

Equity Research

Concert Pharmaceuticals, Inc.

CNCE: Q3 2014--Preclinical Signal Puts '354 On Pause
Partnerships Progressing Well

Outperform / V

Sector: Biotechnology

Market Weight

• **Summary:** On November 12, before the open, CNCE reported Q3 2014 earnings, and disclosed it was delaying the start of its planned phase II trials of CTP-354 for spasticity associated with spinal cord injury and multiple sclerosis, based on preliminary data from an ongoing three-month preclinical toxicology study. The company remains enthusiastic about '499 and recent data continues to show its activity in chronic kidney disease, and the JAZZ, AVNR, and CELG partnered programs continue to advance well. Overall, today's news comes as a setback for '354, Concert's lead proprietary program, and in our view its path forward is now much less clear; still, given that drug's early stage, our estimated probability of success had already been conservative, and we believe the company's diversification across other proprietary ('499) and large-opportunity partnered programs along with its deuterium chemistry platform should help limit impact if '354 were ultimately discontinued. Adjusting 2014/2015 EPS estimates to -\$2.16/-1.41 from -\$2.07/-1.09. Maintaining valuation range at \$15-17, with delay and reduction of probability of success for '354 offset by inclusion of potential future royalties from the AVNR-partnered '786 in Alzheimer's agitation following positive recently-reported ph.II results.

• **Financials:** Concert reported a net loss of \$7.83MM, or EPS of -\$0.43, and ended Q3 with cash and equivalents of \$89.9MM. R&D expenses increased for the quarter to \$8.6MM from \$5.7MM a year earlier, due to increased spending for the phase I trial of JZP-386 in connection with the company's partnership with Jazz, and also from spending for phase I trials of CTP-354. We adjusted our R&D expense estimates for 2015 downward anticipating lower R&D spend in connection with the delayed start of the phase II trials of CTP-354, and pending further clarity on timing of that start. SG&A expenses also ticked higher, as CNCE begins to see higher auditing and reporting costs as a public company.

• *Continued on following page*

Valuation Range: \$15.00 to \$17.00

Our valuation range is based on applying a 30x multiple to our 2022 estimated EPS and discounting at 15%, blended with 6x multiple of 2022 estimated sales, and discounting 12%. Key risks, in our view, are failure of '354 and/or '499 to show efficacy in subsequent studies and regulatory hurdles in spasticity or CKD.

Investment Thesis:

We believe Concert's proprietary and partnered candidates, and drug deuteration platform, will generate long-term value.

Earnings Estimate Revised Down

EPS	2013A	2014E		2015E	
		Curr.	Prior	Curr.	Prior
Q1 (Mar.)	NE	(\$0.76) A	NC	NE	
Q2 (June)	NE	(0.45) A	NC	NE	
Q3 (Sep.)	NE	(0.43) A	(0.48)	NE	
Q4 (Dec.)	(4.66)	(0.63)	(0.50)	NE	
FY	(\$4.99)	(\$2.16)	(2.07)	(\$1.41)	(1.09)
CY	(\$4.99)	(\$2.16)		(\$1.41)	
FY P/EPS	NM	NM		NM	
Rev.(MM)	\$25,408	\$8,146		\$22,520	

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters
NA = Not Available, NC = No Change, NE = No Estimate, NM = Not Meaningful
V = Volatile, * = Company is on the Priority Stock List

Ticker	CNCE
Price (11/12/2014)	\$12.83
52-Week Range:	\$7-17
Shares Outstanding: (MM)	17.9
Market Cap.: (MM)	\$229.7
S&P 500:	2,038.25
Avg. Daily Vol.:	109,480
Dividend/Yield:	\$0.00/0.0%
LT Debt: (MM)	\$0.0
LT Debt/Total Cap.:	0.0%
ROE:	NM
3-5 Yr. Est. Growth Rate:	NM
CY 2014 Est. P/EPS-to-Growth:	NM
Last Reporting Date:	11/12/2014
	Before Open

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters

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All estimates/forecasts are as of 11/13/14 unless otherwise stated.

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Continued from Front-page Bullets

- **The company has put the brakes on initiating phase II studies for '354, pending further analysis and preclinical toxicology analysis of a safety signal seen.** Previously, CNCE had intended to initiate a phase II trial of '354 in spasticity associated with spinal cord injury by year-end 2014, and a second phase II in multiple-sclerosis-associated spasticity. Recall, a key competitive advantage for the drug was its enhanced pharmacokinetics from deuteration that led to a highly potent therapeutic without the sedating side effects typical of benzodiazepines. We understand the toxicity event described today occurred in one of the two animal species being studied in an ongoing three-month preclinical study of '354, which is a standard regulatory requirement for clinical development, and no similar events had previously been observed in the one-month toxicology study. With neither the nature of the toxicity nor the dose at which it occurred being disclosed, it is difficult to determine whether the drug poses safety risk to humans that could threaten the program entirely or whether this AE is isolated to one species and would just cause a delay. On the earnings call and in our discussion with the company afterwards, a time frame for resumption of clinical development was not disclosed, though once the company receives further reporting on details from its contract research vendor, likely 1Q15, appropriate studies can be planned to better characterize the toxicity. We assume the program will be set back by about a year, if it is able to resume.
- **CTP-499 and partnership programs remain on track.** Next steps for '499 include a special protocol assessment discussion with the FDA by year-end to move forward with a phase III, for which the company is seeking backing for from a partner. Additional data on improvement in inflammatory biomarkers to be presented on Friday, November 14 at the ASN's Kidney Week should help reinforce the anti-fibrotic potential of '499, and we believe the size of and unmet need in the chronic kidney disease market could be attractive for many potential commercial partners, though a pivotal program will require substantial investment from a partner. CNCE may also look for alternative smaller indications to advance the asset on their own. On partnerships, CNCE's partnership with AVNR is furthest along developmentally, with a phase II for treatment-resistant MDD due for completion by year-end, and a phase III for Alzheimer's indication pending an end of meeting phase II with the FDA, which could elicit further insight into FDA views on safety of deuterated compounds like '786. Completion of the ongoing phase I study of JZP-386, along with a JZP milestone for completion are due this quarter.

Upcoming Milestones

Product	Event	Timeline
CTP-354	Initiate ph.II trial in SCI spasticity patients	delayed, start TBD
	Initiate ph.II trial in MS spasticity patients	delayed, start TBD
	Report ph.II spasticity results	delayed, completion TBD
	Potentially initiate ph.III program	delayed, start TBD
	Complete 3-month non-clinical toxicology study	1Q15
CPT-499	SPA discussions with FDA	year-end 2014
	Sign partnership agreement	4Q14/2015
AVP-786	Ph.II for treatment-resistant MDD first patient enrollment	Sep-14
	Ph.II for treatment-resistant MDD completion	year-end 2014
	Ph.III for Alzheimer's agitation ('786 to replace '923)	2015
CTP-730	Ph.I single ascending dose study completion	4Q14
	Ph.I multiple ascending dose study initiation	2015
JZP-386	Ph.I study completion (with JZP milestone)	4Q14

Source: Company reports and Wells Fargo Securities, LLC estimates

Product Pipeline

Product (partner)	Indication/mechanism	Status
CTP-354	Spasticity, anxiety, pain; subtype selective GABA _A receptor modulator	Phase I
CTP-499	Diabetic nephropathy; multi-subtype selective inhibitor of phosphodiesterases	Phase II
AVP-786 (AVNR)	Neurologic and psychiatric disorders, depression; deuterium-substituted dextromethorphan analog plus low-dose quinidine	Entering phase II
JZP-386 (JZP)	Narcolepsy; deuterium-substituted Xyrem analog	Phase I
CTP-730 (CELG)	Inflammatory diseases	Entering phase I
JZP-386 (JZP)	Narcolepsy; deuterium-substituted Xyrem analog	Phase I
C-10068	Pain and seizures; deuterium-substituted dextromethorphan/ analog	Preclinical
d-ivacaftor	CF, COPD	Preclinical
d-praziquantel (NIH)	Parasitic diseases	Preclinical

Source: Company reports and Wells Fargo Securities, LLC

Concert Pharma (CNCE)
Statement of Operations (Income Statement)

	2012A	1Q A	2Q A	3Q A	4Q A	2013A	1Q A	2Q A	3Q A	4Q E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Revenues (1)																				
Revenues from CTP-354																	\$6,522	\$55,220	\$107,656	\$315,410
Royalties from sales of CTP-499																	\$35,289	\$56,517	\$84,650	\$113,968
Royalties from sales of AIVP-786																	\$35,801	\$54,372	\$76,115	\$101,196
Royalties from sales of JZP-366																	\$39,764	\$64,178	\$83,444	\$122,643
Milestones	\$1,500	\$2,000	\$0	\$0	\$0	\$2,000	\$0	\$0	\$2,000	\$0	\$2,000	\$14,000	\$30,000	\$15,000	\$30,000	\$70,000	\$0	\$63,000	\$52,000	\$0
License and research and development revenue	\$11,249	\$3,873	\$17,441	\$681	\$1,413	\$23,408	\$1,613	\$1,235	\$2,418	\$880	\$6,146	\$8,520	\$12,520	\$12,520	\$12,520	\$9,000	\$9,000	\$9,000	\$9,000	\$9,000
Total revenues, net	\$12,249	\$5,873	\$17,441	\$681	\$1,413	\$25,408	\$1,613	\$1,235	\$4,418	\$880	\$6,146	\$22,520	\$42,520	\$27,520	\$63,562	\$135,493	\$126,376	\$304,288	\$422,864	\$662,217
Expenses																				
Cost of goods sold	\$24,193	\$5,039	\$5,753	\$5,668	\$5,330	\$21,790	\$5,694	\$6,243	\$8,569	\$8,950	\$29,366	\$35,227	\$36,989	\$38,838	\$40,392	\$41,603	\$42,851	\$44,137	\$45,461	\$46,825
Research and development	\$7,265	\$1,964	\$2,273	\$2,129	\$1,862	\$8,028	\$2,538	\$2,718	\$3,457	\$3,200	\$11,913	\$13,462	\$14,000	\$14,560	\$17,472	\$52,417	\$89,108	\$142,573	\$171,088	\$171,088
Selling, general and administrative																				
Total operating expenses	\$31,459	\$7,003	\$8,026	\$7,797	\$6,992	\$29,818	\$8,232	\$8,961	\$12,026	\$12,150	\$41,289	\$48,689	\$50,989	\$53,398	\$57,864	\$94,020	\$132,612	\$194,150	\$226,697	\$234,220
Operating income	(\$18,610)	(\$1,130)	\$9,415	(\$7,116)	(\$5,579)	(\$4,410)	(\$6,619)	(\$7,726)	(\$7,608)	(\$11,270)	(\$33,123)	(\$26,169)	(\$8,469)	(\$25,878)	\$5,699	\$41,474	(\$6,236)	\$112,158	\$196,167	\$427,997
Investment income	\$22	\$0	\$3	\$14	\$4	\$21	\$0	\$16	\$24	\$21	\$60	\$65	\$102	\$83	\$69	\$80	\$113	\$179	\$313	\$595
Interest and other expense	(\$1,856)	(\$649)	(\$653)	(\$25)	(\$340)	(\$1,667)	(\$431)	(\$280)	(\$247)	(\$148)	(\$1,106)	(\$294)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
CTP-499 commercialization payment to GSK																				
(Loss) income before benefit from income taxes	(\$20,444)	(\$1,770)	\$8,765	(\$7,127)	(\$5,919)	(\$6,050)	(\$6,950)	(\$7,990)	(\$7,631)	(\$11,397)	(\$34,169)	(\$26,377)	(\$8,366)	(\$25,785)	\$3,017	\$41,553	(\$6,123)	\$112,337	\$196,480	\$428,582
Benefit (expense) from income taxes	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Net (loss) income	(\$20,444)	(\$1,770)	\$8,765	(\$7,127)	(\$5,919)	(\$6,050)	(\$6,950)	(\$7,990)	(\$7,631)	(\$11,397)	(\$34,169)	(\$26,377)	(\$8,366)	(\$25,785)	\$2,967	\$40,722	(\$6,123)	\$105,597	\$190,762	\$381,438
Accretion on redeemable convertible preferred stock	(\$386)	(\$98)	(\$99)	(\$99)	(\$100.00)	(\$396)	(\$55)	(\$55)	(\$55)	(\$100)	(\$155)	(\$300)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Net loss applicable to common shareholders	(\$20,830)	(\$1,877)	\$8,765	(\$7,226)	(\$6,019)	(\$6,452)	(\$7,005)	(\$8,045)	(\$7,686)	(\$11,497)	(\$34,324)	(\$26,677)	(\$8,366)	(\$25,785)	\$2,957	\$40,722	(\$6,123)	\$105,597	\$190,762	\$381,438
Earnings per share (EPS)	(\$16.15)	(\$1.46)	\$0.00	(\$5.38)	(\$4.66)	(\$4.59)	(\$0.76)	(\$0.45)	(\$0.43)	(\$0.63)	(\$2.16)	(\$1.41)	(\$0.43)	\$0.13	\$0.13	\$1.74	(\$0.29)	\$4.02	\$6.72	\$13.88
Shares Outstanding (Basic)	1,250	1,230	1,230	1,234	1,230	1,232	9,188	17,937	18,095	18,298	15,880	18,695	19,498	20,698	20,698	21,298	23,564	24,164	24,764	25,364
Shares Outstanding (Diluted)	1,290	1,237	2,638	13,237	13,237	13,237	11,296	20,045	20,206	20,406	17,988	21,006	21,606	22,206	22,806	23,406	25,672	26,272	26,872	27,472

Source: Company reports and Wells Fargo Securities, LLC

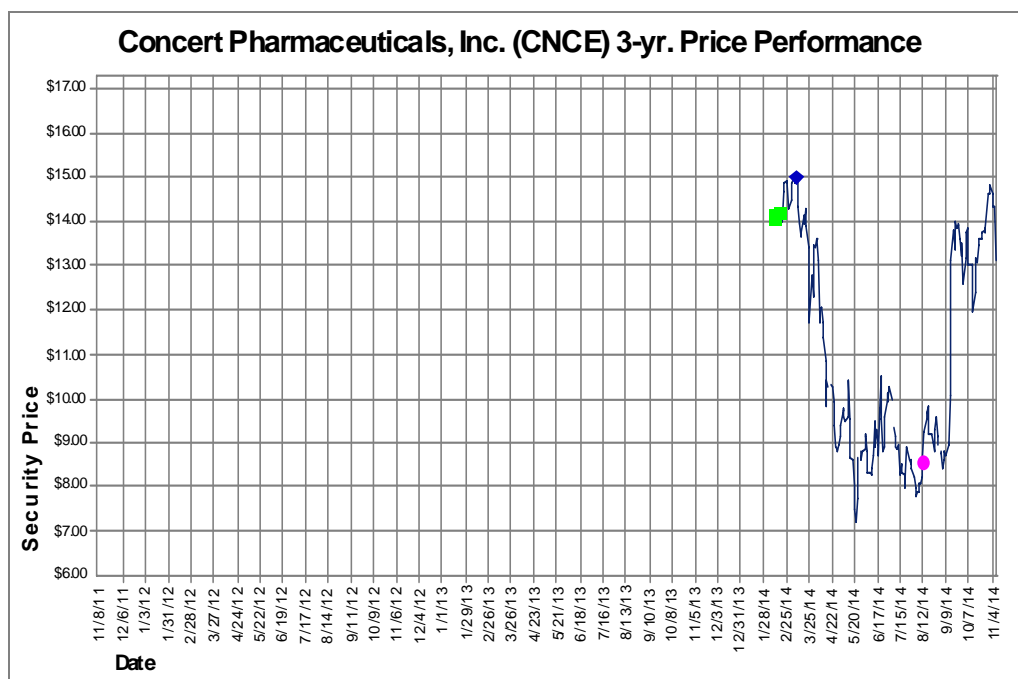
Note: We do not provide estimates of 2015 quarterly EPS at this point. 2014 quarterly EPS does not sum to full year EPS due to share count calculations

Note: In 000's \$, except per share amounts; FY ends 12/31

(1) Not probability weighted

Company Description:

Concert Pharmaceuticals (CNCE), Inc., headquartered in Lexington, Massachusetts, is a biotechnology company focused on improving therapies in a variety of areas such as neurology and kidney disease, using its platform technology around deuterium substitution. The company's lead development candidate is CTP-354, a GABA-A partial agonist in development for muscle spasticity. Another development candidate is CTP-499, a phosphodiesterase enzyme inhibitor in development for diabetic kidney disease. Alongside '354 and '499, its partnered pipeline includes CTP-730, a deuterated anti-inflammatory drug partnered with Celgene, AVP-786 for major depressive disorder partnered with Avanir, and JZP-386, a deuterated version of Xyrem for narcolepsy, partnered with Jazz.

Required Disclosures

	Date	Publication Price (\$)	Rating Code	Val. Rng. Low	Val. Rng. High	Close Price (\$)
□	2/13/2014		IPO at \$14.00			
	3/10/2014		Abrahams, M.D.			
◆	3/10/2014	14.88	1	21.00	23.00	15.03
●	8/12/2014	8.47	1	15.00	17.00	8.60

Source: Wells Fargo Securities, LLC estimates and Reuters data

Symbol Key

▼	Rating Downgrade	◆	Initiation, Resumption, Drop or Suspend
▲	Rating Upgrade	■	Analyst Change
●	Valuation Range Change	□	Split Adjustment

Rating Code Key

1	Outperform/Buy	SR	Suspended
2	Market Perform/Hold	NR	Not Rated
3	Underperform/Sell	NE	No Estimate

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CNCE: Key risks, in our view, are failure of '354 and/or '499 to show efficacy in subsequent studies and regulatory hurdles in spasticity or CKD.

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