

Healthcare: BioPharmaceuticals

Concert Pharmaceuticals, Inc. | CNCE - \$12.42 - NASDAQ | Buy

Company Update

Stock Data

52-Week Low - High	\$7.12 - \$16.26
Shares Out. (mil)	18.01
Mkt. Cap.(mil)	\$223.7
3-Mo. Avg. Vol.	193,128
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

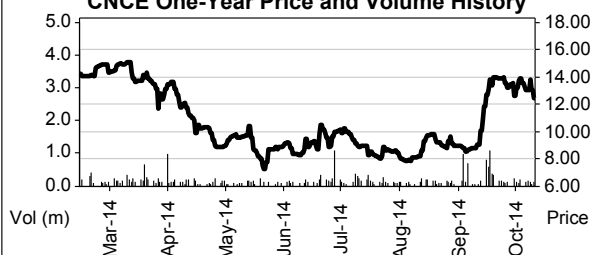
Concert's IPO was on February 9, 2014

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: Free of Common DLTs, '354 Is Ready for Phase II by YE14; Reiterate Buy

Results from the Phase I multiple ascending dose study of CTP-354 in healthy volunteers showed that the drug was safe and well-tolerated at doses as high as 12 mg. The results show that high plasma levels of the drug can be achieved without the common DLTs of sedation or ataxia, which are common to the GABA receptor modulator drug class. Data also support once daily dosing. CNCE plans to start a Phase II by the end of 2014. Reiterate Buy.

Event

CNCE reported results from the randomized, placebo-controlled, multiple ascending dose Phase I trial of CTP-354 in 30 healthy volunteers. The drug was well-tolerated at 2, 6, and 12 mg doses, with no serious adverse events, including no reports of sedation or ataxia, which are common dose-limiting side effects of GABA^A receptor modulators.

Impact

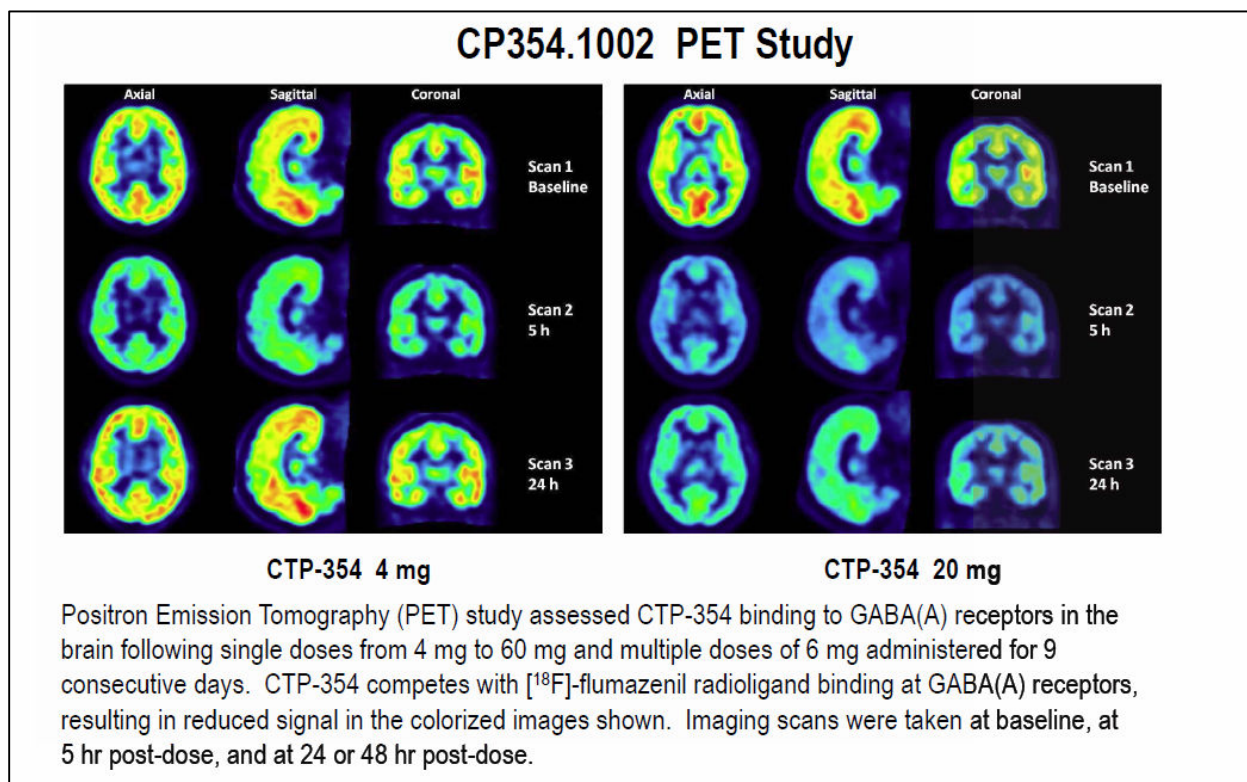
We are encouraged by the Phase I results. We believe that they demonstrate that CTP-354, which was designed to avoid common DLTs, can indeed achieve high plasma concentrations while avoiding DLTs common to this class of drugs. The most common adverse events were mild to moderate dizziness and drowsiness. There were no serious adverse events and no discontinuations. The drug also demonstrated a good pharmacokinetic profile, dose-proportional exposure, similar exposure under fed and fasted conditions, high GABA receptor occupancy (see Summary), and a long half-life (20 h), which the company believes will support once daily dosing. Recall that current standard of care spasticity treatments are dosed 3x daily. CNCE plans to begin a Phase II study of '354 in spasticity patients by the end of 2014 and to subsequently start a Phase II trial in multiple sclerosis in early 2015. We believe CNCE is making good progress on its clinical programs. The company is well positioned to advance CTP-499 into Phase III. Following a recent end of Phase II meeting with the FDA, CNCE intends on initiating discussion with the FDA regarding Phase III later this year, which will include talks of the possibility to conduct the trial under SPA. Regarding the partnered programs, a first-in-human Phase I study of JZP-386 was recently initiated. A Phase I study of CTP-730 is expected to initiate in the fall. AVP-786 is expected to advance into Phase II in September.

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: \$12.24 at 10:26am ET on 10/13/14.

PET Scans Showing CTP-354 Receptor Occupancy at 5 Hours and 24 Hours Post-Dose



Source: Braman *et al.*, poster: Preliminary Clinical Outcomes for CTP-354, a Novel Subtype-selective GABA(A) Modulator, 2014

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.

(\$ in millions except per share data)

Profit & Loss	2012A	2013A	2014E	2015E	2016E	2017E
Licensing and R&D revenue	11.3	23.4	6.3	6.6	7.3	8.0
Milestone revenue	1.5	2.0	2.0	12.0	13.2	14.5
Product and Royalties	0.0	0.0	0.0	0.0	0.0	0.0
Other revenues	0.0	0.0	0.0	0.0	0.0	0.0
Revenues	12.8	25.4	8.3	18.6	20.5	22.5
CoGS	0.0	0.0	0.0	0.0	0.0	0.0
Gross Profit	12.8	25.4	8.3	18.6	20.5	22.5
<i>Gross margin</i>	<i>100%</i>	<i>100%</i>	<i>100%</i>	<i>100%</i>	<i>100%</i>	<i>100%</i>
G&A	7.3	8.0	11.0	11.9	13.1	14.4
R&D	24.2	21.8	24.6	27.1	30.3	34.0
Other op ex	0.0	0.0	0.0	0.0	0.0	0.0
EBIT	(18.6)	(4.4)	(27.3)	(20.4)	(23.0)	(25.9)
<i>EBIT margin</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>
Depreciation	0.0	0.0	0.0	0.0	0.0	0.0
Amortisation Intangibles	0.0	0.0	0.0	0.0	0.0	0.0
EBITDA	(18.6)	(4.4)	(27.3)	(20.4)	(23.0)	(25.9)
<i>EBITDA margin</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>
Non operating expenses	0.0	0.0	0.0	0.0	0.0	0.0
Net Interest Income/Other	0.0	0.0	(0.2)	(0.2)	0.1	0.1
Interest expense	1.9	1.7	1.8	1.8	0.2	0.2
EBT	(20.4)	(6.1)	(29.4)	(22.4)	(23.0)	(25.9)
<i>EBT margin</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>
Provision for taxes	0.0	0.0	0.0	0.0	0.0	0.0
Net Income	(20.4)	(6.1)	(29.4)	(22.4)	(23.0)	(25.9)
Participation of preferred stock	(0.4)	(0.4)	0.0	0.0	0.0	0.0
Net Income to common	(20.8)	(6.5)	(29.4)	(22.4)	(23.0)	(25.9)
<i>net margin</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>
NoSH	1.3	1.3	18.1	18.5	22.0	22.5
EPS - basic	(16.15)	(4.99)	(1.62)	(1.21)	(1.05)	(1.15)
EPS - diluted	(16.15)	(4.99)	(1.62)	(1.21)	(1.05)	(1.15)

Source: SEC filings and ROTH Capital Partners estimates

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Quarterly P&L

	Q1'14A	Q2'14A	H1'14A	Q3'14E	9M'14E	Q4'14E	FY'14E	Q1'15E	Q2'15E	H1'15E	Q3'15E	9M'15E	Q4'15E	FY'15E
Licensing and R&D revenue	1.61	1.24	2.85	2.00	4.85	1.45	6.3	1.20	1.70	2.90	1.20	4.10	2.52	6.6
Milestone revenue	0.00	0.00	0.00	0.00	2.00	0.00	2.0	0.00	0.00	0.00	4.00	4.00	8.00	12.0
Product and Royalties	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Other revenues	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Revenues	1.61	1.24	2.85	2.00	6.85	1.45	8.3	1.20	1.70	2.90	5.20	8.10	10.52	18.6
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Gross Profit	1.61	1.24	2.85	2.00	6.85	1.45	8.3	1.20	1.70	2.90	5.20	8.10	10.52	18.6
Gross margin	nm	nm	nm	nm	nm	nm	100%	nm	nm	nm	nm	nm	nm	100%
G&A	2.54	2.72	5.26	2.83	8.09	2.91	11.0	2.93	2.95	5.88	3.01	8.89	3.04	11.9
R&D	5.59	6.24	11.84	6.37	18.21	6.42	24.6	6.48	6.54	13.02	6.85	19.87	7.21	27.1
Other op ex	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
EBITDA	(6.5)	(7.7)	(14.2)	(7.2)	(19.4)	(7.9)	(27.3)	(8.2)	(7.8)	(16.0)	(4.7)	(20.7)	0.3	(20.4)
EBITDA margin							nm							nm
Non operating expenses	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Net Interest Income/Other	(0.06)	0.00	(0.06)	(0.06)	(0.12)	(0.13)	(0.2)	(0.04)	(0.04)	(0.08)	(0.04)	(0.12)	(0.04)	(0.2)
Interest expense	0.43	0.26	0.70	0.35	1.05	0.76	1.8	0.43	0.44	0.87	0.45	1.32	0.48	1.8
EBT	(7.0)	(8.0)	(15.0)	(7.6)	(20.6)	(8.8)	(29.4)	(8.7)	(8.3)	(17.0)	(5.2)	(22.1)	(0.3)	(22.4)
EBT margin							nm							nm
Provision for taxes	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Participation of preferred stock														
Net Income to common	(7.0)	(8.0)	(15.0)	(7.6)	(20.6)	(8.8)	(29.4)	(8.7)	(8.3)	(17.0)	(5.2)	(22.1)	(0.3)	(22.4)
net margin							nm							nm
NoSH	9.2	17.9	13.56	18.10	15.08	18.40	18.10	18.5	18.5	18.50	18.50	18.50	18.50	18.50
EPS - basic	(0.76)	(0.45)	(1.11)	(0.42)	(1.37)	(0.48)	(1.62)	(0.47)	(0.45)	(0.92)	(0.28)	(1.19)	(0.01)	(1.21)

Source: SEC filings and ROTH Capital Partners estimates

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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 10/13/14	
			Count	Percent
Buy [B]	195	81.25	116	59.49
Neutral [N]	27	11.25	11	40.74
Sell [S]	1	0.42	0	0
Under Review [UR]	16	6.67	8	50.00

Our rating system attempts to incorporate industry, company and/or overall market risk and volatility. Consequently, at any given point in time, our investment rating on a stock and its implied price movement may not correspond to the stated 12-month price target.

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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