

## Healthcare: BioPharmaceuticals

# Concert Pharmaceuticals, Inc. | CNCE - \$15.65 - NASDAQ | *Buy*

### Company Update

Estimates Changed, Target Price Changed

#### Stock Data

52-Week Low - High	\$7.12 - \$15.84
Shares Out. (mil)	18.19
Mkt. Cap.(mil)	\$284.6
3-Mo. Avg. Vol.	139,066
12-Mo.Price Target	\$19.00
Cash (mil)	\$79.2
Tot. Debt (mil)	\$9.1

#### EPS \$

Yr Dec	—2013—	—2014—		—2015E—	
		Curr	Prev	Curr	Prev
1Q	-	(0.76)A	(0.76)A	(0.28)E	(0.34)E
2Q	-	(0.45)A	(0.45)A	(0.32)E	(0.35)E
3Q	-	(0.43)A	(0.43)A	(0.35)E	(0.37)E
4Q	-	(0.48)A	(0.57)E	(0.44)E	(0.39)E
YEAR	(4.99)A	(2.00)A	(1.84)E	(1.39)E	(1.45)E
P/E	NM	NM	NM	NM	NM

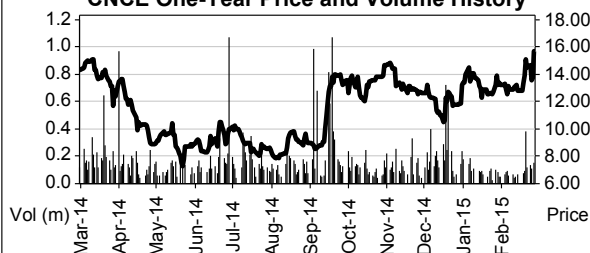
Concert's IPO was on February 9, 2014

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

#### Revenue (\$ millions)

Yr Dec	—2013—	—2014—		—2015E—	
		Curr	Prev	Curr	Prev
1Q	-	1.6A	1.6A	5.4E	5.4E
2Q	-	1.2A	1.2A	5.4E	5.4E
3Q	-	4.4A	4.4A	5.4E	5.4E
4Q	-	1.3A	2.0E	4.6E	5.4E
YEAR	25.4A	8.6A	9.3E	20.9E	21.7E

#### CNCE One-Year Price and Volume History



## CNCE: FY14 Results; Partnered Programs Progress; Tweaking Target to \$19

CNCE reported 2014 results, reporting EPS of (\$2.00) vs. our estimate of (\$1.84) and a consensus of (\$1.99). CNCE revenues were \$8.6 million vs. our estimate of \$9.3 million and a consensus of \$8.7 million. CNCE ended the quarter with \$79.2 million in cash, which CNCE expects to fund operations into 2H16. The company expects to receive \$14 million in milestone payments this year. Reiterate Buy but lowering target to \$19 from \$21.

### Event

CNCE also provided updates on pipeline developments. Partner Avanir/Otsuka (TYO:4768-NC) will engage the FDA with regards to the planned Phase III study of AVP-786 for treatment of agitation in Alzheimer's disease. CNCE began negotiations for SPA protocol of CTP-499 with the FDA, with expectations to finalize them this year so as to inform next steps. Data from the Phase I study of JZP-386 for narcolepsy is expected in 2Q15, at which point partner Jazz (JAZZ-NC) and CNCE will analyze data and decide on how to progress into Phase II. CNCE expects to complete the Phase I of CTP-730 in inflammatory disease upon which they will be entitled to milestone development payment from partner Celgene (CELG-NC). CNCE is carrying on with non-clinical studies of CTP-354 following adverse events observed in one species and does not expect to proceed into Phase II this year. CNCE announced its plans to advance deuterated ivacaftor into the clinic in 1H15. The company aims to assess two analogs of the molecule in cystic fibrosis patients in a single and multiple ascending dose study.

### Impact

We're encouraged by the progress made in the partnered programs and believe focus this year should be placed on them, with data expected and study initiations expected in 2015 and 2016. We look forward to learning the outcome of Avanir's discussions with FDA regarding the potential Phase III as this would represent CNCE's most advanced program. As CNCE deals with CTP-354's uncertain future, we're encouraged by the advancement of ivacaftor into the clinic. We believe that assessment of two analogs increases chances of finding the optimal molecule for later clinical stages. Ivacaftor has the potential to act alone and be combined with other cystic fibrosis transmembrane conductance regulator (CFTR) to improve efficacy.

### 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: \$14.99 at 10:12am ET on 2/27/15.

## VALUATION

We reiterate our Buy rating but are lowering our price target to \$19 from \$21 based on removal of CTP-354 from our projections.

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)

<b>Profit &amp; Loss</b>	<b>2012A</b>	<b>2013A</b>	<b>2014A</b>	<b>2015E</b>	<b>2016E</b>	<b>2017E</b>
Licensing and R&D revenue	11.3	23.4	6.6	6.9	7.6	8.4
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
<b>Revenues</b>	<b>12.8</b>	<b>25.4</b>	<b>8.6</b>	<b>20.9</b>	<b>23.0</b>	<b>25.3</b>
CoGS	0.0	0.0	0.0	0.0	0.0	0.0
<b>Gross Profit</b>	<b>12.8</b>	<b>25.4</b>	<b>8.6</b>	<b>20.9</b>	<b>23.0</b>	<b>25.3</b>
<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	11.7	14.6	16.1	17.7
R&D	24.2	21.8	27.5	30.2	33.8	37.9
Other op ex	0.0	0.0	0.0	0.0	0.0	0.0
<b>EBIT</b>	<b>(18.6)</b>	<b>(4.4)</b>	<b>(30.6)</b>	<b>(23.9)</b>	<b>(26.9)</b>	<b>(30.3)</b>
<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
<b>EBITDA</b>	<b>(18.6)</b>	<b>(4.4)</b>	<b>(30.6)</b>	<b>(23.9)</b>	<b>(26.9)</b>	<b>(30.3)</b>
<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	0.0	(0.2)	0.1	0.1
Interest expense	1.9	1.7	1.1	1.8	0.2	0.2
<b>EBT</b>	<b>(20.4)</b>	<b>(6.1)</b>	<b>(31.7)</b>	<b>(25.9)</b>	<b>(27.0)</b>	<b>(30.4)</b>
<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
<b>Net Income</b>	<b>(20.4)</b>	<b>(6.1)</b>	<b>(31.7)</b>	<b>(25.9)</b>	<b>(27.0)</b>	<b>(30.4)</b>
Participation of preferred stock	(0.4)	(0.4)	(0.1)	0.0	0.0	0.0
<b>Net Income to common</b>	<b>(20.8)</b>	<b>(6.5)</b>	<b>(31.7)</b>	<b>(25.9)</b>	<b>(27.0)</b>	<b>(30.4)</b>
<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	15.8	18.6	22.0	22.5
<b>EPS - basic</b>	<b>(16.15)</b>	<b>(4.99)</b>	<b>(2.00)</b>	<b>(1.39)</b>	<b>(1.23)</b>	<b>(1.35)</b>
<b>EPS - diluted</b>	<b>(16.15)</b>	<b>(4.99)</b>	<b>(2.00)</b>	<b>(1.39)</b>	<b>(1.23)</b>	<b>(1.35)</b>

Source: SEC filings and ROTH Capital Partners estimates

Joseph Pantginis, Ph.D. jpantginis@roth.com

## Quarterly P&amp;L

	Q1'14A	Q2'14A	H1'14A	Q3'14A	9M'14A	Q4'14A	FY'14A	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	1.31	6.6	1.93	1.93	3.85	1.93	5.78	1.13	6.9
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
<b>Revenues</b>	<b>1.61</b>	<b>1.24</b>	<b>2.85</b>	<b>4.42</b>	<b>7.27</b>	<b>1.31</b>	<b>8.6</b>	<b>5.43</b>	<b>5.43</b>	<b>10.85</b>	<b>5.43</b>	<b>16.28</b>	<b>4.63</b>	<b>20.9</b>
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
<b>Gross Profit</b>	<b>1.61</b>	<b>1.24</b>	<b>2.85</b>	<b>4.42</b>	<b>7.27</b>	<b>1.31</b>	<b>8.6</b>	<b>5.43</b>	<b>5.43</b>	<b>10.85</b>	<b>5.43</b>	<b>16.28</b>	<b>4.63</b>	<b>20.9</b>
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	2.99	11.7	3.13	3.38	6.51	3.89	10.40	4.23	14.6
R&D	5.59	6.24	11.84	8.57	20.41	7.07	27.5	7.19	7.42	14.61	7.66	22.27	7.95	30.2
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
<b>EBITDA</b>	<b>(6.5)</b>	<b>(7.7)</b>	<b>(14.2)</b>	<b>(7.6)</b>	<b>(21.9)</b>	<b>(8.7)</b>	<b>(30.6)</b>	<b>(4.9)</b>	<b>(5.4)</b>	<b>(10.3)</b>	<b>(6.1)</b>	<b>(16.4)</b>	<b>(7.5)</b>	<b>(23.9)</b>
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)	0.08	0.0	(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	0.18	1.1	0.31	0.48	0.79	0.42	1.21	0.59	1.8
<b>EBT</b>	<b>(7.0)</b>	<b>(8.0)</b>	<b>(15.0)</b>	<b>(7.8)</b>	<b>(22.8)</b>	<b>(8.9)</b>	<b>(31.7)</b>	<b>(5.2)</b>	<b>(5.9)</b>	<b>(11.1)</b>	<b>(6.6)</b>	<b>(17.7)</b>	<b>(8.2)</b>	<b>(25.9)</b>
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														
<b>Net Income to common</b>	<b>(7.0)</b>	<b>(8.0)</b>	<b>(15.0)</b>	<b>(7.8)</b>	<b>(22.8)</b>	<b>(8.9)</b>	<b>(31.7)</b>	<b>(5.2)</b>	<b>(5.9)</b>	<b>(11.1)</b>	<b>(6.6)</b>	<b>(17.7)</b>	<b>(8.2)</b>	<b>(25.9)</b>
net margin							nm							nm
NoSH	9.2	17.9	13.56	18.10	15.07	18.30	15.84	18.6	18.6	18.60	18.60	18.60	18.60	18.60
<b>EPS - basic</b>	<b>(0.76)</b>	<b>(0.45)</b>	<b>(1.11)</b>	<b>(0.43)</b>	<b>(1.51)</b>	<b>(0.48)</b>	<b>(2.00)</b>	<b>(0.28)</b>	<b>(0.32)</b>	<b>(0.60)</b>	<b>(0.35)</b>	<b>(0.95)</b>	<b>(0.44)</b>	<b>(1.39)</b>

Source: SEC filings and ROTH Capital Partners estimates

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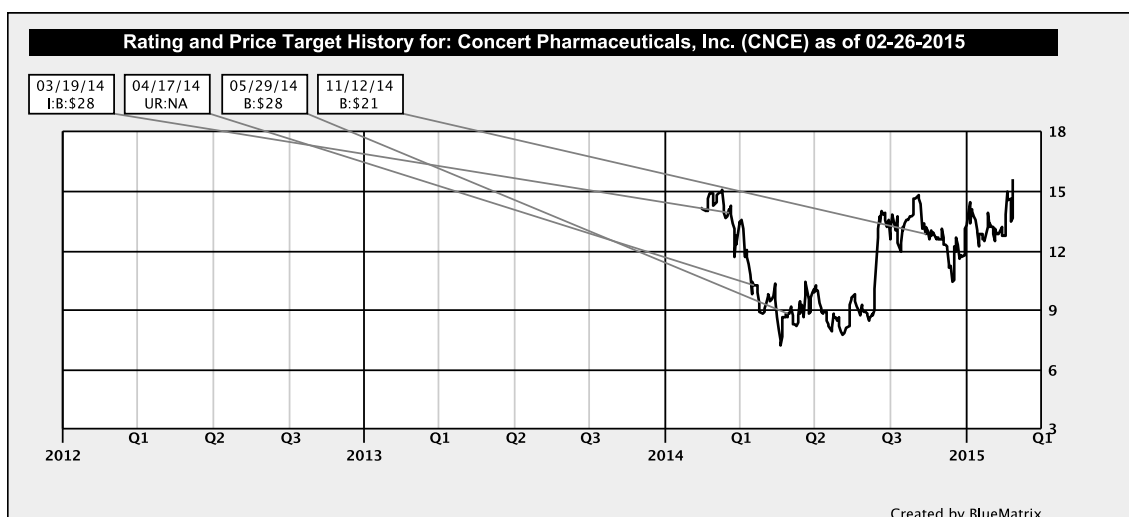
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On September 28, 2010, ROTH changed its rating system in order to replace the Hold rating with Neutral.

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 02/27/15	
			Count	Percent
Buy [B]	215	81.13	131	60.93
Neutral [N]	34	12.83	12	35.29
Sell [S]	0	0.00	0	0
Under Review [UR]	15	5.66	8	53.33

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**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.

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