Equity Research

Flash Comment



July 9, 2014 CNCE-NASDAQ--Outperform (1) / V

Biotechnology

CNCE: In-Line Regulatory Feedback On '499 Helps Set Stage For Next Steps Into Ph.III

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Sector Rating: Biotechnology, Market Weight

- **On July 8, CNCE provided updates on the conclusion of its end-of-phase II meeting with FDA for CPT-499 for diabetic nephropathy (DN). We had the opportunity to speak with the company for additional details.
- **FDA is generally in agreement with the company's proposed ph.III study design, with additional flexibility being an option to either conduct two studies or a single study exploring two doses. We continue to believe the size of the studies will likely necessitate a partnership with a larger company, and believe that this regulatory feedback is an important step towards that goal.
- **The primary endpoint acceptable to the FDA consists of a reduction of progression of renal disease, measured by the composite of increase in serum creatinine (>=50%, approximately equivalent to 30-40% decline in eGFR) or end stage renal disease, in line with what requirements for other companies have been in diabetic nephropathy.
- **FDA also appeared on board with the concept of "enriching" the phase III program by enrolling patients with higher baseline proteinuria, who performed better in ph.II and could increase the likelihood of success, as well as exploring higher doses, which might be indicative of FDA's level of comfort with the drug's safety.
- **The company plans to submit a request for an SPA later this year. While the study design appears to be relatively straightforward, CNCE felt that an SPA could confirm FDA's buy-in on other variables--such as statistical calculations and assumptions-to further reduce regulatory uncertainties.
- **BOTTOM LINE: While the regulatory feedback was generally in-line with expectations, we view this as an important step towards potentially partnering '499 and enabling it to move into ph.III. We believe CNCE is undervalued based on its multiple proprietary and partnered shots on goal, as well as its deuteration technology platform.

Concert Pharmaceuticals, Inc. (CNCE-NASDAQ)

Price as of 7/8/2014: \$9.12

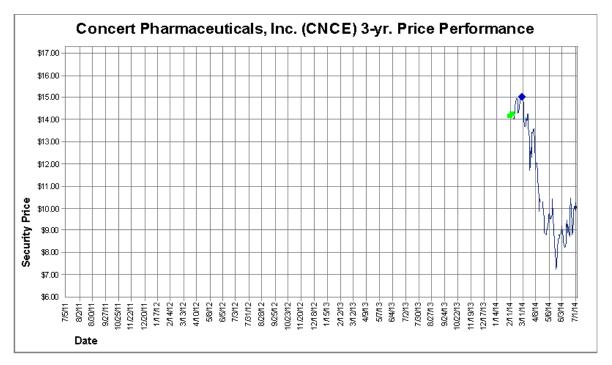
FY 14 EPS: \$-1.88 FY 15 EPS: \$-0.74 Shares Out.: 17.9 MM Market Cap.: \$163.25 MM

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All estimates/forecasts are as of 07/09/14 unless otherwise stated.

DISCLOSURE APPENDIX

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

Source: Wells Fargo Securities, LLC estimates and Reuters data

Symbol Key

- Rating Downgrade
- Rating Upgrade
- Valuation Range Change

Initiation, Resumption, Drop or Suspend

- Analyst Change
- □ Split Adjustment

Rating Code Key

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

Additional Information Available Upon Request

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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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SECTOR RATING

O = Overweight: Industry expected to outperform the relevant broad market benchmark over the next 12 months.

M = Market Weight: Industry expected to perform in-line with the relevant broad market benchmark over the next 12

U = Underweight: Industry expected to underperform the relevant broad market benchmark over the next 12 months.

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As of: July 9, 2014

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