Concert Pharmaceuticals, Inc. (CNCE)

Concert Presents Positive Phase II data for CTP-499 in Late Breaking Abstract at National Kidney Foundation Spring Meeting

MARKET OUTPERFORM | Price: $9.01 | Target Price: $28.00

MARKET DATA

Price	$9.01
52-Week Range:	$9.26 - $16.26
Shares Out. (M):	17.9
Market Cap ($M):	$161.3
Average Daily Vol. (000):	128.0
Cash (M):	$10
Cash/Share:	$0.54
Enterprise Value (M):	$316
Float (M):	16.2
LT Debt (M):	$9

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2013A	2014E	2015E
Revenue ($M)	1Q	--	$0.0	$0.0
	2Q	$24.0	$0.0	$0.0
	3Q	$24.0	$0.0	$0.0
	4Q	$1.4	$0.0	$0.0
	FY	**$25.4**	**$0.0**	**$2.0**
EPS	1Q	--	($0.45)	--
	2Q	($0.01)	($0.53)	--
	3Q	($0.01)	($0.64)	--
	4Q	($4.66)	($0.70)	--
	FY	**($4.99)**	**($2.33)**	**($2.40)**

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

INVESTMENT HIGHLIGHTS

New data from Phase II trial for CTP-499 in diabetic kidney disease demonstrate reduction in biomarkers of kidney fibrosis and protection against large increases in serum creatinine; reaffirm Market Outperform rating and $28 year-end 2014 price target on Concert Pharmaceuticals. At last week's 2014 National Kidney Foundation conference, Concert announced additional results from its 48-week Phase II clinical trial of CTP-499 in patients with diabetic kidney disease. The results were presented during a Late Breaking session by Dr. Bhupinder Singh, a clinical investigator and Medical Director of Apex Research of Riverside. Previously, CNCE had reported that the primary endpoint of change after 24 weeks in UACR, a marker of kidney tissue damage, was not met. However, additional data presented by Dr. Singh for the longer-term, 48-week treatment duration suggests a favorable trend in UACR for patients receiving CTP-499 as compared to placebo. At 48 weeks, UACR in patients receiving CTP-499 increased 24 mg/g from baseline compared to a 223 mg/g increase in patients receiving placebo ($p = 0.097$). These data may indicate a stabilization of UACR in patients treated with CTP-499 compared to those who received placebo. In addition, a statistically significant reduction of the fibrotic biomarkers collagen IV and urinary fibronectin was observed, suggesting that CTP-499 may act as an anti-fibrotic agent. The results indicate that CTP-499 may have protective effects on kidney function through a reduction in fibrosis in patients with type II diabetic kidney disease. CTP-499, when used in addition to the standard of care ACE or ARB therapy, may therefore be used to slow the progression of kidney disease to end-stage renal failure, which results in a lifetime of dialysis or kidney transplantation.

Reduction in serum creatinine indicates potential for a significant activity in a FDA approval endpoint. The data for the CNCE NKF presentation was taken from a Phase II randomized, double-blind, placebo-controlled study to evaluate safety and efficacy of CTP-499 in type II diabetic nephropathy patients currently treated with ACEI and/or ARB therapy (NCT01487109). In the Phase II study, CNCE enrolled 182 patients at 39 U.S. sites with eGFR between 23 and 89 into oral treatment with 600 mg CTP-499 twice daily or placebo. The study design incorporates three parts: an initial, blinded, 24-week treatment period; an additional, blinded, 24-week safety and efficacy follow-up period; and a 48-week, open-label evaluation period. Results from the first 48 weeks showed mean serum creatinine (SCr) levels in 65 patients receiving CTP-499 increased by 0.13 mg/dL as compared to an increase of 0.21 mg/dL in 58 patients in the placebo arm ($p=0.057$). In addition, only one patient (1.5%) in the treatment arm experienced an increase in SCr of $\geq$50% vs. six patients (10.3%) in the placebo arm ($p<0.05$). We remind investors that CNCE is will meet with the FDA mid-year to discuss the incorporation of an approvable endpoint such as the change in SCr or eGFR in a future study.

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Reduction in biomarkers of fibrosis highlights the potential mechanism for improving kidney function with CTP-499. The treatment impact on serum creatinine observed at 48 weeks was accompanied by statistically significant changes in urinary fibronectin and plasma collagen IV. While serum collagen IV is a biomarker of systemic fibrosis, urinary fibronectin is more specific to scarring in the glomerular filtration apparatus of the kidneys. Treatment with CTP-499 resulted in 52% less urinary fibronectin ($p = 0.0081$) and 18% less plasma collagen IV ($p = 0.022$) after 48 weeks compared to placebo. Of note, similar to other endpoints assessed in the trial, no significant changes in fibronectin and collagen IV were observed after 24 weeks of treatment, whereas significant effects in these biomarkers were seen after 48 weeks of treatment. This may indicate a potential need for a longer Phase III trial design to establish efficacy for CTP-499.

Treatment with CTP-499 is safe and well tolerated. Gastrointestinal events were reported more frequently in the CTP-499 arm, with mild to moderate nausea being the most commonly reported event. There were a total of 33 patients with at least one serious adverse event reported in the trial; none of these serious adverse events were judged by the investigators to be possibly related to study drug. These events occurred in 20% of patients receiving CTP-499 vs. 17% of patients receiving placebo. Fewer patients dropped out of the CTP-499 arm than the placebo arm throughout the course of the trial.

Significant upside potential for deuterated drug company. We recommend the purchase of Concert Pharmaceuticals shares to those investors who have a long-term perspective and a vision toward the kind of company that we believe CNCE can grow into over the course of the next several years. In addition to CTP-499, the company has several in-house and partnered deuterium based agents in clinical trials 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 PT for CNCE shares based on our DCF and SOTP valuation methodologies.

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	CTP-499	Phase II meeting with FDA
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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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.

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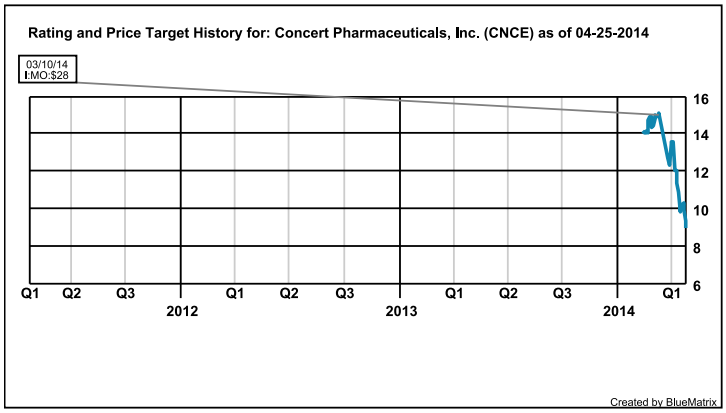
MARKET OUTPERFORM	Buy	254	*58.53%*	Buy	254	*58.53%*	99	*38.98%*
MARKET PERFORM	Hold	133	*30.65%*	Hold	133	*30.65%*	17	*12.78%*
MARKET UNDERPERFORM	Sell	5	*1.15%*	Sell	5	*1.15%*	0	*0%*
COVERAGE IN TRANSITION		42	*9.68%*		42	*9.68%*	0	*0%*
TOTAL:		434	*100%*		434	*100%*	116	*26.73%*

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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