$9.44 at 9:50am ET, 7/8/14

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.

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Disclosures:

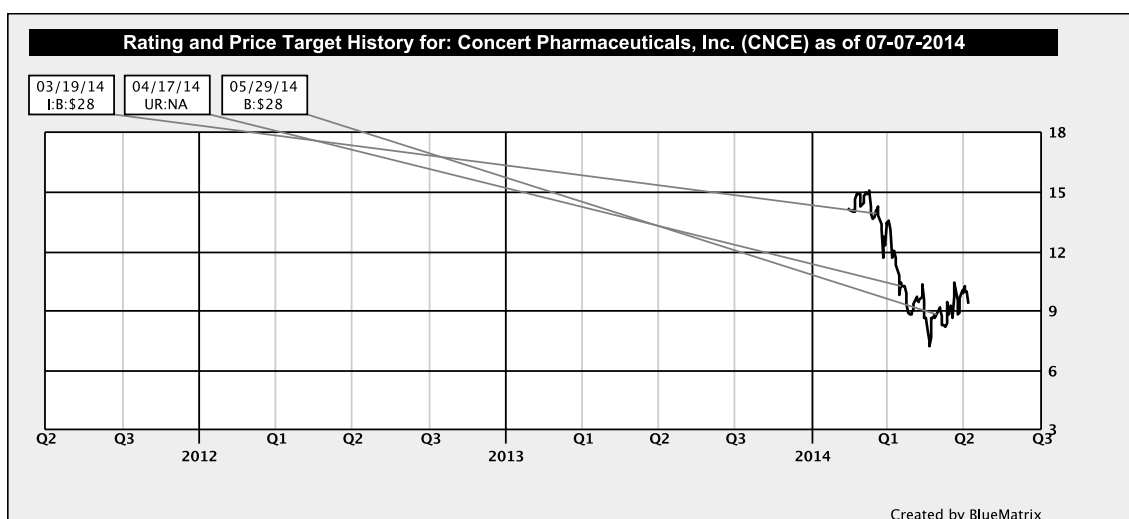
Within the last twelve months, ROTH has received compensation for investment banking services from Concert Pharmaceuticals, Inc..

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 07/08/14	
			Count	Percent
Buy [B]	182	79.48	102	56.04
Neutral [N]	23	10.04	8	34.78
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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