# **Equity Research**

## Flash Comment



Biotechnology

# CNCE: Positive Data On '354 And AVP-923 Pulls CNCE Closer To An Eventual Drug

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Sector Rating: Biotechnology, Market Weight

\*\*Yesterday (10/13), at the 2014 ANA meeting, CNCE presented full results of its ph.Ib multiple ascending dose study of CTP-354, and partner AVNR presented full results of its ph.II of AVP-923 in Alzheimer's agitation.

\*\*New multiple-dose PK data for '354 at doses of 2mg, 6mg, and 12mg (the highest cohort having been studied following lifting of the partial clinical hold) demonstrated a long plasma half-life of 20 hours. Correlating the multiple-dose PK curves with the previously-reported ~50% receptor occupancy observed with 6mg (6 and 12mg dosing resulted in day 10 Cmax of 175 and 472 ng/mL, respectively), we believe the higher dose planned for the upcoming spasticity study (8mg) should enable them to achieve the target 60% GABA-A receptor occupancy likely sufficient for efficacy. Though safety data was not quantified, the fact that the poster noted no AE-related discontinuations, not MTD reached, and dizziness/somnolence being only mild/moderate, may suggest this dose would get to desired activity without the substantial side effects that would be expected from traditional benzos at doses producing even close to such a receptor occupancy-- reaffirming '354's potential to be a less-sedating benzo.

\*\*Additional detail on efficacy of AVP-923 showed the drug produced clinically and statistically meaningful reductions in clinical measurements of Alzheimer's agitation/aggression, evident as early as the first week. '923 treated patients saw mean reduction from baseline agitation/aggression score in the neuropsychiatric inventory (NPI) of 47% versus 22% (placebo) in the first stage of the sequential parallel comparison study, and a 26% reduction versus 6.7% (placebo) in the second stage that excluded placebo responders. We believe AVNR will move forward in future studies of its dextromethorphan products with the CNCE-partnered AVP-786.

\*\*BOTTOM LINE: Continued positive pipeline data and partnership progress for CNCE highlight what we believe remains an underappreciated small-cap story.

Concert Pharmaceuticals, Inc. (CNCE-NASDAQ)

Price as of 10/14/2014: \$12.33

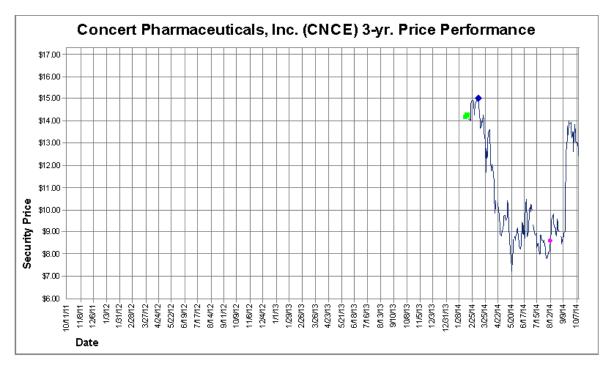
FY 14 EPS: \$-2.07 FY 15 EPS: \$-1.09 Shares Out.: 17.9 MM Market Cap.: \$220.71 MM

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

All estimates/forecasts are as of 10/14/14 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
•	8/12/2014	8.47	1	15.00	17.00	8.60

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

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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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