

Equity Research

Concert Pharmaceuticals, Inc.

CNCE: We Are Initiating Coverage With An Outperform Rating

Outperform / V

Sector: Biotechnology

Market Weight

Initiation of Coverage

• **Summary:** We are initiating coverage of Concert Pharmaceuticals with an Outperform rating and a \$21-23 valuation range. We believe both CTP-354 and CTP-499 have the potential to address broad markets where there remains a need for better tolerated and/or more effective agents, and see multiple long-term shots on goal for CNCE with a high aggregate revenue opportunity (about \$700 million by 2023E) should CNCE's proprietary and partnered candidates be successful. We also believe CNCE's deuteration chemistry platform provides a solid long-term foundation for the continued production of differentiated pipeline products. Overall we believe this promise is underappreciated; our range is based on a blend of probability-adjusted, discounted out-year EPS and sales multiples.

• **Lead candidate CTP-354, in our view, has considerable long-term potential as a selective, non-sedating benzodiazepine-like drug for muscle spasticity and other neuropsychiatric indications.** Benzos are a mainstay of treatment for many disorders, but are limited by side effects. Although '354 is early stage and activity needs to be tested in patients, initial pharmacokinetic data looked solid and a receptor occupancy study helps support the potential for a broader therapeutic window than existing therapies, a characteristic we believe would be embraced in the market.

• **CTP-499 has shown promising signals in diabetic kidney disease, an area in which we foresee a large future opportunity if the drug is successful.** Though the phase II missed its primary endpoint, we believe there were signals suggestive of activity that warrant exploring moving the drug into pivotal studies with a partner; should '499 ultimately be approved, we believe \$1B+ in long-term end-user sales would be very achievable.

• **Partnerships provide key validation for CNCE's approach and the possibility of meaningful long-term milestone/royalty revenue.** CNCE has partnerships with CELG, JAZZ, and AVNR on deuterated drugs. While these candidates are generally early, if deuteration meaningfully enhances dosing and/or PK, we believe each candidate could capture significant long-term market share. We believe these partnerships strongly validate CNCE's platform, and the FDA's amenability to an expedited path for AVNR reflects to us, regulatory comfort with deuteration that could bode well for CNCE's future programs.

• **We see significant value in the company's deuteration chemistry platform.** Deuteration can potentially improve PK/metabolism of drugs without affecting pharmacology, and we believe CNCE has established itself as the leader in analyzing where selective deuterium substitution of compounds could provide meaningful clinical benefits. We believe this provides a strong foundation for long-term pipeline sustainability and additional partnerships.

Valuation Range: \$21.00 to \$23.00 from NE to NE

Our valuation range is based on applying a 30x multiple to our 2022 estimated EPS and discounting at 15%, blended with 2.5x multiple of 2022 estimated sales, and discounting 12%. 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.

Investment Thesis:

We believe Concert's proprietary and partnered candidates, and drug deuteration platform, will generate long-term value.

Please see page 3 for rating definitions, important disclosures and required analyst certifications

All estimates/forecasts are as of 03/10/14 unless otherwise stated.

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	2013A	2014E	2015E
EPS		Curr. Prior	Curr. Prior
Q1 (Mar.)	NE	(\$0.64)	NE NE
Q2 (June)	NE	(0.41)	NE NE
Q3 (Sep.)	NE	(0.52)	NE NE
Q4 (Dec.)	NE	(0.52)	NE NE
FY	NE	\$2.05	NE (\$2.05)
CY	NE	\$2.05	(\$2.05)
FY P/E	NM	7.3x	NM
Rev.(MM)	NE	\$3,520	\$22,520

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters
NA = Not Available, NC = No Change, NE = No Estimate, NM = Not Meaningful
V = Volatile, * = Company is on the Priority Stock List

Ticker	CNCE
Price (03/07/2014)	\$14.88
52-Week Range:	\$12-17
Shares Outstanding: (MM)	0.0
Market Cap.: (MM)	\$0.0
S&P 500:	1,878.04
Avg. Daily Vol.:	0
Dividend/Yield:	\$0.00/0.0%
LT Debt: (MM)	\$0.0
LT Debt/Total Cap.:	0.0%
ROE:	NM
3-5 Yr. Est. Growth Rate:	NM
CY 2014 Est. P/E-to-Growth:	NM
Last Reporting Date:	12/31/2013

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters

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Together we'll go far



Company Description:

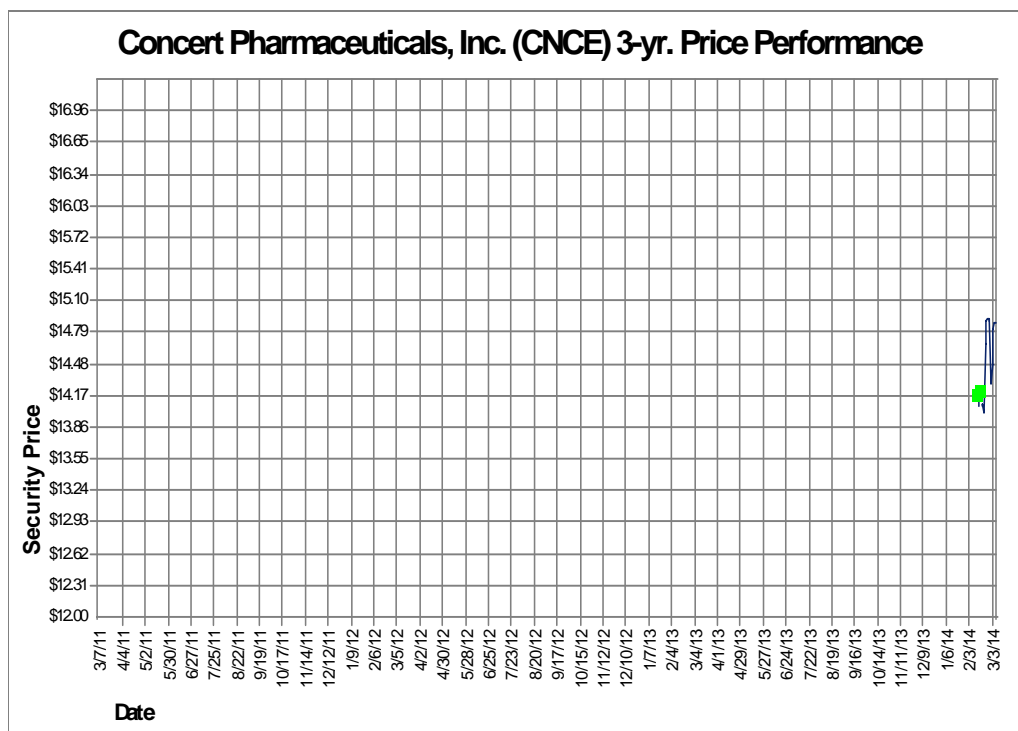
Concert Pharmaceuticals (CNCE), Inc., headquartered in Lexington, Massachusetts, is a biotechnology company focused on improving therapies in a variety of areas such as neurology and kidney disease, using its platform technology around deuterium substitution. The company's lead development candidate is CTP-354, a GABA-A partial agonist in development for muscle spasticity. Another development candidate is CTP-499, a phosphodiesterase enzyme inhibitor in development for diabetic kidney disease. Alongside '354 and '499, its partnered pipeline includes CTP-730, a deuterated anti-inflammatory drug partnered with Celgene, AVP-786 for major depressive disorder partnered with Avanir, and JZP-386, a deuterated version of Xyrem for narcolepsy, partnered with Jazz.

Key Risks

- **Clinical risk.** Lead product CTP-354 is in early-stage development and has not been advanced into proof-of-concept studies as of yet. While receptor occupancy studies show the drug may be reaching its target, it is possible studies in patients with spasticity may not show effects or demonstrate a wide enough therapeutic window to support clinical differentiation or movement into future studies in spasticity, anxiety, or pain. It is also possible safety signals (QTc changes were observed in the phase I, but were not deemed clinically relevant) could emerge in longer, larger studies, as the clinical exposure to date has been limited, which could delay or halt future development or compromise the agent's long-term (LT) opportunity. CTP-499 showed signals of potential activity in CKD, but kidney disease has historically been a difficult indication to develop drugs for, and data in the phase II proof-of-concept study were mixed. Partnered programs remain early stage, adding risk as to whether they ultimately succeed.
- **Regulatory risk.** CTP-354 is on partial clinical hold, and while CNCE's modeling predicts that doses needed for adequate receptor occupancy to treat spasticity should be achievable with allowable tested doses, if higher doses are required for other indications (or appear to be needed for spasticity) and CNCE's preclinical work is not sufficient for the FDA to remove this restriction on dose escalation, it could limit the ultimate opportunity. Regulatory views on endpoints in spasticity may be evolving, and it will likely be important for the future phase III development program to conform to most current FDA requirements; the endpoint used at present, Ashworth score, can be somewhat unreliable and requires careful study conduct, adding risk to the drug demonstrating efficacy, in our view. The regulatory safety bar for broader market indications such as anxiety and pain is likely to be high, so tolerability and the AE profile will likely need to be very clean in order for CNCE to be able to capture these potential opportunities. For potential new CKD drugs like CTP-499, the regulatory path in the United States is not completely well established. While we believe protection from major creatinine worsening could be part of a future registrational endpoint, any need for additional long-term outcomes could require a larger, longer phase III program, potentially adding costs and dissuading a potential partner.
- **Commercial risk.** There are several other drugs on the market for spasticity, anxiety, and pain, many of which are generic, which could potentially compete with '354. As such, we believe it will be important not only for '354 to demonstrate clear differentiation such as on dosing frequency and tolerability profile, but for CNCE to build a sales force that effectively communicates those attributes to enable successful physician adoption and payer amenability. '499 would likely need to be commercialized by a larger company with an existing sales infrastructure; as such, CNCE will need to find a collaborator interested in investing in the phase III and commercialization costs for the drug even with the somewhat mixed data and on favorable terms to CNCE.
- **Financial risk.** CNCE's candidates are generally at an early stage of development, and while the company should be able to generate some meaningful non-dilutive cash from existing and future partnerships, this will likely rely on the clinical successes of their programs, and CNCE may require additional funding as '354 advances in the clinic. Raising cash in the equity market could result in dilution to shareholders.

For more details, please see our full-length report, to be published shortly.

Required Disclosures



	Date	Publication Price (\$)	Rating Code	Val. Rng. Low	Val. Rng. High	Close Price (\$)
■	2/13/2014		IPO at \$14.00			

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
- 2 Market Perform/Hold
- 3 Underperform/Sell
- SR Suspended
- NR Not Rated
- 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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M=Market Weight: Industry expected to perform in-line with the relevant broad market benchmark over the next 12 months.

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