

September 15, 2014

CNCE-NASDAQ--Outperform (1) / V

Biotechnology

## CNCE: Avanir's Win In Alzheimer's A Positive For CNCE, Likely To Be First CNCE-Related Program To Move Into Pivotal

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### Sector Rating: Biotechnology, Market Weight

**\*\***Avanir announced its ph.II study of AVP-923 (dextromethorphan+quinidine) in Alzheimer's agitation hit its primary endpoint of reducing agitation, as measured by the agitation/aggression component of the NPI scale. Recall, Avanir is partnered with CNCE on AVP-786, a deuterated form of dextromethorphan combined with a lower quinidine dose compared to '923.

**\*\***Success was achieved on both the primary endpoint ( $p < 0.01$ ), in both stage 1 and 2 ( $p < 0.01$ ,  $p = 0.021$ ) of the sequential parallel comparison study design, as well as on most of the secondary clinical endpoints. We believe use of the SPCD has several advantages, including increasing power for a given sample size, and avoiding recruitment of eligible patients who are then unused (unlike a placebo lead-in). Although there has been some controversy regarding the hypothesis being tested in the SPCD, the large number of SPCD trials that have addressed psychiatric conditions including depression, schizophrenia, and bipolar disorder suggest to us the design is accepted and validated by regulatory authorities.

**\*\***Based on our recent discussion with AVNR, we believe AVNR plans to move forward in all future studies of its dextromethorphan products in additional indications with the CNCE-partnered AVP-786. AVNR plans to meet with U.S./EU regulators shortly regarding pivotal plans, and we believe '786 for Alzheimer's agitation could represent the first CNCE deuterated program to advance into ph.III.

**\*\***We believe the market in this indication could be large, and provide meaningful future revenues to CNCE. AVNR noted ~2/3 of diagnosed U.S. Alzheimer's patients (2.5M+) have agitation, and 5% share-which could theoretically be achievable given the lack of approved therapies and limitations of currently-used antipsychotics-at pricing parity to Nuedexta would lead to ~\$650M future annual sales, which at an estimated ~5-12% royalty rate would bring in ~\$32-77M/year to CNCE (nonwithstanding \$200M+ in potential milestones, and royalties on any other dextromethorphan indications like MDD).

**\*\***BOTTOM LINE: We see positive read-throughs for CNCE, and at the company's \$80M EV believe the partnered programs and proprietary pipeline are undervalued.

### Concert Pharmaceuticals, Inc. (CNCE-NASDAQ)

Price as of 9/12/2014: \$10.06

FY 14 EPS: \$-2.07

FY 15 EPS: \$-1.09

Shares Out.: 17.9 MM

Market Cap.: \$180.07 MM

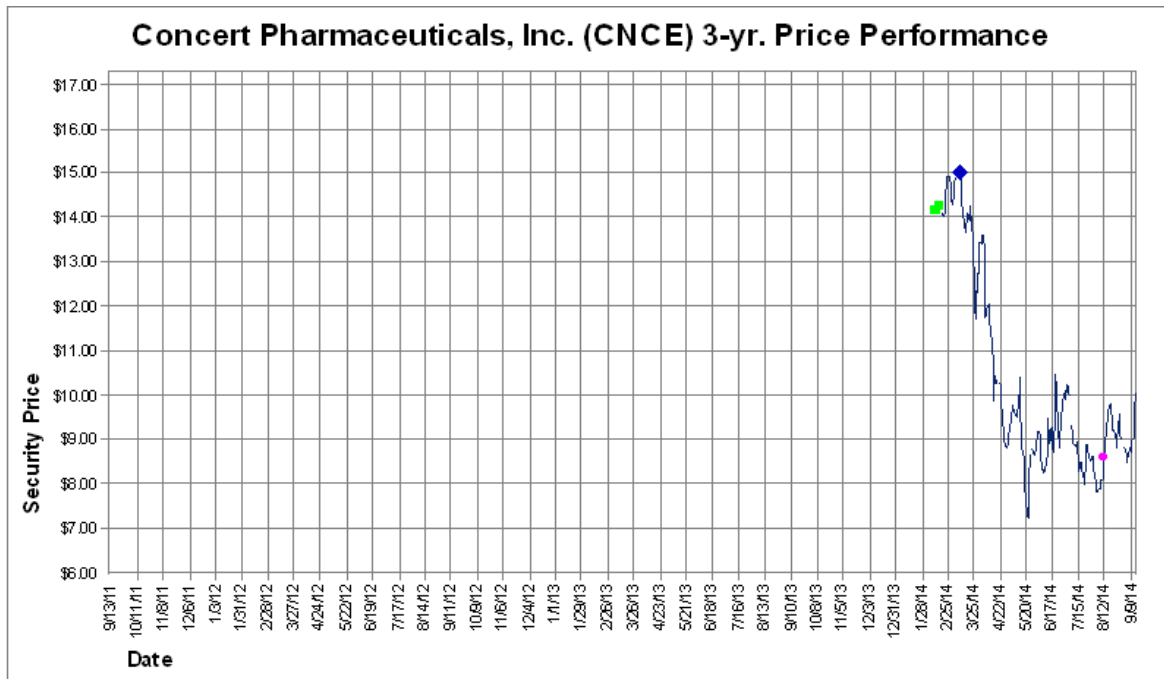
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### Required Disclosures



	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	◆	Initiation, Resumption, Drop or Suspend
▲	Rating Upgrade	■	Analyst Change
●	Valuation Range 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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**2 = Market Perform:** The stock appears appropriately valued, and we believe the stock's total return will be in line with the market over the next 12 months. HOLD

**3 = Underperform:** The stock appears overvalued, and we believe the stock's total return will be below the market over the next 12 months. SELL

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