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FLASH NOTE | EQUITY RESEARCH | September 15, 2014

## Healthcare: BioPharmaceuticals

# Concert Pharmaceuticals, Inc. | CNCE - $10.06 - NASDAQ | *Buy*

### Company Update

| Stock Data | |
|---|---|
| 52-Week Low - High | $7.12 - $16.26 |
| Shares Out. (mil) | 18.01 |
| Mkt. Cap.(mil) | $181.2 |
| 3-Mo. Avg. Vol. | 177,008 |
| 12-Mo.Price Target | $28.00 |
| Cash (mil) | $98.3 |
| Tot. Debt (mil) | $13.0 |

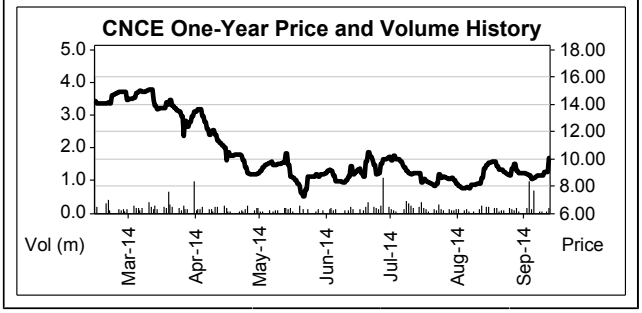
**EPS $**

| Yr Dec | —2013— | —2014E— | —2015E— |
|---|---|---|---|
| | | Curr | Curr |
| 1Q | - | (0.76)A | (0.47)E |
| 2Q | - | (0.45)A | (0.45)E |
| 3Q | - | (0.42)E | (0.28)E |
| 4Q | - | (0.48)E | (0.01)E |
| YEAR | (4.99)A | (1.62)E | (1.21)E |
| P/E | NM | NM | NM |

*Concert's IPO was on February 9, 2014*
*Quarterly EPS may not add to full year due to increases in share count and rounding*

**Revenue ($ millions)**

| Yr Dec | —2013— | —2014E— | —2015E— |
|---|---|---|---|
| | | Curr | Curr |
| 1Q | - | 1.6A | 1.2E |
| 2Q | - | 1.2A | 1.7E |
| 3Q | - | 2.0E | 5.2E |
| 4Q | - | 1.5E | 10.5E |
| YEAR | 25.4A | 8.3E | 18.6E |




## CNCE: Positive Phase II Results for Partnered Alzheimer's Drug; Reiterate Buy

Avanir Pharmaceuticals (AVNR-NC) announced positive Phase II results from a study of AVP-923 (licensed from CNCE) for agitation in Alzheimer's disease. The study met its primary endpoint of reduction in agitation, as well as most secondary endpoints. KOLs believe reduction in agitation would significantly reduce patient and caregiver burden in Alzheimer's disease. Avanir plans to meet with the FDA and EMA to discuss pivotal study designs. Reiterate Buy.

**Event**

Concert's partner Avanir Pharmaceuticals announced positive Phase II results from a study evaluating the safety and efficacy of AVP-923 for the treatment of agitation in Alzheimer's disease patients.

**Impact**

We are encouraged by the Phase II data from the 220-patient study, which showed significant improvement in agitation (primary endpoint) over placebo as measured on the agitation/progression domain score of the neuropsychiatry inventory (NPI). Most secondary endpoints were also met, including NPI total score, clinical global impression of change-agitation, patient global impression of change, and measures of caregiver burden. The drug was well-tolerated, with no serious adverse events seen in the 10-week study. The most common AEs, which occurred in <10% of patients, included diarrhea, falls, and urinary tract infections. Avanir will request meetings with the FDA and EMA to discuss pivotal study designs. KOLs commented that with no currently approved treatment for Alzheimer's disease-associated agitation, treatment with '923 could lead to a significant reduction in the burden to both patients and caregivers. Further data from the study are expected to be presented at the American Neurological Association Annual Meeting on October 12-14, 2014. CNCE has a busy schedule ahead. The company expects to initiate the Phase II study of CTP-354 in spinal cord injury spasticity later this year. We look forward to top-line data from the Phase I portion of this study in October. CNCE also plans to initiate discussions with the FDA regarding a Phase III design for CTP-499, including the possibility of conducting the Phase III under a SPA. A Phase I study of CTP-730 is expected to initiate in the fall. Recall that CNCE received a $2 million milestone payment last month due to Avanir's initiation of a 10-week Phase II study of AVP-786 in MDD.

**Action**

Reiterate Buy and $28 price target. With a 1) proprietary platform in modifying drugs with deuterium, 2) growing internal pipeline, 3) three partnerships in hand, to date and 4) a strong IP portfolio, we believe Concert is poised for success, which should be supported by upcoming catalysts.

**Intraday Price: $10.58 at 10:51 am ET, 9/15/14**

## VALUATION

We reiterate our Buy rating and $28 price target. Our valuation of Concert is based on our probability-weighted clinical net present value (NPV) valuation model. We believe that this method is appropriate in capturing the value of the clinical stage pipeline. It allows for the flexing of assumptions based on key factors such as chance of success, peak sales estimates, and year of commercial launch.

Factors that could impede shares from reaching our price target include negative clinical data flow from Concert's clinical stage programs as well as any potential delays or issues on the regulatory front and financing risk.

## RISKS

- **Pipeline product risk** - Concert's pipeline consists of earlier stage developmental candidates. With this stage of development comes increased risk from negative trial readouts. Additionally, CPT-499 and CTP-354 represent major contributors to our valuation and any negative readouts, clinical or regulatory delays could negatively impact the stock. We believe Concert looks to mitigate some of this risk by having a platform technology which can generate a broad set of drug candidates for its pipeline.
- **Partnering risk** - Concert currently has signed partnerships and is continually engaging in business development activities. Because these programs are under the direction of other companies, there is no guarantee those programs will progress to meaningful catalysts, including potential commercialization. Any delays or terminated partnerships in the future, could have a negative impact on Concert's valuation.
- **Regulatory** - Should Concert's products successfully complete pivotal registrational studies, there is no guarantee that regulatory agencies would approve these products. Unforeseen issues may arise during clinical development which could impact the approvability of a therapeutic candidate.
- **Financing risk**- As with all non-profitable biotechnology companies, funding is continuously necessary to fund operations and ongoing clinical studies. Should Concert encounter problems in raising sufficient funds to continue its operations, this could significantly impact that stock"s valuation

## COMPANY DESCRIPTION

Concert Pharmaceuticals create novel medicines that address medically important needs by applying its DCE Platform (Deuterated Chemical Entity Platform) to compounds with well-characterized pharmacological activity. This approach may enable drug discovery and clinical development that is more efficient and less expensive than conventional small molecule drug research and development. The company was co-founded in 2006 by Richard Aldrich, Roger Tung and Christoph Westphal, and is located in the historic town of Lexington, Massachusetts.

Regulation Analyst Certification ("Reg AC"): The research analyst primarily responsible for the content of this report certifies the following under Reg AC: I hereby certify that all views expressed in this report accurately reflect my personal views about the subject company or companies and its or their securities. I also certify that no part of my compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

## Disclosures:

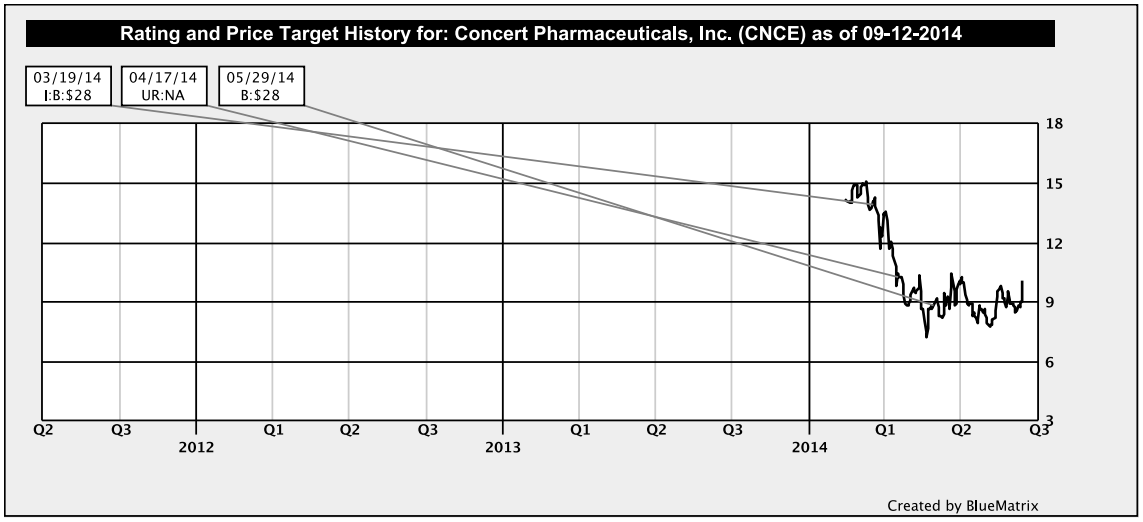
Within the last twelve months, ROTH has received compensation for investment banking services from Concert Pharmaceuticals, Inc..

ROTH makes a market in shares of Concert Pharmaceuticals, Inc. and as such, buys and sells from customers on a principal basis.

Within the last twelve months, ROTH has managed or co-managed a public offering for Concert Pharmaceuticals, Inc..

**On September 28, 2010, ROTH changed its rating system in order to replace the Hold rating with Neutral.**

**On May 26, 2011, ROTH changed its rating system in order to incorporate coverage that is Under Review.**




Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years. **Distribution Ratings/IB Services** shows the number of companies in each rating category from which Roth or an affiliate received compensation for investment banking services in the past 12 month.

**Distribution of IB Services Firmwide**

| | | | IB Serv./Past 12 Mos. as of 09/15/14 | |
|---|---|---|---|---|
| **Rating** | **Count** | **Percent** | **Count** | **Percent** |
| **Buy [B]** | **194** | **81.51** | **111** | **57.22** |
| **Neutral [N]** | **23** | **9.66** | **10** | **43.48** |
| **Sell [S]** | **1** | **0.42** | **0** | **0** |
| **Under Review [UR]** | **19** | **7.98** | **11** | **57.89** |

Ratings System Definitions - ROTH employs a rating system based on the following:

**Buy:** A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return of at least 10% over the next 12 months.

**Neutral:** A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return between negative 10% and 10% over the next 12 months.

**Sell:** A rating, which at the time it is instituted and or reiterated, that indicates an expectation that the price will depreciate by more than 10% over the next 12 months.

**Under Review [UR]:** A rating, which at the time it is instituted and or reiterated, indicates the temporary removal of the prior rating, price target and estimates for the security. Prior rating, price target and estimates should no longer be relied upon for UR-rated securities.

**Not Covered [NC]:** ROTH does not publish research or have an opinion about this security.