## **Equity Research**

### Flash Comment



July 16, 2014 CNCE-NASDAQ--Outperform (1) / V

Biotechnology

# CNCE: '354 Partial Clinical Hold Lifted; 12mg Dosing To Be Explored In ph.Ib MAD Study

Brian Abrahams, M.D., Senior Analyst (212) 214-8060

### Sector Rating: Biotechnology, Market Weight

\*\*This morning (7/16), CNCE reported that based on updated preclinical results submitted to the FDA, FDA has lifted its partial clinical hold on dosing for CTP-354. This will enable CNCE to escalate doses further beyond 6mg multiple doses per day or 60mg single doses per day, for spasticity and other indications. We had the opportunity to speak with the company for additional details.

\*\*Recall the partial clinical hold was placed in 11/13, and appeared unrelated to any specific concerns, as FDA noted minimal, if any, toxicities, and likely represented FDA conservatism. The company will now explore 12mg doses in the ph. Ib MAD study in addition to 2mg and 6mg doses. The company had previously noted that while 6mg may be sufficient for spasticity based on its modeling, higher doses may be of interest for other indications.

\*\*While there was no specific commentary on safety and tolerability, the fact it was doubling the dose suggests to us that tolerability at multiple doses of 6mg was likely acceptable, though results from the receptor occupancy study would be important to fully understand its potential for activity and the extent of the drug's therapeutic window advantage vs. traditional benzos. Receptor occupancy data for the 6mg dose is expected very shortly (mid-year).

\*\*BOTTOM LINE: While we believe the partial clinical hold itself had not been a major controversy, we view this an incremental de-risking step for '354. We believe the company continues to be 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 7/15/2014: \$8.29

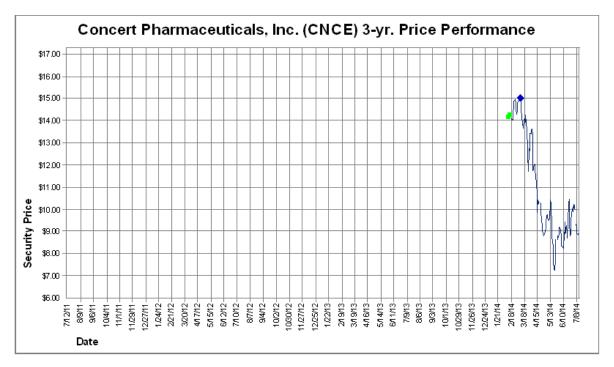
FY 14 EPS: \$-1.88 FY 15 EPS: \$-0.74 Shares Out.: 17.9 MM Market Cap.: \$148.39 MM

Please see Disclosure Appendix for rating definitions, important disclosures, and required analyst certifications.

All estimates/forecasts are as of 07/16/14 unless otherwise stated.

### DISCLOSURE APPENDIX

### **Required Disclosures**



	Date	Publication Price (\$)	Rating Code	Val. Rng. Low	Val. Rng. High	Close Price (\$)
0	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 ChangeSplit Adjustment

#### Rating Code Key

l Outperform/Buy SR Suspended ? Market Perform/Hold NR Not Rated 6 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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#### 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

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### **VOLATILITY RATING**

V = A stock is defined as volatile if the stock price has fluctuated by +/-20% or greater in at least 8 of the past 24 months or if the analyst expects significant volatility. All IPO stocks are automatically rated volatile within the first 24 months of trading.

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