

Healthcare: BioPharmaceuticals

Concert Pharmaceuticals, Inc. | CNCE - \$13.20 - NASDAQ | Buy

Analysis of Sales/Earnings

Estimates Changed, Target Price Changed

Stock Data

52-Week Low - High	\$7.12 - \$16.26
Shares Out. (mil)	18.01
Mkt. Cap.(mil)	\$237.8
3-Mo. Avg. Vol.	184,509
12-Mo.Price Target	\$21.00
Cash (mil)	\$89.9
Tot. Debt (mil)	\$9.1

EPS \$

Yr Dec	—2013—	—2014E—		—2015E—	
		Curr	Prev	Curr	Prev
1Q	-	(0.76)A	(0.76)A	(0.34)E	(0.47)E
2Q	-	(0.45)A	(0.45)A	(0.35)E	(0.45)E
3Q	-	(0.43)A	(0.42)E	(0.37)E	(0.28)E
4Q	-	(0.57)E	(0.48)E	(0.39)E	(0.01)E
YEAR	(4.99)A	(1.84)E	(1.62)E	(1.45)E	(1.21)E
P/E	NM	NM	NM	NM	NM

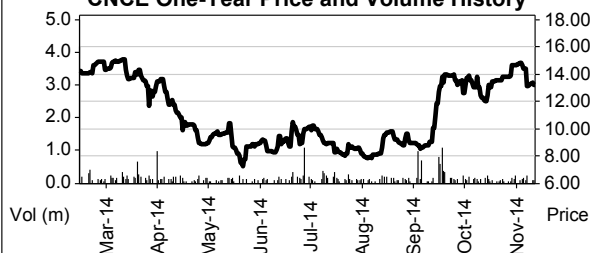
Concert's IPO was on February 9, 2014

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

Revenue (\$ millions)

Yr Dec	—2013—	—2014E—		—2015E—	
		Curr	Prev	Curr	Prev
1Q	-	1.6A	1.6A	5.4E	1.2E
2Q	-	1.2A	1.2A	5.4E	1.7E
3Q	-	4.4A	2.0E	5.4E	5.2E
4Q	-	2.0E	1.5E	5.4E	10.5E
YEAR	25.4A	9.3E	8.3E	21.7E	18.6E

CNCE One-Year Price and Volume History



CNCE: Partner News Flow Drivers and '354 Delay; Target to \$21

Concert announced a delay to the start of the CTP-354 Phase II program based on an undisclosed toxicity signal in a 3-month animal model. The company anticipates a six month or more delay as it defines the issue more clearly and any potential impact to '354's clinical path forward. We are lowering our price target to \$21 from \$28 based on lack of visibility on potential outcomes.

Event

CNCE reported 3Q14 results, posting EPS of (\$0.43) compared with our estimate of (\$0.42) and consensus of (\$0.49). The company ended the quarter with \$89.9 million in cash. Concert announced that it identified an undisclosed toxicity signal for CTP-354 in a 3-month animal model. Two animal models were being conducted and management did not disclose which species saw the signal. This signal is now delaying the start of the Phase II program. The company is projecting six months or more to fully understand the signal as it will be questioning areas such as 1) is it specific to the undisclosed species, 2) what are the metabolite effects and 3) how will the FDA react to the ongoing discussions and sharing of data with respect to the clinical path forward (i.e. will it go on clinical hold?)

Impact

It is encouraging that Concert's pipeline is broad with both internal and partnered product candidates to help mitigate some of the risks such as seen with today's issues with CTP-354. We need to take a cautious approach at this point with regard to '354 based primarily now on lack of visibility of potential timelines and outcomes in moving the drug forward. Regarding CTP-499, the company will begin discussing plans with the FDA for a Special Protocol Assessment by year end, which we project could be granted in 1Q15. Recall the company is looking to partner this drug and we believe a granted SPA would be a significant boost to these ongoing discussions. Avanir (AVNR-NC) will be seeking an end-of-Phase II meeting request for AVP-786. Jazz (JAZZ-NC) will announce Phase I safety data for JZP-386 by year end. Concert will complete the Phase I program for CTP-730 in 2015, at which point Celgene (CELG-NC) will take over the program.

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: \$13.12 at 10:40am ET on 11/12/14.

VALUATION

We maintain our Buy rating but are lowering our price target to \$21 from \$28 based on lack of visibility on timelines and potential outcomes for CTP-354. The primary changes to our valuation model revolve around CTP-354: 1) change projected launch year from 2019 to 2020 and 2) lower projected chance of success from 15% to 5%, which we will reassess following future updates on the drug.

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	7.3	7.7	8.4	9.3
Milestone revenue	1.5	2.0	2.0	14.0	15.4	16.9
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	9.3	21.7	23.8	26.2
CoGS	0.0	0.0	0.0	0.0	0.0	0.0
Gross Profit	12.8	25.4	9.3	21.7	23.8	26.2
<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	12.3	15.4	16.9	18.6
R&D	24.2	21.8	28.3	31.2	34.9	39.1
Other op ex	0.0	0.0	0.0	0.0	0.0	0.0
EBIT	(18.6)	(4.4)	(31.3)	(24.8)	(28.0)	(31.4)
<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)	(31.3)	(24.8)	(28.0)	(31.4)
<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)	(33.3)	(26.8)	(28.0)	(31.5)
<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)	(33.3)	(26.8)	(28.0)	(31.5)
Participation of preferred stock	(0.4)	(0.4)	0.0	0.0	0.0	0.0
Net Income to common	(20.8)	(6.5)	(33.3)	(26.8)	(28.0)	(31.5)
<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)	(1.84)	(1.45)	(1.27)	(1.40)
EPS - diluted	(16.15)	(4.99)	(1.84)	(1.45)	(1.27)	(1.40)

Source: SEC filings and ROTH Capital Partners estimates

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Quarterly P&L

	Q1'14A	Q2'14A	H1'14A	Q3'14A	9M'14A	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	2.42	5.27	2.03	7.3	1.93	1.93	3.85	1.93	5.78	1.89	7.7
Milestone revenue	0.00	0.00	0.00	2.00	2.00	0.00	2.0	3.50	3.50	7.00	3.50	10.50	3.50	14.0
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	4.42	7.27	2.03	9.3	5.43	5.43	10.85	5.43	16.28	5.39	21.7
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	4.42	7.27	2.03	9.3	5.43	5.43	10.85	5.43	16.28	5.39	21.7
Gross margin	nm	nm	nm	nm	nm	nm	100%	nm	nm	nm	nm	nm	nm	100%
G&A	2.54	2.72	5.26	3.46	8.71	3.57	12.3	3.61	3.74	7.35	3.89	11.24	4.11	15.4
R&D	5.59	6.24	11.84	8.57	20.41	7.92	28.3	7.62	7.74	15.36	7.82	23.18	7.98	31.2
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)	(7.6)	(21.9)	(9.5)	(31.3)	(5.8)	(6.1)	(11.9)	(6.3)	(18.1)	(6.7)	(24.8)
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)	0.00	(0.06)	(0.19)	(0.2)	(0.04)	(0.04)	(0.08)	(0.04)	(0.12)	(0.04)	(0.2)
Interest expense	0.43	0.26	0.70	0.22	0.92	0.88	1.8	0.43	0.44	0.87	0.45	1.32	0.48	1.8
EBT	(7.0)	(8.0)	(15.0)	(7.8)	(22.8)	(10.5)	(33.3)	(6.3)	(6.5)	(12.8)	(6.8)	(19.6)	(7.2)	(26.8)
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)	(7.8)	(22.8)	(10.5)	(33.3)	(6.3)	(6.5)	(12.8)	(6.8)	(19.6)	(7.2)	(26.8)
net margin							nm							nm
NoSH	9.2	17.9	13.56	18.10	15.07	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)	(0.43)	(1.51)	(0.57)	(1.84)	(0.34)	(0.35)	(0.69)	(0.37)	(1.06)	(0.39)	(1.45)

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 11/12/14	
			Count	Percent
Buy [B]	194	79.84	115	59.28
Neutral [N]	31	12.76	12	38.71
Sell [S]	1	0.41	0	0
Under Review [UR]	16	6.58	9	56.25

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.

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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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