

Healthcare: BioPharmaceuticals

Concert Pharmaceuticals, Inc. | CNCE - \$7.97 - NASDAQ | Buy

Company Update

Stock Data

52-Week Low - High	\$7.12 - \$16.26
Shares Out. (mil)	17.90
Mkt. Cap.(mil)	\$142.7
3-Mo. Avg. Vol.	152,412
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

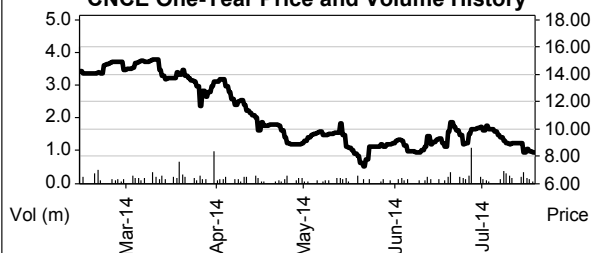
Concert's IPO was on February 9, 2014

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: Partnered Products Advance; \$2M Milestone Check on Horizon; Reiterate Buy

CNCE and partner Jazz (JAZZ-NC) initiated a Phase I study of JZP-386, which is being developed for narcolepsy. CNCE partner Avanir (AVNR-NC) announced that the FDA accepted its IND for AVP-786. CNCE is eligible for a \$2 million milestone payment on first Phase II dosing, expected 3Q14. With CNCE's partnered products making material progress in the clinic, we believe visibility should increase in this name in the near term. Reiterate Buy.

Event

CNCE and partner Jazz Pharmaceuticals initiated a Phase I, first-in-human study of JZP-386, a deuterated version of Jazz's sodium oxybate drug Xyrem, which is used to treat narcolepsy. CNCE is entitled to developmental milestones and tiered royalties on worldwide sales of JZP-386. Also, CNCE partner Avanir (AVNR-NC) Pharmaceuticals announced that the FDA has accepted its IND for AVP-786 for the adjunctive treatment of major depressive disorder. CNCE is eligible for a \$2 million milestone payment upon the initiation of dosing in the Phase II trial of the drug, which is expected 3Q14.

Impact

We are encouraged to see CNCE's partnered programs advancing materially in the clinic. The JZP-386 study will assess the safety and pharmacodynamics of '386 versus a Xyrem control in up to 28 healthy patients in Europe, with the goal of identifying a dose for future studies. We see the narcolepsy market as having the potential to yield significant royalties for CNCE, if the drug is ultimately approved, as narcolepsy is a common disease that affects 1 in 2,000 people in U.S. Recall that CNCE is responsible for clinical development activities for the compound through Phase I. We are also encouraged by the \$2 million milestone payment on the horizon from Avanir as AVP-786 continues to advance. Recall that the FDA recently removed the partial clinical hold on the CTP-354 multiple ascending dose study. CNCE will now initiate the 12 mg dosing cohort. The Phase II is expected to be initiated in 2H14. Recall that CTP-499 has generated positive Phase II data in diabetic kidney disease. CNCE and the FDA agreed on study design/endpoints at the end-of-Phase II meeting, which we believe could drive partner interest in this drug. CNCE plans to submit an application for a SPA for the Phase III study.

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.

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Disclosures:

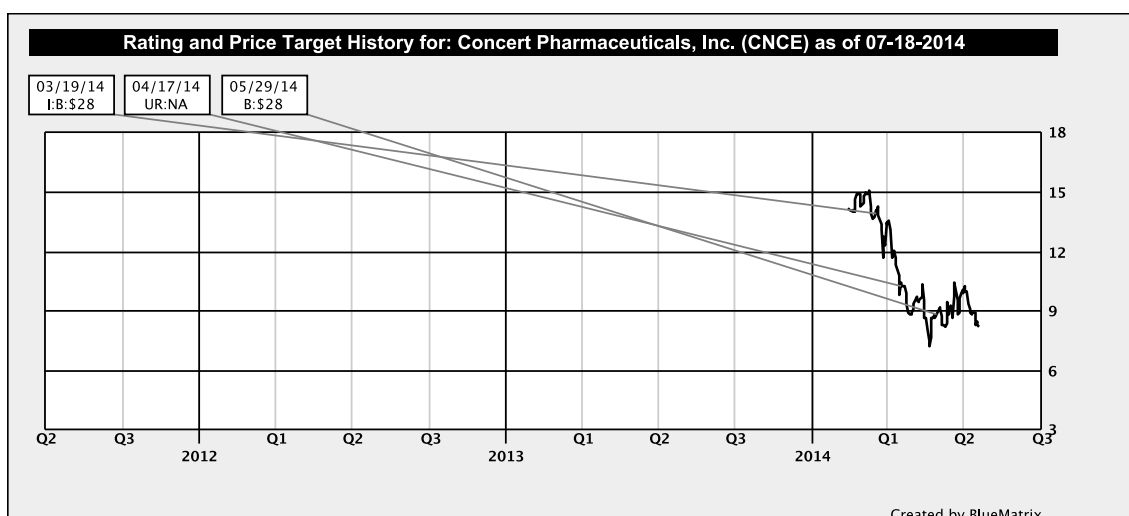
Within the last twelve months, ROTH has received compensation for investment banking services from Concert Pharmaceuticals, Inc..

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 07/21/14	
			Count	Percent
Buy [B]	182	78.79	101	55.49
Neutral [N]	25	10.82	10	40.00
Sell [S]	1	0.43	0	0
Under Review [UR]	22	9.52	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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