Concert Pharmaceuticals, Inc. (CNCE)

Encouraging Signals Coming Out of Phase II Meeting

MARKET OUTPERFORM | Price: $9.12 | Target Price: $28.00

MARKET DATA

Price	$9.12
52-Week Range:	$7.12 - $16.26
Shares Out. (M):	17.9
Market Cap ($M):	$163.2
Average Daily Vol. (000):	113.0
Cash (M):	$108
Cash/Share:	$6.04
Enterprise Value (M):	$274
Float (M):	16.2
LT Debt (M):	$9

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2013A	2014E	2015E
Revenue ($M)	1Q	--	$1.6A	$0.0
	2Q	$24.0	$0.0	$0.0
	3Q	$24.0	$0.0	$0.0
	4Q	$1.4	$0.0	$1.6
	FY	**$25.4**	**$1.6**	**$14.0**
EPS	1Q	--	($0.76)A	--
	2Q	($0.01)	($0.53)	--
	3Q	($0.01)	($0.64)	--
	4Q	($4.66)	($0.70)	--
	FY	**($4.99)**	**($2.27)**	**($1.81)**

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

INVESTMENT HIGHLIGHTS

Positive feedback from the FDA surpasses expectations, indicating flexibility of CTP-499 Phase III trial design and favorable guidance on patient recruitment and endpoint determination; reiterate our Market Outperform rating on Concert Pharmaceuticals and $28 price target based on our DCF and SOTP valuation methodologies. CNCE announced the successful completion of its end-of-Phase II meeting with the U.S. Food and Drug Administration (FDA) for the development of CTP-499 as a treatment for diabetic nephropathy. The FDA provided guidance to CNCE that was centered on two major aspects of the Phase III trial design: the requirement for only a single Phase III trial for approval and enrollment and outcome criteria. These two criteria, in particular, enhance our outlook on the likelihood of a positive trial outcome.

FDA trial guidance given CNCE optionality with CPT-499 Phase III trial design heading into SPA discussions. FDA made it clear that it would consider a single multi-dose Phase III trial for approval, compared to our initial expectation of a requirement for two separate Phase III trials. Time-to-event analysis – a composite endpoint including ≥50% serum creatinine levels or progression to ESRD-will likely be confirmed as the approval endpoint. This inclusion of a rapidly assessable biomarker to support the responder analysis is highly encouraging from both a time and cost perspective, in our view. Furthermore, based on feedback related to current PK/PD data, the single-arm Phase III trial would likely incorporate a high-dose regimen (not yet specified), in addition to the current recommended Phase II dose of 1,200mg QD, in order to better inform treatment practice. The potential incorporation of higher baseline UACR levels (as a predictor of more rapid disease progression) as inclusion criteria may also allow for a shorter time to trial read-out. Finally, this mid-stage CKD patient population would require 96 weeks of study, compared to 144 weeks for an early stage population

Significant upside potential for a deuterated drug company. We remain bullish on Concert Pharmaceuticals shares and see 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
2H2014	CTP-354	Phase I MAD results
2H2014	CTP-354	Phase II clinical trial in MS and SCI expected to begin
2H2014	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

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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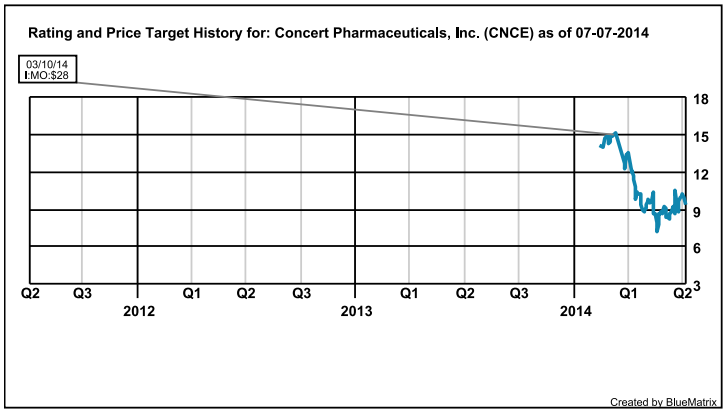
MARKET OUTPERFORM	Buy	265	*59.68%*	Buy	265	*59.68%*	100	*37.74%*
MARKET PERFORM	Hold	138	*31.08%*	Hold	138	*31.08%*	17	*12.32%*
MARKET UNDERPERFORM	Sell	4	*0.90%*	Sell	4	*0.90%*	0	*0%*
COVERAGE IN TRANSITION		37	*8.33%*		37	*8.33%*	0	*0%*
TOTAL:		444	*100%*		444	*100%*	117	*26.35%*

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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