

# **Concert Pharmaceuticals, Inc.** (CNCE)

Top-line Alzheimer's Results Bolsters Confidence in AVP-786

MARKET DATA	
Price	\$10.06
52-Week Range:	\$7.12 - \$16.26
Shares Out. (M):	17.9
Market Cap (\$M):	\$180.1
Average Daily Vol. (000):	55.0
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	

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
	FY	\$25.4	\$2.8	\$2.0
EPS	1Q		(\$0.76)A	
	2Q	(\$0.01)	(\$0.45)A	
	3Q	(\$0.01)	(\$0.65)	
	4Q	(\$4.66)	(\$0.71)	
	FY	(\$4.99)	(\$2.20)	(\$2.39)
Source: Company r	eports ar	nd JMP Securitie	s LLC	



MARKET OUTPERFORM | Price: \$10.06 | Target Price: \$28.00

# **INVESTMENT HIGHLIGHTS**

Avanir Pharmaceuticals announced top-line results from AVP-923, supporting the further collaborative development of AVP-786 with Concert Pharmaceuticals; reiterate our Market Outperform rating and \$28 price target for CNCE shares based on our DCF and SOTP valuation methodologies. Today's announcement of favorable results of Phase II clinical trials of AVP-923 in treating agitation in 220 Alzheimer's patients supports the continued advancement of the AVP-786, a stabilized form of AVP-923. Treatment with AVP-923 resulted in a highly significant (p=0.0008) reduction in agitation compared to placebo in both early- and late-stage patients. Additionally, several secondary endpoints were met: the NPI total score (p=0.014), clinical global impression of change-agitation (p=0.0003), patient global impression of change (p=0.001) and measures of caregiver burden (p≤0.05). We anticipate that this will inform Phase III development of AVP-786.

Significant read-through to the clinical potential of AVP-786. Avanir has previously stated that today's results will help guide the Phase III development of AVP-786. In February 2012, Avanir entered into a collaborative licensing agreement with Concert to develop AVP-786, a stabilized deuterated form of dextromorphan hydrobromide and ultra-low dose quinidine, the active pharmaceutical ingredients in AVP-923. Stabilization allows decreased coadministration of quinidine, a CYP2D6 enzyme inhibitor, which normally increases bioavailability of dextromorphan, and decreases the potential adverse event profile attributable to quinidine, a cardiac prolonged QT interval effector. Under the original licensing agreement, Concert is still eligible to receive \$37MM in additional regulatory milestones and \$125MM in sales based payments. Data from this trial will be presented at the American Neurological Association 2014 in Baltimore on October 12-14.

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.

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# FIGURE 1. Upcoming CNCE Milestones

Timing	Drug	Milestones
3Q14	CTP-354	Phase I MAD continuation
4Q14	AVP-786	Results from Phase II Alzheimer's trial at ANA
1H15	CTP-354	Phase II clinical trial in MS and SCI expected to begin
2014	JZP-386	First Phase I in-human trial
2014	CTP-730	Clinical trials expected to begin

Source: CNCE company presentations



# **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.

September 15, 2014



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The research analyst(s) who prepared this report does/do hereby certify that the views presented in this report are in accordance with my/our personal views on the securities and issuers discussed in this report. As mandated by SEC Regulation AC no part of my/our compensation was, is or will be directly or indirectly related to the specific views or recommendations expressed herein. This certification is made under the obligations set forth in SEC Regulation AC. Any other person or entity may not use it for any other purpose. This certification is made based on my/our analysis on the date of this report's publication. I/We assume no obligation to update this certification to reflect any facts, circumstances or events that may subsequently come to my/our attention. Signed Michael G. King and Eric Joseph

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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.

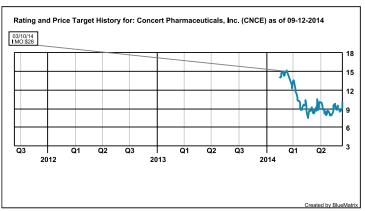
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

JMP Securities Research Ratings and Investment Banking Services: (as of September 15, 2014)

	Ū						# Co's Receiving IB	
		# Co's	%		# Co's	%	Services in	% of Co's
	Regulatory	Under	of	Regulatory	Under	of	Past 12	With This
JMP Rating	Equivalent	Coverage	Total	Equivalent	Coverage	Total	Months	Rating
MARKET OUTPERFORM	Buy	274	60.62%	Buy	274	60.62%	104	37.96%
MARKET PERFORM	Hold	138	30.53%	Hold	138	30.53%	19	13.77%
MARKET UNDERPERFORM	Sell	4	0.88%	Sell	4	0.88%	0	0%
COVERAGE IN TRANSITION		36	7.96%		36	7.96%	0	0%
TOTAL:		452	100%		452	100%	123	27.21%

#### **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 guarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.





September 15, 2014

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