

# Concert Pharmaceuticals, Inc. (CNCE)

Highlights Early Clinical Progress in 2Q14 Earnings Results

## MARKET DATA

Price	\$8.60
52-Week Range:	\$7.12 - \$16.26
Shares Out. (M):	17.9
Market Cap (\$M):	\$153.9
Average Daily Vol. (000):	137.0
Cash (M):	\$18
Cash/Share:	\$1.00
Enterprise Value (M):	\$52
Float (M):	16.2
LT Debt (M):	\$5

Source: Thomson Reuters and JMP Securities LLC

**MARKET OUTPERFORM** | Price: \$8.60 | Target Price: \$28.00

## INVESTMENT HIGHLIGHTS

**Concert Pharmaceuticals detailed development plans and current Phase I results for CTP-354, and discussed progress for CTP-499 and partnered programs; reiterate Market Outperform rating and \$28 price target based on DCF and SOTP valuation methodologies.** CNCE reported 2Q14 net loss of \$7.73MM, or EPS of (\$0.45) that was higher than the JMP estimate of (\$0.53), primarily on lower than anticipated operating expenses and higher total revenues. License revenue of \$1.24MM was higher than our estimate of \$0MM. Total operating expense of \$8.96MM was lower than our \$9.5MM estimate, comprising \$6.24MM of R&D expense (lower than our estimate of \$7.5MM) and \$2.72MM of SG&A expense (higher than our estimate of \$2MM). CNCE finished the quarter with \$101MM in cash, cash equivalents and short-term investments providing sufficient cash runway into 2016. A summary of 2Q14 actual results versus JMP estimates is shown in Figure 2. Incremental changes to our model reflecting 2Q14 results and calculated share count are summarized in Figure 3.

**Results from Phase I Multiple Ascending Dose Phase I trial of CTP-345 support advancement into spasticity indication.** CNCE initially plans to advance CTP-354, a deuterated subtype selective GABA<sub>A</sub> receptor antagonist, into Phase II clinical trials to treat spasticity in patients with spinal cord injury. The company discussed results from its Phase I trial covering two multiple-dose data points of 6mg at five hours and 6mg at 48 hours demonstrating receptor occupancy of up to 50%. We believe this information, coupled with the results previously reported in single-ascending Phase I trials, support the potential to achieve a clinical response at dosages that are below the threshold for adverse events. Unwanted sedative effects had previously been seen at doses of 20mg, reflective of receptor occupancy levels of up to 70-80%, while anti-spasticity effects are expected at receptor occupancy levels of 30% (as seen with other benzodiazepines). CTP-345 is easily hitting sustained plasma concentrations sufficient for these occupancy levels in the 6mg cohort for up to 48 hours after a single dose and additionally avoiding concentrations that would cause serious sedative effects. Also, Phase II plans for CTP-345 in spinal cord injury will include a three-dose trial design with the highest dose likely to be 12mg. The company stated its goal is to improve Ashcroft scores by 25-30%.

**FDA trial guidance gives CNCE optionality with CPT-499 Phase III trial design heading into SPA discussions.** During the call, the company reiterated the results from its successful FDA end-of-Phase II meeting where consideration would be given to a single multi-dose, placebo-controlled Phase III trial for approval, in contrast to initial expectations of two separate Phase III trials. Time-to-event analysis – a composite endpoint including a ≥50% increase in serum creatinine levels or progression to ESRD – will likely be confirmed as the approval endpoint. This inclusion of a rapidly assessable

FY DEC		2013A	2014E	2015E
Revenue (\$M)	1Q	--	\$1.6A	\$1.2
	2Q	\$24.0	\$1.2A	\$0.0
	3Q	\$24.0	\$0.0	\$0.0
	4Q	\$1.4	\$0.0	\$2.8
	<b>FY</b>	<b>\$25.4</b>	<b>\$2.8</b>	<b>\$2.0</b>
EPS	1Q	--	(\$0.76)A	--
	2Q	(\$0.01)	(\$0.45)A	--
	3Q	(\$0.01)	(\$0.65)	--
	4Q	(\$4.66)	(\$0.71)	--
	<b>FY</b>	<b>(\$4.99)</b>	<b>(\$2.20)</b>	<b>(\$2.39)</b>
Previous FY		NC	(\$2.27)	(\$1.81)

Source: Company reports and JMP Securities LLC

## STOCK PRICE PERFORMANCE



biomarker to support the responder analysis is highly encouraging from both a time and cost perspective, in our view. The potential incorporation of higher baseline UACR levels (as a predictor of more rapid disease progression) as inclusion criteria may also shorten the time to trial readout.

**Significant upside potential for this deuterated drug company.** We remain bullish on Concert Pharmaceuticals shares seeing several opportunities for growth over the next several years in addition to CTP-499 including: CTP-354, JZP-386, AVP-786 and CTP-730. In our opinion, the company's DCE Platform® has all the requisite ingredients to allow CNCE to become one of the leading developers of unique, deuterated-therapeutic compounds. We reiterate our Market Outperform rating and \$28 price target for CNCE shares based on our DCF and SOTP valuation methodologies.

**FIGURE 1. Upcoming CNCE Milestones**

Timing	Drug	Milestones
3Q14	CTP-354	Phase I MAD continuation
1H15	CTP-354	Phase II clinical trial in MS and SCI expected to begin
2H14	AVP-786	Phase II trial for treatment of resistant major depressive disorder
2014	JZP-386	First Phase I in-human trial
2014	CTP-730	Clinical trials expected to begin

Source: CNCE company presentations

**FIGURE 2. 2Q14 CNCE Results vs. JMP Estimates**

Concert Pharmaceuticals (CNCE) Abridged Income Statement (\$ MM)	2Q14 Results		
	JMP Estimate	Actual	Variance (JMP vs. Actual)
<b>Total Revenues</b>	-	1.24	
License revenue	-	1.24	
Milestone revenue	-	-	
<b>Operating Expenses</b>	9.50	8.96	(0.5)
Research and development	7.50	6.24	(1.3)
General and administrative	2.00	2.72	0.7
<b>Operating income (loss)</b>	(9.50)	(7.73)	1.8
<b>Other income (expense)</b>	0.00	(0.26)	(0.26)
			0.00
<b>Pretax income (loss)</b>	(9.50)	(7.99)	1.51
<b>Net income (loss)</b>	(9.50)	(7.99)	1.51
<b>EPS Calculations</b>			
<b>Basic EPS</b>	\$ (0.53)	\$ (0.45)	\$ 0.08
<b>Diluted EPS</b>	\$ (0.53)	\$ (0.45)	\$ 0.08
Basic shares outstanding	17.890	17.809	(0.081)
Diluted shares outstanding	17.890	17.809	(0.081)

Source: JMP Securities LLC and Company Reports

**FIGURE 3. Changes to Our Model**

Concert Pharmaceuticals (CNCE) (\$ MM)	3Q14E		4Q14E		FY 2014E		FY 2015E		FY 2015E	
	Old	New	Old	New	Old	New	Old	New	Old	New
License revenue	0.0	0.0	0.0	2.8	0.0	2.8	0.0	0.0	0.0	0.0
Milestone revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other										
<b>Total Revenues</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>2.8</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>COGS</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>
<b>Gross Profit</b>	<b>-</b>	<b>0.0</b>	<b>-</b>	<b>0.0</b>	<b>1.61</b>	<b>2.85</b>	<b>2.00</b>	<b>2.00</b>	<b>2.00</b>	<b>2.00</b>
<b>Operating Expenses</b>	<b>11.5</b>	<b>11.5</b>	<b>12.5</b>	<b>12.5</b>	<b>41.6</b>	<b>41.1</b>	<b>51.0</b>	<b>51.0</b>	<b>64.6</b>	<b>64.6</b>
Research and development	9.0	9.0	9.5	9.5	31.6	30.3	39.5	39.5	51.3	51.3
General and administrative	2.5	2.5	3.0	3.0	10.0	10.8	11.5	11.5	13.3	13.3
<b>Operating income (loss)</b>	<b>(11.5)</b>	<b>(11.5)</b>	<b>(12.5)</b>	<b>(12.5)</b>	<b>(40.0)</b>	<b>(38.2)</b>	<b>(49.0)</b>	<b>(49.0)</b>	<b>(62.6)</b>	<b>(62.6)</b>
<b>Other income (expense)</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
Interest income	0.0	0.0	0.0	0.0	-	-	-	-	-	-
<b>Pretax income</b>	<b>(11.5)</b>	<b>(11.5)</b>	<b>(12.5)</b>	<b>(12.5)</b>	<b>(40.0)</b>	<b>(38.2)</b>	<b>(49.0)</b>	<b>(49.0)</b>	<b>(62.6)</b>	<b>(62.6)</b>
<b>Net income</b>	<b>(11.5)</b>	<b>(11.5)</b>	<b>(12.5)</b>	<b>(12.5)</b>	<b>(40.4)</b>	<b>(38.9)</b>	<b>(49.0)</b>	<b>(49.0)</b>	<b>(62.6)</b>	<b>(62.6)</b>
<b>Basic EPS</b>	<b>(\$0.64)</b>	<b>\$ (0.65)</b>	<b>(\$0.70)</b>	<b>\$ (0.70)</b>	<b>(\$2.27)</b>	<b>\$ (2.20)</b>	<b>(\$2.41)</b>	<b>\$ (2.71)</b>	<b>(\$2.74)</b>	<b>\$ (1.11)</b>
<b>Diluted EPS</b>	<b>(\$0.64)</b>	<b>\$ (0.65)</b>	<b>(\$0.70)</b>	<b>\$ (0.70)</b>	<b>(\$2.27)</b>	<b>\$ (2.20)</b>	<b>(\$2.41)</b>	<b>\$ (2.71)</b>	<b>(\$2.74)</b>	<b>\$ (1.11)</b>
Basic shares outstanding	17.89	17.72	17.89	17.89	17.81	17.68	20.38	20.38	22.87	22.87
Diluted shares outstanding	17.89	17.72	17.89	17.89	17.81	17.68	20.38	20.38	22.87	22.87

Source: JMP Securities LLC and Company Reports

**FIGURE 4. Income Statement**

Income Statement (\$MM)	1Q14A	2Q14A	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
<b>Total Product Sales and Royalties</b>	0.0	0.0	0.0	0.0	0.0	2.0	2.0	8.0	64.4	156.1	341.6	546.0	852.3
License and research and development revenue	1.6	1.2			2.8								
Milestone Revenue	0.0				0.0								
<b>Total Revenue</b>	1.6	1.2	0.0	0.0	2.8	2.0	2.0	8.0	64.4	156.1	341.6	546.0	852.3
Cost of Goods Sold							0.0	0.0	2.2	7.8	17.5	28.2	37.7
<b>Gross Profit</b>	1.6	1.2	0.0	0.0	2.8	2.0	2.0	8.0	62.2	148.4	324.1	517.9	814.5
<b>Operating Expenses:</b>													
Research and Development	5.6	6.2	9.0	9.5	30.3	37.9	49.3	56.7	63.5	68.6	74.1	80.0	86.4
General and administrative	2.5	2.7	2.5	3.0	10.8	12.4	14.2	21.3	26.7	30.7	33.1	35.8	38.6
<b>Total operating expenses</b>	8.1	9.0	11.5	12.5	41.1	50.3	63.5	78.0	90.2	99.2	107.2	115.8	125.0
<b>Operating income (loss)</b>	(6.5)	(7.7)	(11.5)	(12.5)	(38.2)	(48.3)	(61.5)	(70.0)	(27.9)	49.1	216.9	402.1	689.5
<b>Other income (expense):</b>													
Investment income	0.0	0.0											
Interest expense	(0.4)	-0.3											
Payment to GSK									(2.5)				
<b>Total other income, net</b>	(0.4)	(0.3)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Other comprehensive loss:</b>													
Unrealized loss on investments	0.0												
<b>Change in fair value of preferred stock warrant liability</b>													
<b>Foreign currency transaction gain (loss)</b>													
<b>Pretax income (loss)</b>	(6.9)	(8.0)	(11.5)	(12.5)	(38.9)	(48.3)	(61.5)	(70.0)	(27.9)	49.1	216.9	402.1	689.5
Income tax benefit (provision)					0.0	0.0	0.0	0.0	0.0	0.0	(32.5)	(80.4)	(172.4)
Tax Rate					0%	0%	0%	0%	0%	0%	15%	20%	25%
<b>Comprehensive income (loss)</b>	(6.9)	(8.0)	(11.5)	(12.5)	(38.9)	(48.3)	(61.5)	(70.0)	(27.9)	49.1	184.4	321.7	517.1
<b>Accretion of redeemable convertible preferred stock</b>	0.06												
<b>Net income (loss) attributable to common stockholders</b>	(6.9)	(8.0)	(11.5)	(12.5)	(38.9)	(48.3)	(61.5)	(70.0)	(27.9)	49.1	184.4	321.7	517.1
<b>Basic EPS to common shareholders</b>	\$ (0.76)	\$ (0.45)	\$ (0.65)	\$ (0.71)	\$ (2.20)	\$ (2.39)	\$ (2.71)	\$ (3.09)	\$ (1.11)	\$ 1.78	\$ 6.67	\$ 10.68	\$ 15.86
<b>Diluted EPS to common shareholders</b>	\$ (0.76)	\$ (0.45)	\$ (0.65)	\$ (0.71)	\$ (2.20)	\$ (2.39)	\$ (2.71)	\$ (3.09)	\$ (1.11)	\$ 1.78	\$ 6.70	\$ 10.73	\$ 15.92
Basic shares outstanding	9.2	17.8	17.7	17.7	17.7	20.2	22.7	22.7	25.2	27.7	27.6	30.1	32.6
Diluted shares outstanding	9.2	17.8	17.7	17.7	17.7	20.2	22.7	22.7	25.2	27.5	27.5	30.0	32.5

Source: JMP Securities LLC and Company Reports

## Company Description

Concert Pharmaceuticals is a clinical stage biopharmaceutical company seeking to discover and develop novel small molecule drugs through the improvement of existing drugs and clinical candidates, via deuterium substitution. Deuterium substitution can lead to drugs with superior pharmacokinetic or metabolic properties, improved clinical safety, tolerability, and/or efficacy. Deuterated analogs of approved drugs may also be able to enjoy expedited pathways to FDA approval. The firm currently has a trio of clinical-stage product candidates, including CTP-354, for spasticity associated with multiple sclerosis, CTP-499 for diabetic kidney disease, and AVP-786 for neurologic and psychiatric disorders, through a collaboration with Avanir Pharmaceuticals. The firm is also in ongoing collaboration with Celgene Corporation for deuterated compounds, including CTP-730 for inflammatory diseases, and with Jazz Pharmaceuticals for JZP-386, the active ingredient in Xyrem, which is in pre-clinical development for narcolepsy.

## Investment Risks

**Clinical risk.** Products undergoing clinical trials may have serious safety concerns, lack efficacy, or fail to demonstrate statistical significance, any of which would preclude them from continuing clinical development and eventual commercialization. If the company's Deuterated Chemical Entity (DCE) Platform® technology is not proven, there will likely be downside to the share price as well as risk to the viability of the company. In addition, CNCE has not yet demonstrated an ability to successfully conduct a large-scale pivotal clinical trial, obtain marketing approvals, manufacture a commercial scale product, or to conduct the sales and marketing activities necessary for successful product commercialization.

**Collaboration risk.** CNCE will depend upon collaborations with third parties for the development and commercialization of some of the company's product candidates and expects to continue to do so in the future. CNCE's business model relies on making use of its DCE platform to partner with Pharmaceutical and Biotechnology companies to improve existing drug candidates. CNCE's prospects with respect to those product candidates will depend in significant part on the success of those collaborations.

**Manufacturing risk.** CNCE is a clinical-stage biopharmaceutical company applying its extensive knowledge of deuterium chemistry to discover and develop novel small molecule drugs. Because there are limited sources of deuterium, CNCE and its collaborators are exposed to a number of risks and uncertainties associated with the company's deuterium supply. In particular, manufacturing processes for many drug candidates, including those for CTP-499 and certain others, are projected to require large quantities of deuterium for late-stage clinical trials and for commercialization. Consequently, any adverse impact on CNCE's ability to obtain deuterium oxide could have a significant impact on the company's ability to develop or commercialize product candidates. Similarly, CNCE's collaborators will also need to obtain supplies of deuterium and will be subject to risks and requirements in connection with sourcing deuterium similar to the ones the company faces.

**Intellectual property risk.** As of December 31, 2013, CNCE held 100 issued patents worldwide, including 50 issued patents in the United States. CNCE's patents and patent applications for its lead programs are set to expire between 2028 and 2034. The company may be sued by a competitor on patent infringement or have to undergo litigation that would incur substantial fees. The company could lose a case, which would make it susceptible to generic risk.

**Financial risk.** Concert Pharmaceuticals currently derives revenue from research and development funding and from license or collaboration agreements. The company is not yet profitable and has a history of operating losses that are expected to continue in the near future. Developing pharmaceutical products, including conducting pre-clinical studies and clinical trials, is a time-consuming, expensive, and uncertain process that takes years to complete. CNCE needs to continue financing clinical trials through to completion and it may be unable to secure additional funding, forcing it to delay, reduce, or eliminate product development programs or commercialization efforts. The company has incurred significant losses since its inception and should expect losses to occur for the next several years.

**Competitive risk.** CNCE faces competition from marketers of other treatments for the indications that it seeks to develop drugs for, including major pharmaceutical firms and biotech firms. The firm's products will also have to compete with existing treatments that have already become generically available (e.g., CTP-354 will have to compete with other spasticity drugs, such as baclofen, tizanidine, diazepam, and dantrolene).

**Regulatory risk.** CNCE or its collaborators, may, in some instances, be able to secure clearances from the FDA or comparable foreign regulatory authorities to use expedited development pathways. If it is unable to obtain such clearances, CNCE or its collaborators may be required to conduct additional pre-clinical studies or clinical trials beyond those contemplated, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals.

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JMP Securities was manager or co-manager of a public offering of securities for Concert Pharmaceuticals, Inc. (CNCE) in the past 12 months, and received compensation for doing so.

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Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.

Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months.

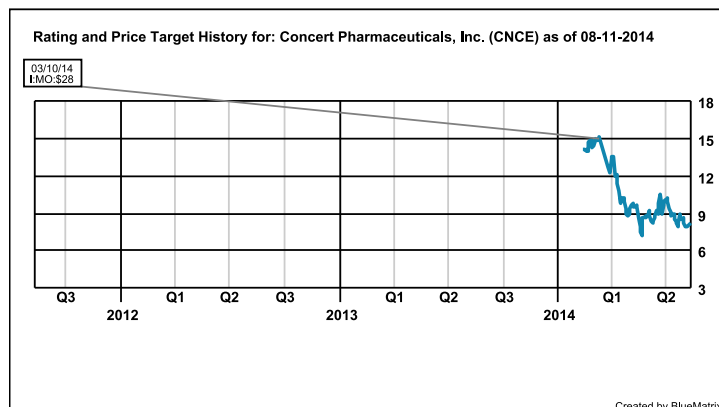
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

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JMP Rating	Regulatory Equivalent	# Co's Under Coverage	% of Total	Regulatory Equivalent	# Co's Under Coverage	% of Total	# Co's Receiving IB Services in Past 12 Months	% of Co's With This Rating
MARKET OUTPERFORM	Buy	267	60.14%	Buy	267	60.14%	97	36.33%
MARKET PERFORM	Hold	137	30.86%	Hold	137	30.86%	18	13.14%
MARKET UNDERPERFORM	Sell	4	0.90%	Sell	4	0.90%	0	0%
COVERAGE IN TRANSITION		36	8.11%		36	8.11%	0	0%
TOTAL:		444	100%		444	100%	115	25.90%

### Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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