# Concert Pharmaceuticals, Inc. (CNCE)

Initiating Coverage with a Market Outperform Rating – Making a Big Bang in the DCE Space

**MARKET DATA**

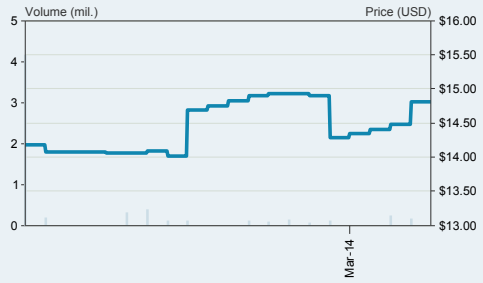
| | |
|---|---|
| Price | $14.88 |
| 52-Week Range: | $12.43 - $16.26 |
| Shares Out. (M): | 17.9 |
| Market Cap ($M): | $266.4 |
| Average Daily Vol. (000): | 413,056.0 |
| Cash (M): | $115 |
| Cash/Share: | $5.17 |
| Enterprise Value (M): | $346 |
| Float (M): | 16.2 |
| LT Debt (M): | $9 |

Source: Thomson Reuters and JMP Securities LLC

| FY DEC | | 2013E | 2014E | 2015E |
|---|---|---|---|---|
| Revenue ($M) | 1Q | -- | $0.0 | $0.0 |
| | 2Q | $24.0A | $0.0 | $0.0 |
| | 3Q | $24.0A | $0.0 | $0.0 |
| | 4Q | $6.5 | $0.0 | $0.0 |
| | **FY** | **$0.0** | **$0.0** | **$2.0** |
| EPS | 1Q | -- | ($0.48) | -- |
| | 2Q | ($0.01)A | ($0.59) | -- |
| | 3Q | ($0.01)A | ($0.67) | -- |
| | 4Q | ($0.25) | ($0.73) | -- |
| | **FY** | **($0.10)** | **($2.46)** | **($2.56)** |

Source: Company reports and JMP Securities LLC

**STOCK PRICE PERFORMANCE**




**MARKET OUTPERFORM** | Price: $14.88 | Target Price: $28.00

## INVESTMENT HIGHLIGHTS

**We are initiating coverage of Concert Pharmaceuticals with a Market Outperform rating and 12-month price target of $28 based on the composite of our DCF, NPV, and SOTP valuation methodologies**. Concert is a development-stage biopharmaceutical company that recently completed its IPO on February 13, 2014 and is focused on the incorporation of deuterium into its drug candidates in order to bestow them with superior properties without changing the fundamental activities. Founded in 2006, the company has been adept at creating multiple clinical candidates across a diverse set of therapeutic areas, including renal disease, CNS disorders, inflammatory conditions, cancer, and infectious diseases. The company currently has five product candidates that it is developing with partners or for its own account. By the end of 2014, Concert plans to have three of these compounds in Phase II trials for four indications, with two additional compounds entering the clinic.

**Leadership team has an extensive and relevant track record of successful drug discovery and development.** The prospects for Concert's future rest mainly on the shoulders of Co-Founder and CEO, Roger Tung. A founding scientist and former eventual VP of Drug Discovery at Vertex (VRTX, MO, $115 PT, Bayko), Tung is an accomplished drug hunter responsible for co-inventing the HIV protease inhibitors, amprenavir (Agenerase) and fosamprenavir (Lexiva), and oversaw the discovery of cystic fibrosis (CF) drug ivacaftor (Kalydeco) and HCV protease inhibitor telaprevir (Incivek).

**The Concert model is all about developing drugs more quickly and less expensively than before.** Because there is an existing database of information for the majority of CNCE's product candidates—whether they be drugs that failed to make it to the market due to sub-optimal pharmaceutical properties, or those that are or were marketed but never achieved full potential for similar reasons—Concert is able to draw upon the industry's vast database of compounds as a repository of potential candidates. By making a relatively small number of changes to the scaffold compound, Concert can create a new pipeline asset in a relatively rapid and capital-efficient manner. The company can often use the parent compound's existing drug master file (DMF), thus reducing the time and expense of pre-clinical development. The approach also enables diversification of efforts across a variety of therapeutic categories, allowing the company to blend the risk/reward profile of its portfolio and enabling it to participate at a variety of interest levels (e.g., wholly owned, profit split, royalty).

**In our opinion, validating partnerships convincingly answers the question of the feasibility of Concert's DCE approach; the focus now turns to how big it can be.** We believe that the multiplicity of partnerships across a spectrum of therapeutic areas should firmly convince even the most hardened skeptic of the validity of the Concert

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DCE (deuterated chemical entity) approach. The company's partnerships include Avanir (AVNR, MO, $7 PT, Butler) in neurologic disorders, Jazz (JAZZ, NC) in narcolepsy, and Celgene (CELG, MO, $205 PT) in inflammation and oncology. In addition to the scientific validation that these partnerships provide, they also allow Concert to develop CTP-354 (spasticity associated with MS and SCI) and CTP-499 (diabetic kidney disease) for its own account, for which the company retains 100% of the economics of the programs.

**Active event calendar for 2014 should keep CNCE at the top of mind for biotech investors, in our view.** We anticipate substantive progress across all of Concert's clinical programs, both proprietary and partnered. In terms of the company's wholly owned programs, perhaps the most important milestones will be the data from the multiple ascending dose (MAD) study for CTP-354 and both the top-line data from the randomized study of CTP-499 in diabetic kidney disease as well as the outcome of the company's discussions with the FDA regarding the forward development plan for the molecule. Regarding the company's partnered programs, progress is expected in all three, with Avanir commencing Phase II development of AVP-786 in major depressive disorder during 2H14, and Celgene and Jazz commencing clinical development with their respective programs. While not an explicit goal, it would not surprise us to see either one of the CNCE proprietary development candidates move toward the clinic or for another partnership to emerge with a biopharmaceutical company.

## INVESTMENT THESIS - CHEMICAL DIVERSITY OF COSMIC PROPORTIONS

Deuterium, also known as heavy hydrogen, is the less common of the two isotopes of hydrogen (the other being protium). Even though it only accounts for about 0.015% of all of the hydrogen on the planet, deuterium is widely abundant and can be found in varying degrees in different kinds of the earth's water. Harold Urey discovered it in 1931 while he was at Columbia which won him the Nobel Prize in 1934 (Urey was also involved with the work that led to the creation of the atomic bomb). Because deuterium is destroyed in the center of stars faster than it is produced and little is created by other natural means, it is thought that all of the deuterium present on the planet was created at the time of the Big Bang. In fact, the ratio of deuterium to protium in the earth's ocean waters has led to the theory that the oceans may have their origins from comets. Deuterium has an atomic weight roughly twice that of protium, and conveys chemical differences between deuterium- and protium-containing compounds. The bonds formed by deuterium are slightly stronger than similar bonds formed with hydrogen and are sufficient to make meaningful differences in biological reactions. Thus is the fundamental hypothesis that underpins Concert Pharmaceuticals' approach to drug development.

Researchers in the pharmaceutical industry regularly search for ways to increase chemical diversity, speed the synthesis of novel compounds, and devise ways to create molecules with drug-like characteristics from the earliest stages of their development. Overlooked in these overlapping objectives is the fact that a large universe of compounds already exists, for which much of the heavy lifting (so to speak) has already been done. For many of these, a "tweak" here or there on the molecule could potentially make a good drug great or a failed drug viable. Importantly, if such an approach were created, it could allow a company to tap this vast pharmacopeia of existing compounds and enable the technology's discoverer to rapidly create clinical leads in a capital- and time-efficient way. In addition, the inherent risk in such an approach should be lower than that of a de novo drug discovery approach.

As a consequence, this approach would possess an inherently high ROI, as most of the key inputs - time, cost of capital, and discount factor – should all be lower for these compounds compared to those discovered via traditional means at corresponding points of development.

We believe that the good news for investors is that a company with such a technology already exists in Concert Pharmaceuticals. Co-founder and Chief Executive Officer, Roger Tung, conceived of substituting deuterium for hydrogen in well-characterized molecules over a decade ago. Dr. Tung's concept became reality with the founding of the company in 2006. Others can deuterate compounds, but none match Dr. Tung's expertise. Today, using its deuterated chemical entity (DCE) platform, Concert is undertaking five development programs, two for its proprietary account and three under the aegis of partners. Each of these un-partnered and partnered programs has its own respective intellectual property protection. By the end of 2014, the company plans to have two proprietary compounds in three Phase II trials, one of three partnered compounds in Phase II development, while two will enter Phase I development. By 2015, Concert should be a Phase III company with one or more DCE compounds making its way into the company's development pipeline. Concert should also garner broad interest from biotechnology and pharmaceutical companies seeking to extend the patent life of currently marketed drugs using the DCE platform. In our opinion, the novelty and efficiency of the Concert model should swiftly transport Concert across the drug development universe.

### Upcoming Catalysts

Concert Pharmaceuticals has several potential upcoming catalysts that may be of interest to investors. In the second half of 2014, Concert will have read-outs from the company's Phase I multiple ascending dose trial with CTP-354 leading to the start of a Phase II study for treatment of spasticity in multiple sclerosis (MS) and spinal cord injury (SCI). Also in 2H2014, the company also hopes to meet the FDA to finalize endpoints for its Phase II study of CTP-499. Finally, in 2014 many of Concert's partners will also begin clinical trials summarized below (Figure 1).

**FIGURE 1. Upcoming Milestones**

| Timing | Drug | Milestones |
|---|---|---|
| 2H2014 | CTP-354 | Phase I MAD results |
| 2H2014 | CTP-354 | Phase II clinical trial in MS and SCI expected to begin |
| 2H2014 | CTP-499 | Phase II meeting with FDA |
| 2H2014 | AVP-786 | Phase II trial for treatment of resistant major depressive disorder |
| 2014 | JZP-386 | First Phase I in-human trial |
| 2014 | CTP-730 | Clinical trials expected to begin |

*Source: Concert Pharmaceuticals presentations and JMP Securities LLC*

## VALUATION

We arrive at our year-end 2014 price target of $28 based on the synthesis of our discounted cash flow (DCF) analysis and our standardized SOTP methodology (Figure 2).

**FIGURE 2. Price Target Synthesis**

| Synthesis of Valuation Approaches | |
|---|---|
| **Approach** | **Valuation** |
| DCF Analysis | $ 20.41 |
| SOTP | 35.51 |
| **Price Target** | **$ 28.00** |

*Source: JMP Securities LLC and Company reports*

### Discounted Cash Flow Valuation

Our DCF valuation projects revenue from U.S. sales and ex-U.S. royalties for CTP-384 in the treatment of spasticity related to Multiple Sclerosis (MS) and Spinal Cord Injury (SCI). We assume a partnership for CTP-499 in Diabetic CKD, and therefore factor in royalty payments for U.S. and ex-U.S. sales. We also account for milestone and royalty revenue from Avanir Pharmaceuticals related to the development and worldwide commercialization of AVP-786 for Major Depressive disorder refractory to treatment. Finally, we factor in milestones and royalty revenue from Jazz Pharmaceuticals related to JZP-386 for the treatment of narcolepsy. We subtracted cost of goods sold, projected operating expenses, and tax for all four clinical programs. Net cash flows to the company are discounted back to present value by 30%, representing a risk-adjusted, discount rate that takes into account the stage of development of each drug candidate, its likelihood of success, and its relative contribution to peak revenue estimates.

A terminal value for the company, calculated by applying a 2% long-term growth rate, was similarly discounted to present day. The present value of free cash flows, together with the terminal value, were then added to arrive at a residual value for the company, to which estimated cash and long-term debt were added and subtracted, respectively. Thereby, we arrive at an equity valuation of $365MM. When we divide this amount by our estimated 2014 year-end outstanding share count, we derive a per share valuation of $20.41. Our DCF assumptions are detailed further in Figure 3.

## FIGURE 3. Discounted Cash Flow Valuation

| Concert Pharmaceuticals (CNCE) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Discounted Cash Flow Model** | **2014E** | **2015E** | **2016E** | **2017E** | **2018E** | **2019E** | **2020E** | **2021E** | **2022E** | **2023E** | **2024E** | **2025E** | **Terminal value** |
| **Total Revenues** | | | | | | | | | | | | | |
| US Sales | | | | | 27.8 | 104.2 | 243.7 | 409.5 | 581.5 | 763.4 | 856.9 | 893.5 | |
| Ex-US Royalties | | | | | | 4.3 | 12.1 | 33.2 | 69.0 | 107.2 | 128.9 | 138.7 | |
| **Collaboration Revenue** | | | | | | | | | | | | | |
| JZP-386 | | - | - | 8.0 | 36.8 | 7.6 | 25.4 | 46.9 | 81.0 | 187.3 | 142.6 | 147.7 | |
| AVP-786 | | 2.0 | 2.0 | - | - | 41.3 | 59.4 | 45.8 | 89.6 | 134.2 | 271.8 | 161.5 | |
| **Total Revenues** | | **$ 2.0** | **$ 2.0** | **$ 8.0** | **$ 64.6** | **$ 157.4** | **$ 340.6** | **$ 535.3** | **$ 821.1** | **$ 1,192.1** | **$ 1,400.2** | **$ 1,341.5** | |
| **Cost of product sales** | | | | 0.0 | 2.2 | 7.8 | 17.5 | 28.2 | 37.7 | 49.1 | 56.1 | 58.5 | |
| *COGS as % of revenue* | | | | | *8%* | *8%* | *8%* | *8%* | *8%* | *8%* | *8%* | *8%* | |
| **Gross Profit** | 0.0 | 2.0 | 2.0 | 8.0 | 62.4 | 149.6 | 323.1 | 507.1 | 783.4 | 1,143.0 | 1,344.1 | 1,282.9 | |
| **R&D expense** | 35.0 | 43.8 | 56.9 | 65.4 | 73.3 | 79.1 | 85.4 | 92.3 | 99.7 | 104.6 | 113.0 | 122.1 | |
| *R&D as a % of revenue* | | | | *818%* | *113%* | *50%* | *25%* | *17%* | *12%* | *9%* | *8%* | *9%* | |
| **SG&A expense** | 9.0 | 10.4 | 11.9 | 17.9 | 22.3 | 25.7 | 27.7 | 29.9 | 32.3 | 34.9 | 37.7 | 39.6 | |
| *SG&A as a % of revenue* | | | | *223%* | *35%* | *16%* | *8%* | *6%* | *4%* | *3%* | *3%* | *3%* | |
| **Total operating expenses** | 44.0 | 54.1 | 68.8 | 83.3 | 95.6 | 104.8 | 113.2 | 122.2 | 132.0 | 139.6 | 150.7 | 161.7 | |
| *% Margin* | | | | *1041%* | *148%* | *67%* | *33%* | *23%* | *16%* | *12%* | *11%* | *12%* | |
| **Operating income (EBIT)** | **(44.0)** | **(52.1)** | **(66.8)** | **(75.3)** | **(33.2)** | **44.8** | **210.0** | **384.9** | **651.4** | **1,003.4** | **1,193.4** | **1,121.3** | |
| Taxes | 0.0 | 0.0 | (3.3) | (11.3) | (6.6) | 11.2 | 73.5 | 134.7 | 228.0 | 351.2 | 417.7 | 392.4 | |
| *Tax rate* | *0%* | *0%* | *5%* | *15%* | *20%* | *25%* | *35%* | *35%* | *35%* | *35%* | *35%* | *35%* | |
| After tax operating income | (44.0) | (52.1) | (63.4) | (64.0) | (26.6) | 33.6 | 136.5 | 250.2 | 423.4 | 652.2 | 775.7 | 728.8 | 2,603 |
| Discount year | 0.00 | 1.00 | 2.00 | 3.00 | 4.00 | 5.00 | 6.00 | 7.00 | 8.00 | 9.00 | 10.00 | 11.00 | |
| Discount factor | 1.0 | 1.3 | 1.7 | 2.2 | 2.9 | 3.7 | 4.8 | 6.3 | 8.2 | 10.6 | 13.8 | 17.9 | |
| PV | (44.0) | (40.1) | (37.5) | (29.1) | (9.3) | 9.1 | 28.3 | 39.9 | 51.9 | 61.5 | 56.3 | 40.7 | 145.2 |
| **Residual value of cash flow** | $273 | | | | | | | | | | **Terminal Value** | 145.2 | |
| +Cash and Cash equivalents | 92 | | | | | | | | | | | | |
| **Company value** | 365 | | | | | | | | | | | | |
| -Long-term debt on 12/31/13 | 0 | | | | | | | | | | | | |
| **Value of equity** | $365 | | | | | | | | | | | | |
| Fully diluted shares outstanding on 12/31/14 | 17.89 | | | | | | | | | | | | |
| **Price/share** | **$20.41** | | | | | | | | | | | | |
| Discount Rate | 30.0% | | | | | | | | | | | | |
| Terminal growth rate | 2% | | | | | | | | | | | | |

*Source: JMP Securities LLC, Company filings*

### Sum-of-the-Parts Valuation

In valuing CNCE shares based on a sum-of-the-parts (SOTP) analysis, we projected CTP-354 revenues per anticipated approved indication in MS and SPI, CTP-499 for Diabetic CKD, as well as royalty revenue for JZP-386 and AVP-786. For U.S. sales, we applied increasing contribution margins plateauing at 40% to arrive at projected net income within each indication. For the royalty territories, we applied a 100% contribution margin to an estimated straight-line royalty of 15%. Projected U.S. net income and ex-U.S. royalty revenue were discounted to present values using a discount rate of 30%. Meanwhile, terminal values for each of the potential income streams were determined by applying a long-term growth rate of 2%.

In MS and SPI, our model estimates CTP-354 WW revenues approaching ~$1.4B in 2025, contributing to a present valuation of $214MM, or $11.96 per share. Similarly for royalty revenue from WW sales of CTP-499, we derive a present valuation of $159MM, or $8.88 per share. In 2025, we model peak royalties of $146MM from the use of JZP-386, arriving at an incremental valuation of $84MM or $4.67 per share in NPV. Finally, we model $162MM peak royalties from the use of AVP-786 in 2025, resulting in a present valuation of $86MM, equivalent to $4.82 per share. Adding cash on hand of $5.16 per share (including IPO), we arrive at an SOTP valuation of $35.51. Our SOTP valuation, together with revenue and our contribution modeling assumption, is detailed in Figure 4.

**FIGURE 4. Sum-of-the-Parts Valuation**

| NPV Sum of the Parts | WW | US | Ex-US |
|---|---|---|---|
| CTP-354 | **$ 11.96** | $ 9.34 | $ 2.62 |
| CTP-499 | **$ 8.88** | $ 5.38 | $ 3.50 |
| JZP-386 | **$ 4.67** | $ 2.74 | $ 1.93 |
| AVP-786 | **$ 4.82** | $ 2.51 | $ 2.31 |
| Cash and Equivs on Hand | **$ 5.16** | | |
| **Total NPV** | **$ 35.51** | **$ 19.97** | **$ 10.37** |

*Source: Thompson One and JMP Securities LLC*

## INVESTMENT RISKS

**Clinical risk**. Products undergoing clinical trials may have serious safety concerns, lack efficacy, or fail to demonstrate statistical significance, any of which would preclude them from continuing clinical development and eventual commercialization. If the company's Deuterated Chemical Entity (DCE) Platform® technology is not proven, there will likely be downside to the share price as well as risk to the viability of the company. In addition, CNCE has not yet demonstrated an ability to successfully conduct a large-scale pivotal clinical trial, obtain marketing approvals, manufacture a commercial scale product, or to conduct the sales and marketing activities necessary for successful product commercialization.

- **Dependence upon CTP-354:** Concert Pharmaceuticals is particularly dependent upon the success of its lead product candidate CTP-354. The company's ability to develop, obtain marketing approval for, and successfully commercialize CTP-354 drives a significant share of our current valuation. CTP-354 is currently subject to a partial clinical hold from the FDA that prevents CNCE from administering doses in excess of 6 mg per day. It is possible the company will need to complete additional pre-clinical studies in order to increase the dose past 6 mg per day in future clinical trials .

**Collaboration risk.** Concert Pharmaceuticals will depend upon collaborations with third parties for the development and commercialization of some of the company's product candidates and expects to continue to do so in the future. CNCE's business model relies on making use of its DCE platform to partner with Pharmaceutical and Biotechnology companies to improve existing drug candidates. CNCE's prospects with respect to those product candidates will depend in significant part on the success of those collaborations. In particular;

- **Partnership needed for CTP-499:** Without taking into account potential milestone payments, proceeds from Concert's IPO, together with the company's existing cash and cash equivalents and investments as of September 30, 2013, should provide sufficient funds for operating expenses, debt service, and capital expenditure requirements for the next 24 months. However, this estimate assumes that CNCE enters into a collaboration agreement in which a potential partner provides funding to further develop CTP-499. Late-stage clinical trials for CTP-499 in a diabetic population will likely be too expensive for CNCE to manage alone. Therefore, in our opinion, the ability of CNCE to find a partner for the CTP-499 clinical program is paramount for the company's success.

**Manufacturing risk.** Concert Pharmaceuticals is a clinical-stage biopharmaceutical company applying its extensive knowledge of deuterium chemistry to discover and develop novel small molecule drugs. Because there are limited sources of deuterium, CNCE and its collaborators are exposed to a number of risks and uncertainties associated with the company's deuterium supply. In particular, manufacturing processes for many drug candidates, including those for CTP-499 and certain others, are projected to require large quantities of deuterium for late-stage clinical trials and for commercialization. Consequently, any adverse impact on CNCE's ability to obtain deuterium oxide could have a significant impact on the company's ability to develop or commercialize product candidates. Similarly, CNCE's collaborators will also need to obtain supplies of deuterium and will be subject to risks and requirements in connection with sourcing deuterium similar to the ones the company faces. Sources of risk to CNCE's deuterium supply include:

- **Suppliers for deuterium oxide:** All of the deuterium that CNCE uses in manufacturing its drug candidates is derived from deuterium oxide. The company relies on bulk supplies of deuterium from one domestic source located in the United States and one international source that is affiliated with a foreign government. The company may establish a third deuterium oxide supply arrangement with an additional supplier located abroad that is also affiliated with a foreign government. However, it is possible that the current U.S. supplier and that a potential future foreign supplier of deuterium oxide would rely on the same foreign supplier that CNCE utilizes.

- **Supply contracts:** CNCE estimates that its current source of deuterium oxide will be sufficient to meet anticipated requirements through at least 2015. However, CNCE does not have long-term agreements with its current suppliers. If CNCE is not able to establish or maintain supply arrangements with the foreign government-affiliated suppliers or to purchase additional deuterium oxide from U.S. supplier, the company may be unable to secure alternative sources.

- **Regulation of deuterium transport:** In order to internationally transport any deuterium oxide that CNCE may purchase from a foreign supplier, the company may be required to obtain an export license from the country of origin and an International Import Certificate from the country of destination. CNCE is also required to obtain an export license from the Nuclear Regulatory Commission before shipping deuterium oxide from the United States to any contract manufacturer in another country. Each of these documents specifies the maximum amount of deuterium oxide permitted for either import or export; therefore, added/emergency supplies of deuterium oxide will require an additional export license from the country of origin and a U.S. import certificate. While CNCE has obtained similar licenses and certificates in the past, the company may not be able to obtain them in the future in a timely manner or at all.

- **Sourcing of chemical intermediates:** Certain manufacturing processes associated with CNCE's DCE platform require incorporation of deuterium using deuterated chemical intermediates or reagents that are derived from deuterium oxide. These deuterated chemical intermediates and reagents are not subject to the license requirements applicable to deuterium oxide, and most of the manufacturers of these deuterated chemical intermediates and reagents are not located in countries that produce bulk quantities of deuterium oxide. In addition, CNCE does not have long-term agreements with suppliers of deuterated chemical intermediates or reagents and it obtains some of these deuterated chemical intermediates or reagents from single sources, putting CNCE at risk of uncontrolled cost increases or supply interruptions if the company cannot establish alternative sourcing arrangements.

**Intellectual property risk**. As of December 31, 2013, CNCE held 100 issued patents worldwide, including 50 issued patents in the United States. CNCE's patents and patent applications for its lead programs are set to expire between 2028 and 2034. The company may be sued by a competitor on patent infringement or have to undergo litigation that would incur substantial fees. The company could lose a case, which would make it susceptible to generic risk.

**Financial risk**. Concert Pharmaceuticals currently derives revenue from research and development funding and from license or collaboration agreements. The company is not yet profitable and has a history of operating losses that are expected to continue in the near future. As of September 30, 2013, the company had total assets of ~$49MM, revenues of ~24MM, and a net loss of ~($141K). Developing pharmaceutical products, including conducting pre-clinical studies and clinical trials, is a very time-consuming, expensive, and uncertain process that takes years to complete. The company needs to continue financing clinical trials through to completion and it may be unable to secure additional funding, forcing CNCE to delay, reduce, or eliminate product development programs or commercialization efforts. The company has incurred significant losses since its inception and should expect losses to occur for the next several years. CNCE’s accumulated deficit was $107.7 million as of September 30, 2013.

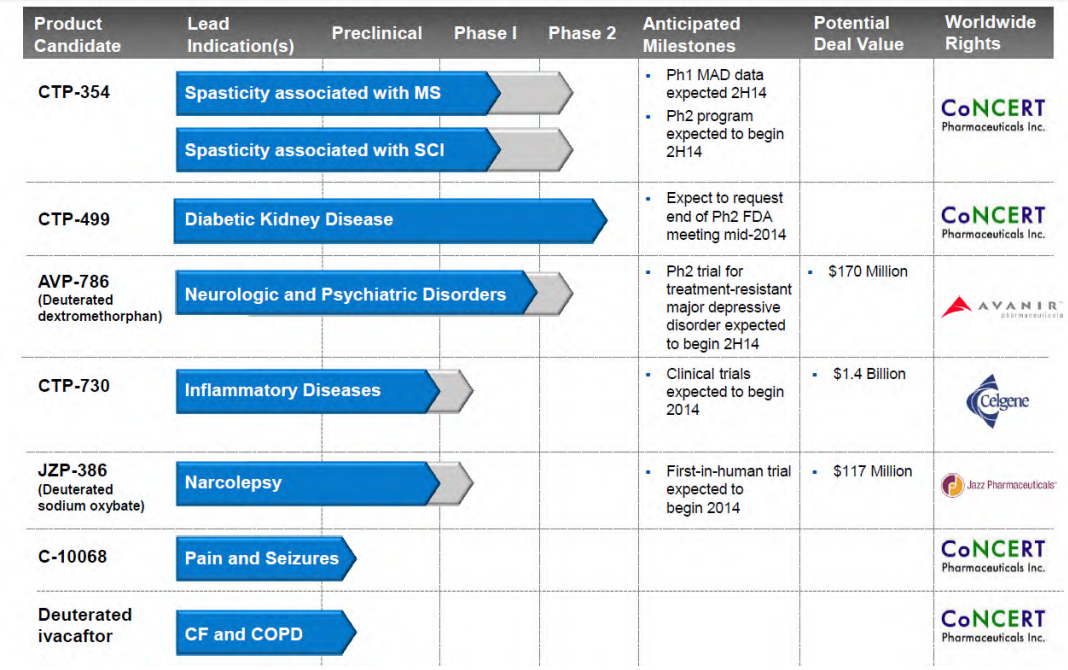
**Competitive risk**. Concert Pharmaceuticals faces competition from marketers of other treatments for the indications that CNCE seeks to develop drugs for, including major pharmaceutical firms and biotech firms. The firm's products will also have to compete with existing treatments that have already become generically available (e.g., CTP-354 will have to compete with other spasticity drugs, such as baclofen, tizanidine, diazepam, and dantrolene). Currently, GW Pharmaceuticals, Osmotica Pharmaceuticals, and others, may have potentially competitive products in Phase III clinical development.

**Regulatory risk.** Concert Pharmaceuticals or the company’s collaborators, may, in some instances, be able to secure clearances from the FDA or comparable foreign regulatory authorities to use expedited development pathways. If the company is unable to obtain such clearances, CNCE or its collaborators may be required to conduct additional pre-clinical studies or clinical trials beyond those contemplated, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals.

## COMPANY DESCRIPTION

Concert Pharmaceuticals is a clinical stage biopharmaceutical company seeking to discover and develop novel small molecule drugs through the improvement of existing drugs and clinical candidates, via deuterium substitution. Deuterium substitution can lead to drugs with superior pharmacokinetic or metabolic properties, improved clinical safety, tolerability, and/or efficacy. Deuterated analogs of approved drugs may also be able to enjoy expedited pathways to FDA approval. The firm currently has a trio of clinical-stage product candidates, including CTP-354, for spasticity associated with multiple sclerosis, CTP-499 for diabetic kidney disease, and AVP-786 for neurologic and psychiatric disorders, through a collaboration with Avanir Pharmaceuticals. The firm is also in ongoing collaboration with Celgene Corporation for deuterated compounds, including CTP-730 for inflammatory diseases, and with Jazz Pharmaceuticals for JZP-386, the active ingredient in Xyrem, which is in pre-clinical development for narcolepsy (Figure 5).

**FIGURE 5. Concert Pharmaceuticals Development Pipeline**



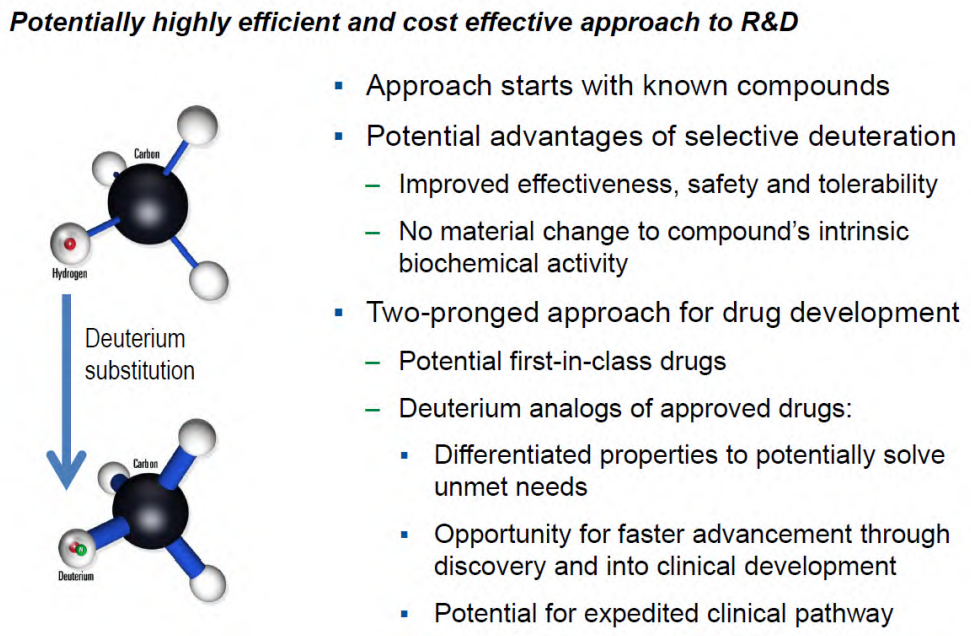

*Source: Concert Pharmaceuticals company reports*

## DEUTERATED CHEMICAL ENTITY (DCE) PLATFORM®

Concert Pharmaceuticals is one of the leaders in applying deuterium chemistry in drug discovery and development. The company has built a DCE Platform® which comprises the proprietary know-how, techniques, and information that it has accumulated since the company's founding in 2006. In our opinion, CNCE's significant experience in deuterium chemistry and pharmaceutical research and development, leaves it well positioned to efficiently identify compounds for deuteration and to design, evaluate, develop, and manufacture deuterated compounds. We believe the advantages that CNCE has over its competition include:

- **Selecting attractive compounds for deuteration.** Candidate compounds are selected for deuteration through the efforts of a team that integrates chemistry, biology, medical, regulatory, intellectual property, and commercial expertise.
- **Testing of deuterated compounds.** CNCE has developed significant proprietary know-how in the design, synthesis, chemical analysis, bioanalytical assessment, pre-clinical evaluation, and clinical development of deuterated compounds.
- **Manufacturing of deuterated compounds.** CNCE can apply manufacturing and analytical know-how and capabilities to reproducibly manufacture deuterated compounds. The company can successfully transfer methods to collaborating partners that can allow them to produce multi-kilogram quantities of clinical trial materials.

**FIGURE 6. DCE Platform® Technology Platform**




*Source: Concert Pharma company reports*

## CTP-354: A NEW HOPE FOR THOSE WITH UNCONTROLLED MUSCLE CONTRACTIONS

### Overview of Spasticity

Spasticity refers to feelings of stiffness and a wide range of involuntary muscle spasms (sustained muscle contractions or sudden movements). It is one of the more common symptoms of Multiple Sclerosis (MS) and Spinal Cord Injury (SCI), occurring in about 75% and 78% of patients, respectively. Spasticity can result from additional disorders, including cerebral palsy, amyotrophic lateral sclerosis, stroke, and hereditary spastic paraplegia. Spasticity may be as mild as a feeling of tightness in muscles or may be so severe as to produce painful, uncontrollable spasms in muscles, as well as pain or tightness in and around associated joints. Spasticity usually affects the legs of MS patients, while it can impact muscles of the limb, trunk, bladder, or rectum in SCI patients. Left untreated, spasticity can lead to serious complications, including contractures (frozen or immobilized joints) and pressure sores. Spasticity may be aggravated by sudden movements or position changes, extremes of temperature, humidity or infections, and can even be triggered by tight clothing. Since sudden movements can also act as spasticity triggers, spastic episodes can set off a dangerous escalation of symptoms. While surgical measures are considered for those rare cases of spasticity that defy all other treatments, medication and physical and occupational therapy are first-line therapy to prevent painful and disabling contractures in the hips, knees, ankles, shoulders, and elbows.

### Current treatments

Spasticity varies greatly from person to person, and therefore must be treated on an individual basis with a true partnership between the patient, physician, and physical therapist. Treatment frequently begins with medications and physical therapy that aim to relieve the painful symptoms associated with spasticity. There are currently several oral medications available including: Baclofen (GABA receptor agonist), Benzodiazepines such as diazepam, clonazepam (GABA modulators), Dantrolene (blocks contraction of muscle cells), and Zanaflex (a2 receptor agonist). The effectiveness of these medications varies with each person and they are frequently not well tolerated, due to adverse side effects such as fatigue or drowsiness, weakness, nausea, or low blood pressure.

### Overview of CTP-354

CTP-354 is a novel, potentially first-in-class, non-sedating treatment for spasticity (Graham P, et. al., Drug Dev 2012) that Concert is developing for use in patients with multiple sclerosis (MS) and in patients with spinal cord injury (SCI). CTP-354 is a subtype selective $GABA_A$ receptor modulator. $GABA_A$ receptors are found in the nervous system and, when activated, reduce the transmission of certain nerve signals. Several classes of widely used drugs target the $GABA_A$ receptor, including benzodiazepines and some sleep agents (Figure 7). However, currently available therapies do not have the receptor subtype selectivity and superior pharmacodynamic properties that CTP-354 possesses (Figure 8). While pharmacotherapy, physical therapy, and surgical intervention treatments currently exist to treat spasticity, current medical therapies are often insufficient to relieve symptoms, and may result in severe sedative side effects. For example, benzodiazepines such as diazepam (Valium®) have strong sedative side effects that severely limit the therapeutic use in spasticity and certain other indications. CNCE engineered CTP-354 to provide therapeutic benefits associated with benzodiazepines, but with significantly reduced sedative effects.

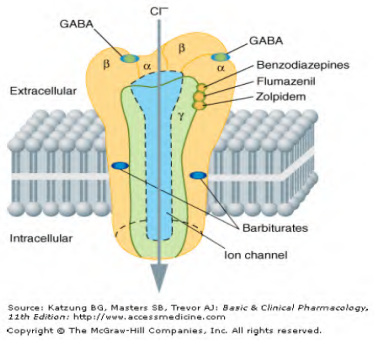
Data to support that CTP-354 has the potential to be a non-sedating treatment that addresses a significant unmet medical need in the treatment of spasticity. CNCE has completed a 71-subject Phase I, single-ascending dose clinical trial of CTP-354 and the company is currently conducting a Phase I imaging study. CNCE's initial Phase I clinical trial results indicate that CTP-354 has a favorable pharmacokinetic profile that supports once-daily dosing, and also indicates that CTP-354 did not cause sedation at levels of $GABA_A$ receptor occupancy well above the levels achieved by benzodiazepines at doses that are typically prescribed (Figure 9). $GABA_A$ receptor occupancy is a measure of the percentage of $GABA_A$ receptors to which a compound binds, which in the case of CTP-354 may correlate to therapeutic activity (Pin J, et. al., Curr Neuropharm 2007). Concert has hypothesized that receptor occupancy is the best surrogate for desired activity and believes that the 6mg dose should provide adequate receptor occupancy in order to exert a therapeutic effect.

In the first quarter of 2014, CNCE initiated a multiple-ascending dose, Phase I clinical trial evaluating daily doses of 2 mg and 6 mg of CTP-354 in healthy volunteers. The company's multiple ascending dose Phase I clinical trial is expected to read out in the second half of 2014. If safety and tolerability are demonstrated, CNCE plans to initiate a Phase II clinical program for CTP-354 in the second half of 2014. The company expects that the Phase II clinical program will include one clinical trial for the treatment of spasticity associated with multiple sclerosis and one clinical trial for the treatment of spasticity associated with spinal cord injury. In previous pre-clinical testing, minimal, if any, toxicity was observed for CTP-354, and a maximum feasible dose or a maximum tolerated dose was not determined. Consequently, the FDA has informed CNCE that the company may not administer multiple doses of CTP-354 in excess of 6 mg per day in clinical trials without first conducting an additional higher dose pre-clinical toxicology study. In order to be able to study doses higher than 6mg, CNCE will conduct additional preclinical toxicology studies to enable evaluation of higher doses as per its discussion with the FDA. Doses higher than 6mg may be required for the development of CTP-354 outside of spasticity associated with MS and MCI. Once these studies are complete, we would expect Concert to commence studies in the above indications sometime during the latter part of 2H14.

### IP Status

Concert Pharma holds issued U.S. and Japanese patents and allowed European claims covering the composition of matter of CTP-354 that expire in 2029.

## FIGURE 7. $GABA_A$ Receptor is a Well-Validated Clinical Target



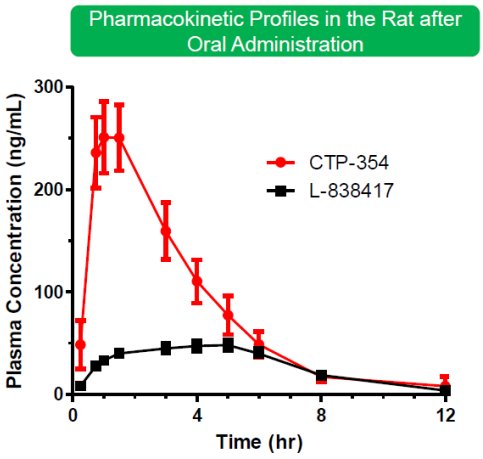

Source: Katzung BG, Masters SB, Trevor AJ: *Basic & Clinical Pharmacology, 11th Edition*: http://www.accessmedicine.com


- CTP-354 binds at same site but in a different manner than benzodiazepines (Valium®, Xanax®) and sleep drugs (Ambien®, Lunesta®)
- Sleep drugs activate $\alpha 1$ – $GABA_A$ receptors
- CTP-354 does not significantly activate $\alpha 1$ – $GABA_A$ receptors

*Source: Concert Pharma company presentation*

## FIGURE 8. CTP-354 has Superior Pharmacodynamics Properties

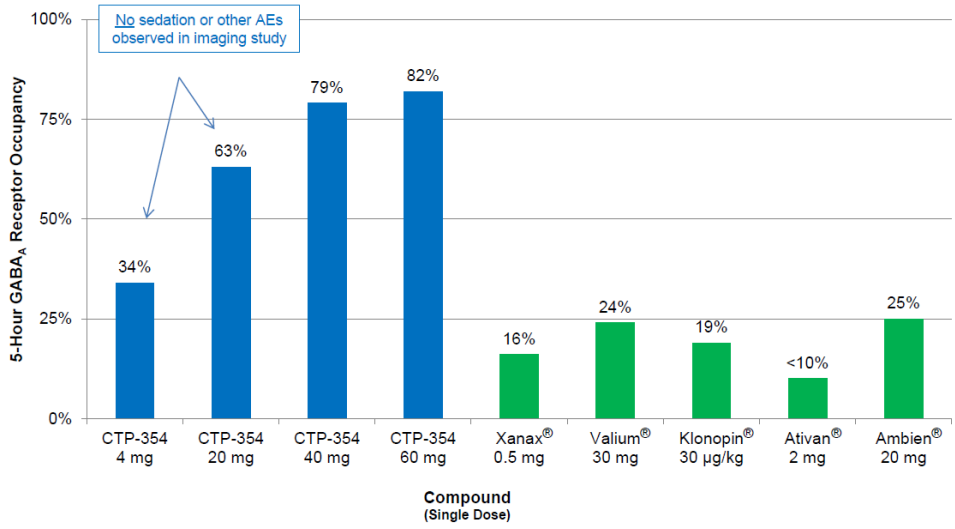
- Modeled after a Merck compound L-838417
  - Not developed — poor pharmacokinetics across preclinical species
- CTP-354 maintains pharmacology but significantly improves pharmacokinetics in rats




*Source: Concert Pharma company presentation*

**FIGURE 9. CTP-354 Phase I Imaging Study**

***CTP-354 less sedating at higher $GABA_A$ receptor occupancy than benzodiazepines***




*Dosing of the marketed $GABA_A$ modulators limited by sedative effects*

*Source: Concert Pharma company presentation*

### CTP-354 Market Potential

The market for CTP-354 is critical as it is the lead drug program for CNCE. The Multiple Sclerosis Society of America estimates there are over 400K patients with MS in the U.S., 85% of which have relapsed/remitting MS (RRMS and experience some spasticity; however, only about 55% of these patients actually receiving treatment. In addition, 5% of the MS population suffers from secondary progressive MS (SPMS), a worse prognosis that almost always includes spasticity, and subsequently most, if not all patients, will require treatment at some point. Our model estimates that CTP-354 can achieve 25% market penetration in RRMS and 50% penetration in PRMS patients by 2025. In addition, there are up to 270K patients suffering from Spinal Cord Injuries (SCI) in the U.S., 28% of which will require treatment. We believe CTP-354 can achieve up to 25% penetration in the SCI market by 2025. Further details of our U.S. CTP-354 model are detailed in Figure 10.

## FIGURE 10. CTP-354 U.S. Revenue Model

| US | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| CTP-354 for MS ($MM) | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E |
| MS | | | | | | | | | |
| MS Incidence, US | 416,242 | 420,404 | 424,608 | 428,854 | 433,143 | 437,474 | 441,849 | 446,267 | 450,730 |
| *% Growth* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* |
| *% Relapse-Remitting MS (RRMS)* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* |
| Number of RRMS Patients | 353,805 | 357,343 | 360,917 | 364,526 | 368,171 | 371,853 | 375,572 | 379,327 | 383,121 |
| *% treated for spaciticity* | *55%* | *55%* | *55%* | *55%* | *55%* | *55%* | *55%* | *55%* | *55%* |
| # Spacticity Treated RRMS Patients | 194,593 | 196,539 | 198,504 | 200,489 | 202,494 | 204,519 | 206,564 | 208,630 | 210,716 |
| ***Market Penetration*** | | **2%** | **7%** | **14%** | **20%** | **25%** | **30%** | **30%** | **30%** |
| MS patients on CTP-354 | - | 3,931 | 13,895 | 28,069 | 40,499 | 51,130 | 61,969 | 62,589 | 63,215 |
| Duration of Therapy (months) | | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 | 9.0 | 9.0 | 9.0 |
| MS patient months on therapy | - | 27,515 | 104,215 | 224,548 | 344,240 | 460,168 | 557,724 | 563,301 | 568,934 |
| **Progressive replapsing MS (PRMS)** | | | | | | | | | |
| Prevalence of MS | 400,000 | 400,000 | 400,000 | 400,000 | 400,000 | 400,000 | 400,000 | 400,000 | 400,000 |
| *% PRMS* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* |
| Addressable PRMS Patients | 20,000 | 20,000 | 20,000 | 20,000 | 20,000 | 20,000 | 20,000 | 20,000 | 20,000 |
| ***Market Penetration*** | | **3%** | **7%** | **14%** | **20%** | **35%** | **45%** | **48%** | **50%** |
| MS patients on CTP-354 | - | 500 | 1,300 | 2,800 | 4,000 | 7,000 | 9,000 | 9,600 | 10,000 |
| Duration of Therapy (months) | | 8.0 | 9.0 | 10.0 | 10.5 | 11.0 | 11.0 | 11.0 | 11.0 |
| MS months on therapy | - | 4,000 | 11,700 | 28,000 | 42,000 | 77,000 | 99,000 | 105,600 | 110,000 |
| **Total MS patients** | | 31,515 | 115,915 | 252,548 | 386,240 | 537,168 | 656,724 | 668,901 | 678,934 |
| Cost of therapy | | $ 500 | $ 500 | $ 530 | $ 546 | $ 563 | $ 580 | $ 597 | $ 615 |
| Price incresae | | *3.0%* | *3.0%* | *3.0%* | *3.0%* | *3.0%* | *3.0%* | *3.0%* | *3.0%* |
| **MS CTP-354 Sales, US ($MM)** | **$ -** | **$ 15.8** | **$ 58.0** | **$ 134.0** | **$ 211.0** | **$ 302.3** | **$ 380.7** | **$ 399.4** | **$ 417.5** |
| **Spinal Chord Injury** | | | | | | | | | |
| *% with problematic spacticity* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* |
| Total SCI patients | 280,963 | 283,773 | 286,610 | 289,477 | 292,371 | 295,295 | 298,248 | 301,230 | 304,243 |
| *% Growth* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* |
| Adressable SCI patients | 78,670 | 79,456 | 80,251 | 81,053 | 81,864 | 82,683 | 83,509 | 84,345 | 85,188 |
| ***Market Penetration*** | **0%** | **2%** | **6%** | **12%** | **18%** | **20%** | **25%** | **30%** | **30%** |
| SCI patients on CTP-354 | - | 5,675 | 17,197 | 34,737 | 52,627 | 59,059 | 74,562 | 90,369 | 91,273 |
| Duration of Therapy (months) | 4.0 | 4.2 | 4.4 | 4.6 | 4.9 | 5.1 | 5.4 | 5.6 | 5.6 |
| SCI months on therapy | - | 23,837 | 75,665 | 159,791 | 257,871 | 301,201 | 402,635 | 506,067 | 511,128 |
| Cost of therapy | | $ 500 | 515 | 530 | 546 | 563 | 580 | 597 | 615 |
| Price incresae | | *3.0%* | *3.0%* | *3.0%* | *3.0%* | *3.0%* | *3.0%* | *3.0%* | *3.0%* |
| **SCI CTP-354 Sales, US ($MM)** | **$ -** | **$ 11.9** | **$ 39.0** | **$ 84.8** | **$ 140.9** | **$ 169.5** | **$ 233.4** | **$ 302.1** | **$ 314.3** |

*Source: JMP Securities LLC & Company reports*

Ex-U.S., we estimate a proportionally larger population for MS and SPI in the EU and likewise, a proportionally smaller population in Japan. We estimate that the annual price in the U.S. and Japan will be ~$6K per patient, while in the EU it will be closer to $4K annually. We also believe that PRMS patients will have the highest monthly usage rates as they suffer from a worse clinical picture, and that SCI patients may take the drugs sporadically as they may be more accustomed to physical therapy over medical therapy to treat spasticity (Figure 11).

## FIGURE 11. Ex-U.S. CTP-354 Revenue Model

**EU**

| CTP-354 for CTP-354 ($MM) | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E |
|---|---|---|---|---|---|---|---|---|---|
| **MS** | | | | | | | | | |
| MS Incidence, EU | 541,114 | 546,525 | 551,990 | 557,510 | 563,085 | 568,716 | 574,404 | 580,148 | 585,949 |
| *% Growth* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* |
| *% Relapse-Remitting MS (RRMS)* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* |
| Number of RRMS MS Patients | 459,947 | 464,546 | 469,192 | 473,884 | 478,623 | 483,409 | 488,243 | 493,125 | 498,057 |
| *% treated for spaciticity* | *75%* | *75%* | *75%* | *75%* | *75%* | *75%* | *75%* | *75%* | *75%* |
| RRMS Treated MS Patients | 344,960 | 348,410 | 351,894 | 355,413 | 358,967 | 362,557 | 366,182 | 369,844 | 373,542 |
| ***Market Penetration*** | | **0%** | **2%** | **4%** | **8%** | **14%** | **18%** | **20%** | **20%** |
| MS patients on CTP-354 | - | - | 5,278 | 12,439 | 28,717 | 50,758 | 65,913 | 73,969 | 74,708 |
| Duration of Therapy (months) | | 5.0 | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 | 9.0 | 9.0 |
| MS patient months on therapy | - | - | 36,949 | 93,296 | 229,739 | 431,442 | 593,215 | 665,719 | 672,376 |
| **Progressive replapsing MS (PRMS)** | | | | | | | | | |
| Prevalence of MS | 520,000 | 520,000 | 520,000 | 520,000 | 520,000 | 520,000 | 520,000 | 520,000 | 520,000 |
| *% PRMS* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* |
| Addressable MS MS Patients | 26,000 | 26,000 | 26,000 | 26,000 | 26,000 | 26,000 | 26,000 | 26,000 | 26,000 |
| ***Market Penetration*** | | | **2%** | **7%** | **12%** | **18%** | **30%** | **40%** | **50%** |
| MS patients on CTP-354 | - | - | 520 | 1,690 | 2,990 | 4,680 | 7,800 | 10,400 | 13,000 |
| Duration of Therapy (months) | | | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 | 9.0 | 9.0 |
| MS months on therapy | - | - | 3,640 | 12,675 | 23,920 | 39,780 | 70,200 | 93,600 | 117,000 |
| **Total MS patients** | | - | 40,589 | 105,971 | 253,659 | 471,222 | 663,415 | 759,319 | 789,376 |
| Cost of therapy | | | $ 300 | 306 | 312 | 318 | 325 | 331 | 338 |
| Price incresae | | | | *2%* | *2%* | *2%* | *2%* | *2%* | *2%* |
| **MS CTP-354 Sales, EU ($MM)** | | **$ -** | **$ 12.2** | **$ 32.4** | **$ 79.2** | **$ 150.0** | **$ 215.4** | **$ 251.5** | **$ 266.7** |
| | | | | | | | | | |
| **Spinal Chord Injury** | | | | | | | | | |
| *% with problematic spaciticity* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* |
| Total SCI patients | 365,252 | 368,905 | 372,594 | 376,320 | 380,083 | 383,884 | 387,722 | 391,600 | 395,516 |
| *% Growth* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* |
| Addressable SCI patients | 102,271 | 103,293 | 104,326 | 105,369 | 106,423 | 107,487 | 108,562 | 109,648 | 110,744 |
| ***Market Penetration*** | | **0%** | **2%** | **4%** | **8%** | **14%** | **18%** | **20%** | **20%** |
| SCI patients on CTP-354 | | - | 7,452 | 13,171 | 30,407 | 53,744 | 69,790 | 78,320 | 79,103 |
| Duration of Therapy (months) | | 4.0 | 4.2 | 4.4 | 4.6 | 4.9 | 5.1 | 5.4 | 5.6 |
| SCI months on therapy | | - | 31,298 | 57,953 | 139,870 | 263,344 | 355,929 | 422,928 | 442,977 |
| Cost of therapy | | | $ 300 | 306 | 312 | 318 | 325 | 331 | 338 |
| Price incresae | | | *2%* | *2%* | *2%* | *2%* | *2%* | *2%* | *2%* |
| **SCI CTP-354 Sales, EU ($MM)** | | **$ -** | **$ 9.4** | **$ 17.7** | **$ 43.7** | **$ 83.8** | **$ 115.6** | **$ 140.1** | **$ 149.7** |

**JPN**

| CTP-354 for CTP-354 ($MM) | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E |
|---|---|---|---|---|---|---|---|---|---|
| **MS** | | | | | | | | | |
| MS Incidence, JPN | 138,747 | 140,135 | 141,536 | 142,951 | 144,381 | 145,825 | 147,283 | 148,756 | 150,243 |
| *% Growth* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* |
| *% Relapse-Remitting MS (RRMS)* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* |
| Number of RRMS MS Patients | 117,935 | 119,114 | 120,306 | 121,509 | 122,724 | 123,951 | 125,191 | 126,442 | 127,707 |
| *% treated for spaciticity* | *75%* | *75%* | *75%* | *75%* | *75%* | *75%* | *75%* | *75%* | *75%* |
| RRMS Treated MS Patients | 88,451 | 89,336 | 90,229 | 91,132 | 92,043 | 92,963 | 93,893 | 94,832 | 95,780 |
| ***Market Penetration*** | | **0%** | **0%** | **0%** | **3%** | **8%** | **18%** | **25%** | **25%** |
| MS patients on CTP-354 | - | - | - | - | 2,761 | 7,437 | 16,901 | 23,708 | 23,945 |
| Duration of Therapy (months) | | | | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 | 9.0 |
| MS patient months on therapy | - | - | - | - | 20,710 | 59,496 | 143,656 | 213,372 | 215,505 |
| **Progressive replapsing MS (PRMS)** | | | | | | | | | |
| Prevalence of MS | 138,747 | 140,135 | 141,536 | 142,951 | 144,381 | 145,825 | 147,283 | 148,756 | 150,243 |
| *% PRMS* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* |
| Addressable MS MS Patients | 6,937 | 7,007 | 7,077 | 7,148 | 7,219 | 7,291 | 7,364 | 7,438 | 7,512 |
| ***Market Penetration*** | | | | | **3%** | **8%** | **22%** | **28%** | **30%** |
| MS patients on CTP-354 | - | - | | | 217 | 583 | 1,620 | 2,083 | 2,254 |
| Duration of Therapy (months) | | | | | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 |
| MS months on therapy | - | - | | | 1,516 | 4,375 | 12,961 | 17,702 | 20,283 |
| **Total MS patients** | | - | - | - | 22,226 | 63,871 | 156,617 | 231,074 | 235,788 |
| Cost of therapy | | | | | $ 500 | 515 | 530 | 546 | 563 |
| Price incresae | | | | | | *3.0%* | *3.0%* | *3.0%* | *3.0%* |
| **MS CTP-354 Sales, JPN ($MM)** | | | | | **$ 11.1** | **$ 32.9** | **$ 83.1** | **$ 126.3** | **$ 132.7** |
| | | | | | | | | | |
| **Spinal Chord Injury** | | | | | | | | | |
| *% with problematic spaciticity* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* |
| TotalSCI patients | 93,654 | 94,591 | 95,537 | 96,492 | 97,457 | 98,432 | 99,416 | 100,410 | 101,414 |
| *% Growth* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* |
| Addressable SCI patients | 26,223 | 26,485 | 26,750 | 27,018 | 27,288 | 27,561 | 27,836 | 28,115 | 28,396 |
| ***Market Penetration*** | | | | **0%** | **3%** | **12%** | **20%** | **25%** | **25%** |
| SCI patients on CTP-354 | | | | - | 2,924 | 11,812 | 19,883 | 25,103 | 25,354 |
| Duration of Therapy (months) | | | | 4.0 | 4.2 | 4.4 | 4.6 | 4.9 | 5.6 |
| SCI months on therapy | | | | - | 12,280 | 51,972 | 91,463 | 123,002 | 141,980 |
| **Total SCI patients** | | - | - | - | 12,291 | 52,005 | 91,546 | 123,129 | 142,113 |
| Cost of therapy | | | | | $ 500 | 515 | 530 | 546 | 563 |
| Price incresae | | | | | *3.0%* | *3.0%* | *3.0%* | *3.0%* | *3.0%* |
| **SCI CTP-354 Sales, JPN ($MM)** | | | | **$ -** | **$ 6.1** | **$ 26.8** | **$ 48.6** | **$ 67.3** | **$ 80.0** |

| EU | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| CTP-354 for CTP-354 ($MM) | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E |
| **MS** | | | | | | | | | |
| MS Incidence, EU | 541,114 | 546,525 | 551,990 | 557,510 | 563,085 | 568,716 | 574,404 | 580,148 | 585,949 |
| *% Growth* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* |
| *% Relapse-Remitting MS (RRMS)* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* |
| Number of RRMS MS Patients | 459,947 | 464,546 | 469,192 | 473,884 | 478,623 | 483,409 | 488,243 | 493,125 | 498,057 |
| *% treated for spaciticity* | *75%* | *75%* | *75%* | *75%* | *75%* | *75%* | *75%* | *75%* | *75%* |
| RRMS Treated MS Patients | 344,960 | 348,410 | 351,894 | 355,413 | 358,967 | 362,557 | 366,182 | 369,844 | 373,542 |
| ***Market Penetration*** | | **0%** | **2%** | **4%** | **8%** | **14%** | **18%** | **20%** | **20%** |
| MS patients on CTP-354 | - | - | 5,278 | 12,439 | 28,717 | 50,758 | 65,913 | 73,969 | 74,708 |
| Duration of Therapy (months) | | 5.0 | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 | 9.0 | 9.0 |
| MS patient months on therapy | - | - | 36,949 | 93,296 | 229,739 | 431,442 | 593,215 | 665,719 | 672,376 |
| **Progressive replapsing MS (PRMS)** | | | | | | | | | |
| Prevalence of MS | 520,000 | 520,000 | 520,000 | 520,000 | 520,000 | 520,000 | 520,000 | 520,000 | 520,000 |
| *% PRMS* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* |
| Addresable MS MS Patients | 26,000 | 26,000 | 26,000 | 26,000 | 26,000 | 26,000 | 26,000 | 26,000 | 26,000 |
| ***Market Penetration*** | | | **2%** | **7%** | **12%** | **18%** | **30%** | **40%** | **50%** |
| MS patients on CTP-354 | - | - | 520 | 1,690 | 2,990 | 4,680 | 7,800 | 10,400 | 13,000 |
| Duration of Therapy (months) | | | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 | 9.0 | 9.0 |
| MS months on therapy | - | - | 3,640 | 12,675 | 23,920 | 39,780 | 70,200 | 93,600 | 117,000 |
| **Total MS patients** | | - | 40,589 | 105,971 | 253,659 | 471,222 | 663,415 | 759,319 | 789,376 |
| Cost of therapy | | | $ 300 | 306 | 312 | 318 | 325 | 331 | 338 |
| Price incresae | | | | *2%* | *2%* | *2%* | *2%* | *2%* | *2%* |
| **MS CTP-354 Sales, EU ($MM)** | | **$ -** | **$ 12.2** | **$ 32.4** | **$ 79.2** | **$ 150.0** | **$ 215.4** | **$ 251.5** | **$ 266.7** |
| **Spinal Chord Injury** | | | | | | | | | |
| *% with problematic spaciticity* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* |
| Total SCI patients | 365,252 | 368,905 | 372,594 | 376,320 | 380,083 | 383,884 | 387,722 | 391,600 | 395,516 |
| *% Growth* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* |
| Adressable SCI patients | 102,271 | 103,293 | 104,326 | 105,369 | 106,423 | 107,487 | 108,562 | 109,648 | 110,744 |
| ***Market Penetration*** | | **0%** | **2%** | **4%** | **8%** | **14%** | **18%** | **20%** | **20%** |
| SCI patients on CTP-354 | | - | 7,452 | 13,171 | 30,407 | 53,744 | 69,790 | 78,320 | 79,103 |
| Duration of Therapy (months) | | 4.0 | 4.2 | 4.4 | 4.6 | 4.9 | 5.1 | 5.4 | 5.6 |
| SCI months on therapy | | - | 31,298 | 57,953 | 139,870 | 263,344 | 355,929 | 422,928 | 442,977 |
| Cost of therapy | | | $ 300 | 306 | 312 | 318 | 325 | 331 | 338 |
| Price incresae | | | *2%* | *2%* | *2%* | *2%* | *2%* | *2%* | *2%* |
| **SCI CTP-354 Sales, EU ($MM)** | | **$ -** | **$ 9.4** | **$ 17.7** | **$ 43.7** | **$ 83.8** | **$ 115.6** | **$ 140.1** | **$ 149.7** |

| JPN | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| CTP-354 for CTP-354 ($MM) | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E |
| **MS** | | | | | | | | | |
| MS Incidence, JPN | 138,747 | 140,135 | 141,536 | 142,951 | 144,381 | 145,825 | 147,283 | 148,756 | 150,243 |
| *% Growth* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* |
| *% Relapse-Remitting MS (RRMS)* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* | *85%* |
| Number of RRMS MS Patients | 117,935 | 119,114 | 120,306 | 121,509 | 122,724 | 123,951 | 125,191 | 126,442 | 127,707 |
| *% treated for spaciticity* | *75%* | *75%* | *75%* | *75%* | *75%* | *75%* | *75%* | *75%* | *75%* |
| RRMS Treated MS Patients | 88,451 | 89,336 | 90,229 | 91,132 | 92,043 | 92,963 | 93,893 | 94,832 | 95,780 |
| ***Market Penetration*** | | **0%** | **0%** | **0%** | **3%** | **8%** | **18%** | **25%** | **25%** |
| MS patients on CTP-354 | - | - | - | - | 2,761 | 7,437 | 16,901 | 23,708 | 23,945 |
| Duration of Therapy (months) | | | | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 | 9.0 |
| MS patient months on therapy | - | - | - | - | 20,710 | 59,496 | 143,656 | 213,372 | 215,505 |
| **Progressive replapsing MS (PRMS)** | | | | | | | | | |
| Prevalence of MS | 138,747 | 140,135 | 141,536 | 142,951 | 144,381 | 145,825 | 147,283 | 148,756 | 150,243 |
| *% PRMS* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* | *5%* |
| Addresable MS MS Patients | 6,937 | 7,007 | 7,077 | 7,148 | 7,219 | 7,291 | 7,364 | 7,438 | 7,512 |
| ***Market Penetration*** | | | | | **3%** | **8%** | **22%** | **28%** | **30%** |
| MS patients on CTP-354 | - | - | | | 217 | 583 | 1,620 | 2,083 | 2,254 |
| Duration of Therapy (months) | | | | | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 |
| MS months on therapy | - | - | | | 1,516 | 4,375 | 12,961 | 17,702 | 20,283 |
| **Total MS patients** | | - | - | - | 22,226 | 63,871 | 156,617 | 231,074 | 235,788 |
| Cost of therapy | | | | | $ 500 | 515 | 530 | 546 | 563 |
| Price incresae | | | | | | *3.0%* | *3.0%* | *3.0%* | *3.0%* |
| **MS CTP-354 Sales, JPN ($MM)** | | | | | **$ 11.1** | **$ 32.9** | **$ 83.1** | **$ 126.3** | **$ 132.7** |
| **Spinal Chord Injury** | | | | | | | | | |
| *% with problematic spaciticity* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* | *28%* |
| TotalSCI patients | 93,654 | 94,591 | 95,537 | 96,492 | 97,457 | 98,432 | 99,416 | 100,410 | 101,414 |
| *% Growth* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* |
| Adressable SCI patients | 26,223 | 26,485 | 26,750 | 27,018 | 27,288 | 27,561 | 27,836 | 28,115 | 28,396 |
| ***Market Penetration*** | | | | **0%** | **3%** | **12%** | **20%** | **25%** | **25%** |
| SCI patients on CTP-354 | | | | - | 2,924 | 11,812 | 19,883 | 25,103 | 25,354 |
| Duration of Therapy (months) | | | | 4.0 | 4.2 | 4.4 | 4.6 | 4.9 | 5.6 |
| SCI months on therapy | | | | - | 12,280 | 51,972 | 91,463 | 123,002 | 141,980 |
| **Total SCI patients** | | - | - | - | 12,291 | 52,005 | 91,546 | 123,129 | 142,113 |
| Cost of therapy | | | | | $ 500 | 515 | 530 | 546 | 563 |
| Price incresae | | | | | *3.0%* | *3.0%* | *3.0%* | *3.0%* | *3.0%* |
| **SCI CTP-354 Sales, JPN ($MM)** | | | | **$ -** | **$ 6.1** | **$ 26.8** | **$ 48.6** | **$ 67.3** | **$ 80.0** |

*Source: JMP Securities LLC and Company reports*

## CTP-499: A NEW TOOL FOR PREVENTION OF DIABETIC CHRONIC KIDNEY DISEASE

### Overview of CTP-499

CTP-499 is a novel, potentially first-in-class, treatment for type II diabetic kidney disease that CNCE is developing as an additive treatment to the current ACE/ARB standard of care. CTP-499 is a multi-subtype selective inhibitor of phosphodiesterases (PDEs), which are enzymes that may play an important role in the pathogenesis of type II diabetic kidney disease. CNCE is currently conducting a Phase II clinical trial of CTP-499, in which the company has enrolled patients with type II diabetic kidney disease and macroalbuminuria (high levels of the blood protein albumin in the urine), who were receiving standard-of-care treatment. The first 24-week portion of this double-blind, parallel, two-arm, placebo-controlled study enrolled 182 type II diabetics with CKD, receiving either ACE/ARB treatment. The primary endpoint was the change at 24 weeks in urinary albumin to creatinine ratio, or UACR. While CTP-499 was generally well tolerated over the 24 weeks of treatment, CTP-354 did not achieve statistical significance in this primary endpoint of the trial. However, over the course of 48 weeks, preliminary analyses suggest a favorable trend in UACR for patients receiving CTP-499 as compared to placebo. In addition, while UACR has been commonly used as an indicator of efficacy in Phase II trials in type II diabetic kidney disease, it is not accepted by the FDA as an endpoint for a Phase III clinical trial for the treatment of type II diabetic kidney disease.

### Overview of Diabetic CKD

Each year in the United States, more than 100,000 people are diagnosed with kidney failure, a serious condition in which the kidneys fail to rid the body of wastes. End-stage renal disease (ESRD) is the final stage of chronic kidney disease (CKD). Diabetes is the most common cause of ESRD, accounting for up to 44% of new cases. Even when diabetes is controlled, the disease can lead to CKD and potentially to ESRD. Some people with diabetes do not develop CKD that is severe enough to progress to ESRD if they are treated with Angiotensin Converting Enzyme (ACE) inhibitors or Angiotensin Receptor Blockers (ARBs). However, no new drugs for diabetic CKD have come onto the market in the past decade, and the ACE/ARB therapies that exist are not sufficient to prevent many of the nearly 24 million people in the U.S. with diabetes from developing CKD and progressing to ESRD as a result.

### Next Steps

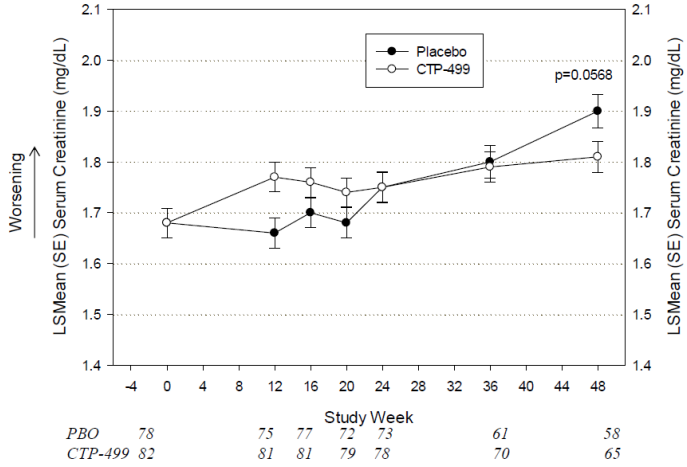
Although CNCE did not achieve statistical significance in the primary endpoint of its Phase II trial for CTP-499, key secondary endpoints showed potential benefits (Braun L, et al., Int J Nephrol Renovasc Dis 2012), including a nearly statistically significant impact on serum creatinine levels (Figure 12) and a positive trend in estimated glomerular filtration rate, or eGFR. Although the Phase II clinical trial was not intended to be powered for statistical significance with respect to serum creatinine or eGFR, and 48 weeks is a limited duration for measuring kidney function, the improvement in serum creatinine was nearly statistically significant after 48 weeks ($p = 0.07$). Furthermore, preliminary analyses of the data at 48 weeks suggest that patients on placebo were more likely to experience a 30% or greater decline in eGFR over the 48 weeks of treatment as compared to patients receiving CTP-499 (Figure 13), with an incidence of 14% among patients receiving placebo compared to 6% for patients receiving CTP-499 ($p = 0.11$). CNCE is currently conducting a complete analysis of these 48 weeks of data in 123 patients, and expects to report final top-line results of the trial in the first half of 2014. As mentioned previously, CNCE will seek one or more collaborators for future development of CTP-499. The company plans to request an end of Phase II meeting with the FDA, and will continue to evaluate CTP-499 in an open-label extension study. CNCE hopes that any large Phase III clinical trial of CTP-499 in type II diabetic kidney disease will proceed in collaboration with one or more partners.

### IP Status

CNCE holds issued U.S. and Japanese patents that cover the composition of matter of CTP-499 and it also has composition of matter patent applications in Europe. The U.S. patent expires in 2029, the Japanese patents expire in 2029 and 2030, and patents that may issue from the European patent applications would expire in 2029 and 2030.

**FIGURE 12. Serum Creatinine in Diabetic CKD Patients Over 48 weeks**

***Preliminary analysis shows a trend for protection against serum creatinine increase***

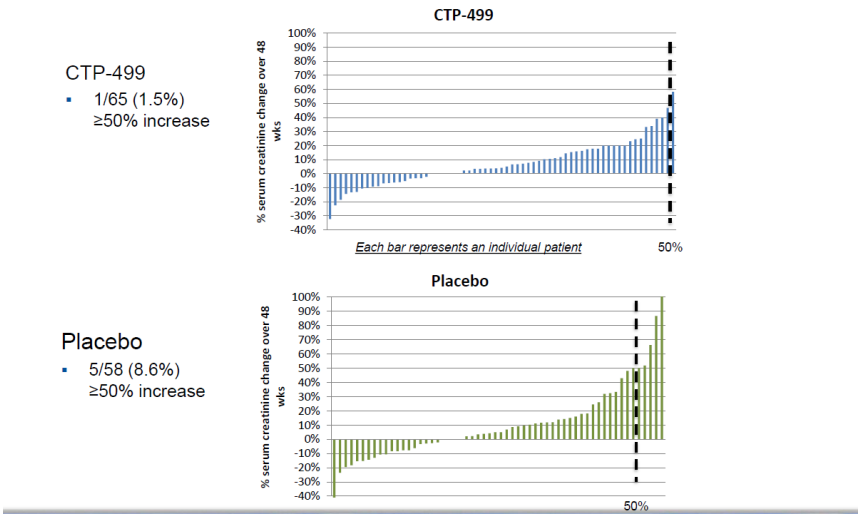



Mean serum creatinine level increase over 48 weeks
CTP-499: 0.13 mg/dL
Placebo: 0.21 mg/dL

*Source: Concert Pharma company presentation*

**FIGURE 13. 48-Week Serum Creatinine Change from Baseline**

*CTP-499 appears to protect against large increases in serum creatinine*




*Source: Concert Pharma company presentation*

### CTP-499 Market Potential

We believe there is significant market potential for CTP-499, given the huge unmet medical need in preventing diabetic patients from progressing to ESRD. As no new therapies have emerged in this indication in the past decade, we believe CTP-499 would be well positioned to join the standard-of-care treatment with ACE inhibitors or ARBs in at-risk populations. There are over 24MM diabetes patients in the U.S., approximately 32% of which have some form of kidney disease. While all of these patients could benefit, in some cases, less than half are on ACE/ARB therapy. Consequently, we have modeled the addressable population for CTP-499 as 40% of the diabetic CKD population and we conservatively estimate that CTP-499 can achieve 12% market penetration by 2025. Further details of our U.S. CTP-499 model are detailed in Figure 14.

Ex-U.S. markets in the EU and Japan are modeled based on proportion to the U.S. population. We estimate that the market penetration in the EU will only reach 9% in 2025 while in Japan we believe it will reach 12%. We believe the annual cost in the U.S. and Japan will be ~$5K per patient while in the EU we model ~$3.5K (Figure 15). Given that the WW diabetic CKD population is so large, we believe this program could be a significant revenue generator once CNCE is able to land a productive partner.

## FIGURE 14. U.S. CTP-499 Model

| US | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| CTP-499 in DMII with CKD ($MM) | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E |
| *Epidemiology* | | | | | | | | | | |
| **DM prevalence population (MM)** | 27 | 28 | 28 | 29 | 29 | 30 | 30 | 31 | 32 | 32 |
| *% growth* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* |
| *% of Dialysis Population with Diabetes Type II* | *90%* | *90%* | *90%* | *90%* | *90%* | *90%* | *90%* | *90%* | *90%* | *90%* |
| # of patients with DM Type IIs | 24 | 25 | 25 | 26 | 26 | 27 | 27 | 28 | 29 | 29 |
| *% pts with DM Type II with CKD* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* |
| *% pts on ACE/ARB* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* |
| Addressable DMII population with CKD (MM) | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 |
| ***CTP-499 Penetration*** | | ***0%*** | ***0%*** | ***1%*** | ***3%*** | ***6%*** | ***10%*** | ***12%*** | ***12%*** | ***12%*** |
| # of Patients on CTP-499 | | 0 | 0 | 32,759 | 100,244 | 204,497 | 347,645 | 425,518 | 434,028 | 442,709 |
| Patient months on therapy | | 3.0 | 3.5 | 4.0 | 4.5 | 5.0 | 5.5 | 6.0 | 6.0 | 6.0 |
| *% Less percent 1-year mortality* | | *20%* | *20%* | *20%* | *20%* | *20%* | *20%* | *20%* | *20%* | *20%* |
| Average months on therapy | | 2.4 | 2.8 | 3.2 | 3.6 | 4.0 | 4.4 | 4.8 | 4.8 | 4.8 |
| **Total Patient Months on Therapy** | | **0** | **0** | **104,830** | **360,878** | **817,989** | **1,529,640** | **2,042,486** | **2,083,336** | **2,125,003** |
| *% growth* | | | | | *244.3%* | *126.7%* | *87.0%* | *33.5%* | *2.0%* | *2.0%* |
| Avg treatment cost per year | | $ - | $ - | $ 1,440 | $ 1,652 | $ 1,873 | $ 2,101 | $ 2,338 | $ 2,385 | $ 2,433 |
| Cost per month | | | | $ 450 | $ 459 | $ 468 | $ 478 | $ 487 | $ 497 | $ 507 |
| % price increase | | | | | *2%* | *2%* | *2%* | *2%* | *2%* | *2%* |
| **US Sales of CTP-499** | | **$0.0** | **$0.0** | **$47.2** | **$165.6** | **$383.0** | **$730.5** | **$994.9** | **$1,035.1** | **$1,076.9** |

*Source: JMP Securities LLC & Company reports*

## FIGURE 15. Ex-U.S. Model of CTP-499

| EU | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| CTP-499 in DMII with CKD ($MM) | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E |
| *Epidemiology* | | | | | | | | | | |
| **DMII with CKD prevalence population** | 40 | 41 | 41 | 41 | 41 | 41 | 42 | 42 | 42 | 42 |
| *% growth* | *0.5%* | *0.5%* | *0.5%* | *0.5%* | *0.5%* | *0.5%* | *0.5%* | *0.5%* | *0.5%* | *0.5%* |
| *% of Dialysis Population on DM Type II* | *90%* | *90%* | *90%* | *90%* | *90%* | *90%* | *90%* | *90%* | *90%* | *90%* |
| # of DMII with CKD Patients on DM Type IIs | 36 | 37 | 37 | 37 | 37 | 37 | 37 | 38 | 38 | 38 |
| *% pts on high dose DM Type IIs* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* |
| *% pts on ACE/ARB* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* |
| Addressable DMII population with CKD (MM) | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| ***CTP-499 Penetration*** | | | | ***0%*** | ***1%*** | ***3%*** | ***6%*** | ***9%*** | ***9%*** | ***9%*** |
| # of Patients on CTP-499 | | | | 0 | 47,035 | 141,810 | 285,037 | 429,694 | 431,842 | 434,001 |
| Patient months on therapy | | | | 3.0 | 3.5 | 4.0 | 4.5 | 5.0 | 5.0 | 5.0 |
| *% Less percent 1-year mortality* | | | | *20%* | *20%* | *20%* | *20%* | *20%* | *20%* | *20%* |
| Average months on therapy | | | | 2.4 | 2.8 | 3.2 | 3.6 | 4.0 | 4.0 | 4.0 |
| **Total Patient months on Therapy** | | | | **0** | **131,697** | **453,791** | **1,026,134** | **1,718,774** | **1,727,368** | **1,736,005** |
| Cost per 3-week month of therapy in beta-thal | | $ - | $ - | $ - | $ 840 | $ 979 | $ 1,124 | $ 1,273 | $ 1,299 | $ 1,325 |
| Cost per month | | | | | $ 300 | $ 306 | $ 312 | $ 318 | $ 325 | $ 331 |
| % price increase | | | | | | *2%* | *2%* | *2%* | *2%* | *2%* |
| **EU Sales of CTP-499** | | | | **$0.0** | **$39.5** | **$138.9** | **$320.3** | **$547.2** | **$560.9** | **$575.0** |

| JPN | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| CTP-499 in DMII with CKD ($MM) | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E |
| *Epidemiology* | | | | | | | | | | |
| **DMII with CKD prevalence population** | 9 | 9 | 9 | 9 | 9 | 10 | 10 | 10 | 10 | 10 |
| *% growth* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* |
| *% of Dialysis Population on DM Type II* | *90%* | *90%* | *90%* | *90%* | *90%* | *90%* | *90%* | *90%* | *90%* | *90%* |
| # of DMII with CKD Patients on DM Type IIs | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 |
| *% pts on high dose DM Type IIs* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* | *31.7%* |
| *% pts on ACE/ARB* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* | *40.0%* |
| Addressable DMII population with CKD (MM) | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| ***CTP-499 Penetration*** | | | | | ***0%*** | ***1%*** | ***3%*** | ***6%*** | ***9%*** | ***12%*** |
| # of Patients on CTP-499 | | | | | 0 | 10,889 | 32,995 | 66,649 | 100,974 | 135,978 |
| Patient months on therapy | | | | | 4.0 | 4.5 | 5.0 | 5.5 | 6.0 | 6.0 |
| *% Less percent 1-year mortality* | | | | | *20%* | *20%* | *20%* | *20%* | *20%* | *20%* |
| Average months on therapy | | | | | 3.2 | 3.6 | 4.0 | 4.4 | 4.8 | 4.8 |
| **Total Patient Months on Therapy** | | | | | **0** | **39,202** | **131,979** | **293,257** | **484,673** | **652,694** |
| *% growth* | | | | | | *#DIV/0!* | *236.7%* | *122.2%* | *65.3%* | *34.7%* |
| Avg treatment cost per year | | | | $ - | $ - | $ 1,620 | $ 1,836 | $ 2,060 | $ 2,292 | $ 2,338 |
| Cost per month | | | | | | $ 450 | $ 459 | $ 468 | $ 478 | $ 487 |
| % price increase | | | | | | *2%* | *2%* | *2%* | *2%* | *2%* |
| **JPN Sales of CTP-499** | | **$0.0** | **$0.0** | **$0.0** | **$0.0** | **$17.6** | **$60.6** | **$137.3** | **$231.5** | **$317.9** |

*Source: JMP Securities LLC & Company reports*

## AVP-786: POTENTIALLY A MAJOR PLAYER IN TREATMENT-RESISTANT MAJOR DEPRESSION

### Overview of Major Depression

Major depression is a common debilitating disorder impacting 10–15% of the U.S. population each year. Despite advances in diagnosing major depression, understanding its psychopharmacology and biomarkers, and the introduction of several novel classes of antidepressants, only 60–70% of patients with depression respond to antidepressant therapy. Treatment-resistant depression represents a dilemma for health care providers as 10–30% of those who exhibit treatment-resistant symptoms also have difficulties in social and occupational function, decline of physical health, suicidal thoughts, and intentions, and increased health care utilization. Treatment-resistant major depression is defined by poor or unsatisfactory response to two adequate (optimal dosage and duration) trials of two different classes of antidepressants. New treatments are needed, as according to the findings from the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) study, 50–66% of patients with depression do not recover fully on an antidepressant medication and one-third of patients experience a remission of their depressive symptoms.

AVP-786 is a combination of a deuterium-substituted dextromethorphan analog and an ultra-low dose of quinidine. CNCE granted Avanir Pharmaceuticals, Inc. an exclusive license to develop and commercialize deuterated dextromethorphan analogs, including the analog in AVP-786 in February, 2012. Just one year later, Avanir reported positive results from a Phase I clinical trial of AVP-786. In June 2013, Avanir reported that the FDA had agreed to an expedited development pathway for AVP-786, permitting Avanir to reference data from its development of dextromethorphan and quinidine in its IND, and any future NDA, for AVP-786. In October 2013, Avanir reported plans to advance AVP-786 into a Phase II clinical trial in the second half of 2014 for treatment-resistant major depressive disorder in patients with insufficient response to conventional antidepressants.

Avanir has stated that it plans to develop AVP-786 for the treatment of neurologic and psychiatric disorders, including pain, behavioral disorders, mood disorders, and movement disorders. Avanir has also reported that it plans to integrate development of AVP-786 into its ongoing clinical development program for AVP-923, a dextromethorphan and quinidine combination product candidate. Avanir reported that AVP-786, which includes a lower dose of quinidine than AVP-923, provided approximately the same pharmacokinetic exposure as AVP-923 in a Phase I clinical trial.

### IP Status

Concert Pharma holds issued U.S., European, and Japanese patents covering the composition of matter of the deuterated dextromethorphan analog in AVP-786. These patents have expirations from 2028 to 2030.

### Market Potential

In February 2012, CNCE entered into a development and license agreement with Avanir under which CNCE granted Avanir an exclusive worldwide license to develop, manufacture, and commercialize deuterated dextromethorphan-containing products. Avanir is initially focused on developing AVP-786, which is a combination of a deuterated dextromethorphan analog and an ultra-low dose of quinidine, for the treatment of neurologic and psychiatric disorders. Under the Avanir agreement, CNCE received a non-refundable upfront payment of $2.0 million in February 2012 and a milestone payment of $2.0 million in April 2013.

CNCE is also eligible to receive, with respect to licensed products comprising a combination of deuterated dextromethorphan and quinidine, up to $4.0 million in development milestone payments, including $2.0 million related to the initiation of dosing in a Phase 2 or Phase 3 clinical trial for AVP-786, up to $37.0 million in regulatory and commercial launch milestone payments and up to $125.0 million in sales-based milestone payments on net product sales of licensed products. In addition, CNCE is eligible for higher development milestones, up to an additional $43.0 million, for licensed products that do not require quinidine. Avanir is currently developing deuterated dextromethorphan only in combination with quinidine and Avanir is required to pay Concert royalties at defined percentages ranging from the mid-single digits to low-double digits below 20% on worldwide net product sales of licensed products (Concert SEC filings and Company reports).

Avanir is responsible for funding 100% of CNCE's research and development costs incurred under the development plan or for activities conducted at Avanir's request, subject to limitations specified in the agreement. However, Avanir is currently conducting all research and development activities without CNCE's services. Major depression is a chronic disorder that impacts the lives of up to 14MM Americans each year. While only 50% of those suffering from depression seek medical treatment, it is estimated that between 10-30% of those on therapy will not respond. These treatment-resistant patients are a potential danger to themselves as many persistently suffer from suicidal ideation. Treatment-resistant depression continues to challenge mental health care providers, and further relevant research involving newer drugs is warranted to improve the quality of life of patients with the disorder. We estimate AVP-786 can achieve up to a 10% penetration into this market by 2025, with further details outlined in Figure 14.

Ex-U.S., we model EU and Japanese revenues in proportion to the U.S. population. Major Depression is becoming more common throughout all industrialized nations, and we believe that in the EU and Japanese markets, AVP-786 will have a similar 10% penetration rate as in the U.S. We estimate that the average cost of AVP-786 will be ~$7K in the U.S. and Japan and ~$5K in the EU. Further details from the ex-U.S. model for AVP-786 can be found in Figure 17.

**FIGURE 16. U.S. AVP-786 Model**

| US<br>AVP-786 for Major Depression ($MM) | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E |
|---|---|---|---|---|---|---|---|---|
| **Major Depression Prevalence** | | | | | | | | |
| Major depression population, US | 15,081,976 | 15,308,206 | 15,537,829 | 15,770,896 | 16,007,460 | 16,247,572 | 16,491,285 | 16,738,654 |
| *% Growth* | *1.5%* | *1.5%* | *1.5%* | *1.5%* | *1.5%* | *1.5%* | *1.5%* | *1.5%* |
| **MD** | | | | | | | | |
| Number of MD Patients | 7,540,988 | 7,654,103 | 7,768,914 | 7,885,448 | 8,003,730 | 8,123,786 | 8,245,643 | 8,369,327 |
| *% of total receiving treatment* | *50%* | *50%* | *50%* | *50%* | *50%* | *50%* | *50%* | *50%* |
| % resistent to current treatment | *10%* | *10%* | *10%* | *10%* | *10%* | *10%* | *10%* | *10%* |
| Addressable Refractory Major Depression population | 754,099 | 765,410 | 776,891 | 788,545 | 800,373 | 812,379 | 824,564 | 836,933 |
| ***Market Penetration*** | | ***2%*** | ***4%*** | ***7%*** | ***9%*** | ***10%*** | ***10%*** | ***10%*** |
| MD patients on AVP-786 | - | 15,308 | 31,076 | 55,198 | 72,034 | 81,238 | 82,456 | 83,693 |
| Duration of Therapy (months) | | 6.7 | 7.5 | 8.1 | 8.9 | 8.9 | 8.9 | 8.9 |
| Total months on therapy | | 102,565 | 233,067 | 447,105 | 641,099 | 723,017 | 733,862 | 744,870 |
| Cost per month therapy | | $ 600 | $ 618 | $ 637 | $ 656 | $ 675 | $ 696 | $ 716 |
| Price increase | | | *3%* | *3%* | *3%* | *3%* | *3%* | *3%* |
| **MD AVP-786 Sales, US ($MM)** | **$ -** | **$ 61.5** | **$ 144.0** | **$ 284.6** | **$ 420.3** | **$ 488.3** | **$ 510.4** | **$ 533.6** |

*Source: JMP Securities LLC & Company reports*

## FIGURE 17. Ex-U.S. AVP-786 Model

**EU**

| AVP-786 for Pseudobulbar affect ($MM) | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E |
|---|---|---|---|---|---|---|---|---|
| **Major Depression Prevalence** | | | | | | | | |
| Major depression population, US | 20,094,925 | 20,195,399 | 20,296,376 | 20,397,858 | 20,499,847 | 20,602,347 | 20,705,358 | 20,808,885 |
| *% Growth* | *0.5%* | *0.5%* | *0.5%* | *0.5%* | *0.5%* | *0.5%* | *0.5%* | *0.5%* |
| **MD** | | | | | | | | |
| Number of MD Patients | 10,047,462 | 10,097,700 | 10,148,188 | 10,198,929 | 10,249,924 | 10,301,173 | 10,352,679 | 10,404,443 |
| *% of total receiving treatment* | *50%* | *50%* | *50%* | *50%* | *50%* | *50%* | *50%* | *50%* |
| % resistent to current treatment | *10%* | *10%* | *10%* | *10%* | *10%* | *10%* | *10%* | *10%* |
| Addressable Refractory Major Depression population | 1,004,746 | 1,009,770 | 1,014,819 | 1,019,893 | 1,024,992 | 1,030,117 | 1,035,268 | 1,040,444 |
| ***Market Penetration*** | | | ***2%*** | ***5%*** | ***8%*** | ***10%*** | ***10%*** | ***10%*** |
| MD patients on AVP-786 | - | - | 20,296 | 50,995 | 81,999 | 103,012 | 103,527 | 104,044 |
| Duration of Therapy (months) | | | 6.7 | 7.5 | 8.1 | 8.9 | 8.9 | 8.9 |
| Total months on therapy | | | 135,986 | 382,460 | 664,195 | 916,804 | 921,388 | 925,995 |
| Cost per month therapy | | $ 450 | $ 450 | $ 450 | $ 450 | $ 450 | $ 450 | $ 450 |
| Price increase | | | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| **MD AVP-786 Sales, US ($MM)** | | **$ -** | **$ 61.2** | **$ 172.1** | **$ 298.9** | **$ 412.6** | **$ 414.6** | **$ 416.7** |

**JPN**

| AVP-786 for Pseudobulbar affect ($MM) | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E |
|---|---|---|---|---|---|---|---|---|
| **Major Depression Prevalence** | | | | | | | | |
| Major depression population, US | 4,784,506 | 4,808,428 | 4,832,471 | 4,856,633 | 4,880,916 | 4,905,321 | 4,929,847 | 4,954,496 |
| *% Growth* | *0.5%* | *0.5%* | *0.5%* | *0.5%* | *0.5%* | *0.5%* | *0.5%* | *0.5%* |
| **MD** | | | | | | | | |
| Number of MD Patients | 2,392,253 | 2,404,214 | 2,416,235 | 2,428,316 | 2,440,458 | 2,452,660 | 2,464,924 | 2,477,248 |
| *% of total receiving treatment* | *50%* | *50%* | *50%* | *50%* | *50%* | *50%* | *50%* | *50%* |
| % resistent to current treatment | *10%* | *10%* | *10%* | *10%* | *10%* | *10%* | *10%* | *10%* |
| Addressable Refractory Major Depression population | 239,225 | 240,421 | 241,624 | 242,832 | 244,046 | 245,266 | 246,492 | 247,725 |
| ***Market Penetration*** | | | | ***5%*** | ***8%*** | ***10%*** | ***10%*** | ***10%*** |
| MD patients on AVP-786 | - | | | 12,142 | 19,524 | 24,527 | 24,649 | 24,772 |
| Duration of Therapy (months) | | | | 6.7 | 7.5 | 8.1 | 8.9 | 8.9 |
| Total months on therapy | | | | 81,349 | 146,427 | 198,665 | 219,378 | 220,475 |
| Cost per month therapy | | | | $ 637 | $ 649 | $ 662 | $ 563 | $ 574 |
| Price increase | | | | | *2%* | *2%* | *-15%* | *2%* |
| **MD AVP-786 Sales, US ($MM)** | | | | **$ 51.8** | **$ 95.1** | **$ 131.6** | **$ 123.5** | **$ 126.6** |

*Source: JMP Securities LLC and, Company reports*

## JZP-386: THE OPPORTUNITY WILL KEEP YOU UP AT NIGHT

### Overview of Narcolepsy

Narcolepsy is a chronic brain disorder that involves poor control of sleep-wake cycles. People with narcolepsy experience periods of extreme daytime sleepiness and sudden, irresistible bouts of sleep that can strike at any time. These "sleep attacks" usually last a few seconds to several minutes. In addition to daytime sleepiness, other major symptoms may include cataplexy (a sudden loss of voluntary muscle tone while awake that makes a person go limp or be unable to move), vivid dream-like images or hallucinations, as well as total paralysis just before falling asleep or just after waking up. Narcolepsy affects both males and females equally and occurs throughout the world. In the U.S., narcolepsy is estimated to affect about one in every 3,000 persons. Symptoms often start in childhood or adolescence, but can occur later in life, and the condition is life-long. Narcolepsy is not rare, but it is an under-recognized and underdiagnosed condition. As such, there is substantial room for JZP-386 to grow given proper patient and physician education.

CNCE is currently conducting certain development activities for a Phase I clinical trial with JZP-386 pursuant to an agreed-upon development plan with Jazz Pharmaceuticals. In addition, CNCE will be responsible for supplying intermediate compounds for making clinical trial material for the Phase I clinical trial. Thereafter, obligations to conduct further development activities are subject to mutual agreement and CNCE has agreed with Jazz Pharmaceuticals that Jazz will assume all manufacturing responsibilities for Phase II development.

### Market Potential

In February 2013, CNCE entered into a development and license agreement with Jazz Pharmaceuticals to research, develop, and commercialize products containing deuterated sodium oxybate, or D-SXB. CNCE is initially focusing on one analog, designated as JZP-386. Under the terms of the agreement, CNCE granted Jazz Pharmaceuticals an exclusive, worldwide, royalty-bearing license under intellectual property controlled by CNCE to develop, manufacture, and commercialize D-SXB products, including JZP-386. Under the Jazz Pharmaceuticals agreement, CNCE received a non-refundable upfront payment of $4MM in February 2013. CNCE is also eligible to receive up to $8MM in development milestone payments, up to $35MM in regulatory milestone payments and up to $70MM in sales milestone payments based on net product sales of licensed products. In addition, Jazz Pharmaceuticals is required to pay CNCE royalties at defined percentages ranging from the mid-single digits to low-double digits below 20%, on a country-by-country and licensed product-by-licensed product basis, on worldwide net product sales of licensed products. The royalty rate is lowered, on a country-by-country basis, under certain circumstances as specified in the agreement.

Pursuant to the agreement, CNCE's costs for activities under the development plan, including pass-through costs and the costs of employees' time at a rate per full-time equivalent year of CNCE's employees' time, which are mutually agreed to, are reimbursed by Jazz Pharmaceuticals. This reimbursement is subject to limitations in the agreement, including adherence within a particular percentage to the development budget.

The American Sleep Society estimates that there are over 100,000 patients in the U.S. suffering from narcolepsy. We estimate that 20% of those may be diagnosed and treated each year, with a potential gain of 0.25% annually given patient and physician education. In the U.S. market, we model JZP-386 hitting 60% penetration in 2025 (Figure 18).

Ex-U.S. we model narcoleptic populations in EU and Japan in proportion to the U.S. population. We believe that market penetration will be similar for each nation. Based on Jazz Pharmaceuticals pricing for Xyrem in narcolepsy of $35K annually, we believe a similar pricing model will be in place for JZP-386 in the U.S. and Japan, while we model the EU slightly lower at ~$27K per year (Figure 19).

**FIGURE 18. U.S. Model of JZP-386**

| US | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **JZP-386 for Narcolepsy ($MM)** | **2016E** | **2017E** | **2018E** | **2019E** | **2020E** | **2021E** | **2022E** | **2023E** | **2024E** | **2025E** |
| **Narcolepsy** | | | | | | | | | | |
| Narcolepsy patients, US | 109,099 | 110,736 | 112,397 | 114,083 | 115,794 | 117,531 | 119,294 | 121,083 | 122,899 | 124,743 |
| *%Growth* | *1.5%* | *1.5%* | *1.5%* | *1.5%* | *1.5%* | *1.5%* | *1.5%* | *1.5%* | *1.5%* | *1.5%* |
| *% diagnosed and treated* | *20.8%* | *21.0%* | *21.3%* | *21.5%* | *21.8%* | *22.0%* | *22.3%* | *22.5%* | *22.8%* | *23.0%* |
| Addressable Narcolepsy patient population | 22,638 | 23,254 | 23,884 | 24,528 | 25,185 | 25,857 | 26,543 | 27,244 | 27,960 | 28,693 |
| ***Market penetration*** | ***0%*** | ***0%*** | ***5%*** | ***10%*** | ***25%*** | ***35%*** | ***50%*** | ***60%*** | ***60%*** | ***60%*** |
| **Narcolepsy patients on JZP-386** | - | - | 1,194 | 2,453 | 6,296 | 9,050 | 13,271 | 16,346 | 16,776 | 17,215 |
| Duration of therapy (months) | - | 6.0 | 7.0 | 8.0 | 9.0 | 9.0 | 9.0 | 9.0 | 9.0 | 9.0 |
| **Total patient months on therapy** | - | - | 8,359 | 19,622 | 56,667 | 81,449 | 119,443 | 147,116 | 150,982 | 154,933 |
| Cost of therapy (per month) | | $ 2,917 | $ 3,004 | $ 3,094 | $ 3,187 | $ 3,283 | $ 3,381 | $ 3,483 | $ 3,587 | $ 3,695 |
| *% price increase* | | | *3%* | *3%* | *3%* | *3%* | *3%* | *3%* | *3%* | *3%* |
| **US sales of JZP-386** | **$ -** | **$ -** | **$ 25.1** | **$ 60.7** | **$ 180.6** | **$ 267.4** | **$ 403.9** | **$ 512.4** | **$ 541.6** | **$ 572.4** |
| *% Growth* | | *#DIV/0!* | *#DIV/0!* | *142%* | *197%* | *48%* | *51%* | *27%* | *6%* | *6%* |

*Source: JMP Securities LLC and Company reports*

## FIGURE 19. Ex-U.S. Model of JZP-386

**EU**

| JZP-386 Narcolepsy ($MM) | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E |
|---|---|---|---|---|---|---|---|---|---|---|
| **Narcolepsy** | | | | | | | | | | |
| Narcolepsy indicence, EU | 150,493 | 151,998 | 153,518 | 155,053 | 156,603 | 158,169 | 159,751 | 161,348 | 162,962 | 164,592 |
| *%Growth* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* |
| *% diagnosed and treated* | *20.8%* | *21.0%* | *21.3%* | *21.5%* | *21.8%* | *22.0%* | *22.3%* | *22.5%* | *22.8%* | *23.0%* |
| Addressable Narcolepsy patient population | 31,227 | 31,919 | 32,622 | 33,336 | 34,061 | 34,797 | 35,545 | 36,303 | 37,074 | 37,856 |
| *Market penetration* | | *0%* | *0%* | *5%* | *15%* | *30%* | *55%* | *60%* | *60%* | *60%* |
| **Narcolepsy patients on JZP-386** | - | - | - | 1,667 | 5,109 | 10,439 | 19,550 | 21,782 | 22,244 | 22,714 |
| Duration of therapy (months) | | 5.7 | 5.8 | 5.9 | 5.9 | 5.9 | 5.9 | 5.9 | 5.9 | 5.9 |
| **Total patient months on therapy** | - | - | - | 9,834 | 30,144 | 61,591 | 115,342 | 128,514 | 131,241 | 134,010 |
| Cost of therapy (per month) | | $ 2,300 | $ 2,300 | $ 2,300 | $ 2,300 | $ 2,300 | $ 2,300 | $ 2,300 | $ 2,300 | $ 2,300 |
| *% price increase* | | | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| **EU sales of JZP-386** | | $ - | $ - | $ 22.6 | $ 69.3 | $ 141.7 | $ 265.3 | $ 295.6 | $ 301.9 | $ 308.2 |
| *% Growth* | | | *#DIV/0!* | *#DIV/0!* | *207%* | *104%* | *87%* | *11%* | *2%* | *2%* |

**JPN**

| JZP-386 Narcolepsy ($MM) | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E |
|---|---|---|---|---|---|---|---|---|---|---|
| **Narcolepsy** | | | | | | | | | | |
| Narcolepsy indicence, EU | 36,906 | 37,645 | 38,397 | 39,165 | 39,949 | 40,748 | 41,563 | 42,394 | 43,242 | 44,107 |
| *%Growth* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* |
| *% diagnosed and treated* | *20.8%* | *21.0%* | *21.3%* | *21.5%* | *21.8%* | *22.0%* | *22.3%* | *22.5%* | *22.8%* | *23.0%* |
| Addressable Narcolepsy patient population | 7,658 | 7,905 | 8,159 | 8,421 | 8,689 | 8,964 | 9,248 | 9,539 | 9,838 | 10,145 |
| *Market penetration* | | | | *8%* | *20%* | *35%* | *45%* | *60%* | *65%* | *60%* |
| **Narcolepsy patients on JZP-386** | - | | | 674 | 1,738 | 3,138 | 4,161 | 5,723 | 6,394 | 6,087 |
| Duration of therapy (months) | | | | 5.7 | 5.8 | 5.9 | 5.9 | 5.9 | 5.9 | 5.9 |
| **Total patient months on therapy** | - | | | 3,840 | 10,079 | 18,512 | 24,553 | 33,767 | 37,727 | 35,912 |
| Cost of therapy (per month) | | | | $ 3,094 | $ 3,156 | $ 3,219 | $ 2,736 | $ 2,791 | $ 2,847 | $ 2,904 |
| *% price increase* | | | | | *2%* | *2%* | *-15%* | *2%* | *2%* | *2%* |
| **EU sales of JZP-386** | | | | $ 11.9 | $ 31.8 | $ 59.6 | $ 67.2 | $ 94.2 | $ 107.4 | $ 104.3 |
| *% Growth* | | | | | *168%* | *87%* | *13%* | *40%* | *14%* | *-3%* |

**EU**

| JZP-386 Narcolepsy ($MM) | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E |
|---|---|---|---|---|---|---|---|---|---|---|
| **Narcolepsy** | | | | | | | | | | |
| Narcolepsy indicence, EU | 150,493 | 151,998 | 153,518 | 155,053 | 156,603 | 158,169 | 159,751 | 161,348 | 162,962 | 164,592 |
| *%Growth* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* | *1.0%* |
| *% diagnosed and treated* | *20.8%* | *21.0%* | *21.3%* | *21.5%* | *21.8%* | *22.0%* | *22.3%* | *22.5%* | *22.8%* | *23.0%* |
| Addressable ederly Narcolepsy patient population | 31,227 | 31,919 | 32,622 | 33,336 | 34,061 | 34,797 | 35,545 | 36,303 | 37,074 | 37,856 |
| *Market penetration* | | *0%* | *0%* | *5%* | *15%* | *30%* | *55%* | *60%* | *60%* | *60%* |
| **Narcolepsy patients on JZP-386** | - | - | - | 1,667 | 5,109 | 10,439 | 19,550 | 21,782 | 22,244 | 22,714 |
| Duration of therapy (months) | | 5.7 | 5.8 | 5.9 | 5.9 | 5.9 | 5.9 | 5.9 | 5.9 | 5.9 |
| **Total patient months on therapy** | - | - | - | 9,834 | 30,144 | 61,591 | 115,342 | 128,514 | 131,241 | 134,010 |
| Cost of therapy (per month) | | $ 2,300 | $ 2,300 | $ 2,300 | $ 2,300 | $ 2,300 | $ 2,300 | $ 2,300 | $ 2,300 | $ 2,300 |
| *% price increase* | | | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| **EU sales of JZP-386** | | $ - | $ - | $ 22.6 | $ 69.3 | $ 141.7 | $ 265.3 | $ 295.6 | $ 301.9 | $ 308.2 |
| *% Growth* | | | *#DIV/0!* | *#DIV/0!* | *207%* | *104%* | *87%* | *11%* | *2%* | *2%* |

**JPN**

| JZP-386 Narcolepsy ($MM) | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E |
|---|---|---|---|---|---|---|---|---|---|---|
| **Narcolepsy** | | | | | | | | | | |
| Narcolepsy indicence, EU | 36,906 | 37,645 | 38,397 | 39,165 | 39,949 | 40,748 | 41,563 | 42,394 | 43,242 | 44,107 |
| *%Growth* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* | *2.0%* |
| *% diagnosed and treated* | *20.8%* | *21.0%* | *21.3%* | *21.5%* | *21.8%* | *22.0%* | *22.3%* | *22.5%* | *22.8%* | *23.0%* |
| Addressable ederly Narcolepsy patient population | 7,658 | 7,905 | 8,159 | 8,421 | 8,689 | 8,964 | 9,248 | 9,539 | 9,838 | 10,145 |
| *Market penetration* | | | | *8%* | *20%* | *35%* | *45%* | *60%* | *65%* | *60%* |
| **Narcolepsy patients on JZP-386** | - | | | 674 | 1,738 | 3,138 | 4,161 | 5,723 | 6,394 | 6,087 |
| Duration of therapy (months) | | | | 5.7 | 5.8 | 5.9 | 5.9 | 5.9 | 5.9 | 5.9 |
| **Total patient months on therapy** | - | | | 3,840 | 10,079 | 18,512 | 24,553 | 33,767 | 37,727 | 35,912 |
| Cost of therapy (per month) | | | | $ 3,094 | $ 3,156 | $ 3,219 | $ 2,736 | $ 2,791 | $ 2,847 | $ 2,904 |
| *% price increase* | | | | | *2%* | *2%* | *-15%* | *2%* | *2%* | *2%* |
| **EU sales of JZP-386** | | | | $ 11.9 | $ 31.8 | $ 59.6 | $ 67.2 | $ 94.2 | $ 107.4 | $ 104.3 |
| *% Growth* | | | | | *168%* | *87%* | *13%* | *40%* | *14%* | *-3%* |

*Source: JMP Securities LLC & Company reports*

## SUMMARY AND CONCLUSION

Currently, CNCE is also involved in collaboration with Celgene that we have not factored into our valuation due to a lack of program detail. However, our work suggests that an agreement was initially focused on one program has the potential to encompass up to four programs. For the initial program, CNCE granted Celgene an exclusive worldwide license to develop, manufacture, and commercialize deuterated analogs of a selected non-deuterated compound and several close chemical derivatives. CNCE further granted Celgene licenses with respect to two additional programs and an option with respect to a third additional program.

Under the Celgene agreement, CNCE received a non-refundable upfront payment of $35MM in April 2013. During the nine months ended September 30, 2013, CNCE recognized $17MM of revenue upon the delivery of a license for the initial program and $400K of revenue related to research and development services performed on the initial program. In addition, CNCE is eligible to earn up to $23MM in development milestone payments, including $8MM related to the completion of a Phase I clinical trial, up to $247.5MM in regulatory milestone payments and up to $50MM in sales-based milestone payments related to products within the initial program. The potential value of this agreement, if all milestones are achieved, is roughly $1.4 billion. As we await further program details, we believe investors should take advantage of a significant store of value in CNCE's pipeline.

We recommend the purchase of Concert Pharmaceuticals shares to those investors who have a long-term perspective and a vision toward the kind of company that we believe CNCE can grow into over the course of the next several years. We hope that we have provided the reader of this report with enough detail to show that, in our opinion, the company has all the requisite ingredients to become one of the leading developers of unique biologic therapeutic agents amongst other publicly traded biotechnology companies. We reiterate our view that shares of CNCE, currently trading with a market cap of roughly $213MM, could be worth $1 billion or more over the course of the next few years, multiple times today's market cap over the longer term.

## MANAGEMENT TEAM

### Roger Tung, Ph.D., Co-Founder, President and CEO

Roger D. Tung, Ph.D. is the co-founder and has served as President and Chief Executive Officer and as a member of the board of directors since April 2006. Before Concert, Dr. Tung was a founding scientist at Vertex, a pharmaceutical company, where he was employed from 1989 to 2005, most recently as its Vice President of Drug Discovery. Prior to Vertex, he held various positions at Merck, Sharp & Dohme Research Laboratories, a global healthcare provider, and The Squibb Institute for Medicinal Chemistry. Dr. Tung received a B.A. in Chemistry from Reed College and a Ph.D. in Medicinal Chemistry at the University of Wisconsin-Madison. Dr. Tung's detailed knowledge of Concert and his 28-year career in the global pharmaceutical and biotechnology industries, including his roles at Vertex, provide a critical contribution to the company's board of directors.

### Nancy Stuart, Chief Operating Officer

Ms. Nancy Stuart has served as the Chief Operating Officer since October 2007 and was the Senior Vice President, Corporate Strategy and Operations from July 2006 to October 2007. Prior to joining Concert Ms. Stuart held various business operations and business development positions at Amgen Inc., a biopharmaceutical company, Kinetix Pharmaceuticals, Inc., a pharmaceutical company subsequently acquired by Amgen, Scion Pharmaceuticals, Inc., a pharmaceutical company, Vertex, a pharmaceutical company and Genzyme Corporation, a biotechnology company subsequently acquired by Sanofi S.A. Ms. Stuart holds a B.S. from the University of Michigan, and an M.B.A. from the Simmons College Graduate School of Management.

### Ryan Daws, Chief Financial Officer

Mr. Ryan Daws has served as the Chief Financial Officer since January 2014. Prior to joining Concert, Mr. Daws served as an independent consultant from June 2013 to January 2014, including an engagement with Concert from September 2013 to January 2014. Mr. Daws served as a Director in the Healthcare Investment Banking Group at Stifel, Nicolaus & Company, Inc., a financial services company, from September 2010 to June 2013. From March 1999 to June 2010, he served in positions of increasing responsibility within the Healthcare Investment Banking Group of Cowen and Company, LLC, a financial services firm. Mr. Daws holds a B.S. in Finance and Organizational Management from the University of South Carolina and an International M.B.A. from the University of South Carolina's Moore School of Business.

### Robert Silverman, J.D., Ph.D., Senior Vice President and General Counsel

Robert Silverman, J.D., Ph.D. has served as the Senior Vice President and General Counsel since December 2010 and prior to that served as Vice President and General Counsel from January 2007 to December 2010. Prior to joining Concert, he served in various legal related roles at Millennium Pharmaceuticals, Inc., a pharmaceutical company, Vertex and FMC Corporation, a chemical manufacturing company. Dr. Silverman received his J.D. from Rutgers-Camden Law School, a Ph.D. in organic chemistry from the University of New Mexico and a B.A. from Lehigh University.

*Source: Company website*

## BOARD OF DIRECTORS

**Richard H. Aldrich**
Chairman of the Board
Co-Founder and Partner, Longwood Founders Fund

Richard H. Aldrich is the co-founder and has served as a member of the board of directors and as Chairman of the board since May 2006. Mr. Aldrich is a Founder and has been a Partner of Longwood Fund, a venture capital firm, since February 2010. Mr. Aldrich founded RA Capital Management LLC, a hedge fund, in 2004 and served as a Managing Member from 2004 to 2008 and as a Co-Founding Member from 2008 until 2011. Mr. Aldrich has co-founded several biotechnology companies including Sirtris Pharmaceuticals, Inc., which was acquired by GlaxoSmithKline in 2008, and Alnara Pharmaceuticals, Inc., which was acquired by Eli Lilly in 2011. He has also held management positions at Vertex, where he was a co-founding employee, and Biogen Corporation (now Biogen Idec Inc., a biotechnology company). Mr. Aldrich co-founded and serves on the board of directors of Verastem, Inc., a public biopharmaceutical company and also serves on the boards of directors of OvaScience, Inc., a public life sciences company of which he serves as chairman of the board, and PTC Therapeutics, Inc., a public biopharmaceutical company. Mr. Aldrich received his undergraduate degree from Boston College, and an M.B.A. from the Amos Tuck School at Dartmouth College. We believe Mr. Aldrich's broad-based experience in business, including his leadership and board experience at life science companies, and his familiarity with our business as a co-founder of our company allows him to be a key contributor to our board of directors.

**Ronald W. Barrett, Ph.D.**
Chief Executive Officer, XenoPort, Inc.

Ronald W. Barrett, Ph.D. has served as a member of the board of directors since December 2007. Dr. Barrett is a founder of XenoPort, Inc., a public biopharmaceutical company, and has served as its Chief Executive Officer since 2001, its Chief Scientific Officer from 1999 to 2001 and as a member of its board of directors since 1999. Prior to XenoPort he held various positions at Affymax Research Institute, a drug discovery company now owned by GlaxoSmithKline plc, and Abbott Laboratories, a healthcare company. Dr. Barrett received a B.S. from Bucknell University and a Ph.D. in pharmacology from Rutgers University. We believe that Dr. Barrett's industry and board experience, including his experience as the chief executive officer of a publicly traded biopharmaceutical company, makes him a key contributor to our board of directors.

**John G. Freund, M.D.**
Managing Director, Skyline Ventures

John G. Freund, M.D. has served as a member of the board of directors since December 2013. Dr. Freund co-founded Skyline Ventures in 1997 and has served as a partner at Skyline since its founding. Prior to joining Skyline, Dr. Freund served as managing director in the private equity group of Chancellor Capital Management, a private capital investment firm. In 1995, he co-founded Intuitive Surgical, a medical device company, and served on its board of directors until 2000. From 1988 to 1994, Dr. Freund served in various positions at Acuson Corporation, a maker of ultrasound equipment that is now part of Siemens, most recently as Executive Vice President. Prior to joining Acuson, Dr. Freund was a general partner of Morgan Stanley Venture Partners from 1987 to 1988. From 1982 to 1988, Dr. Freund was a general partner at Morgan Stanley & Co., an investment banking company, where he co-founded the Healthcare Group in the Corporate Finance Department in 1983. He has served on the board of directors of XenoPort, Inc., a publicly traded biopharmaceutical company, since

1999, and Tetraphase Pharmaceuticals, Inc., a publicly traded biopharmaceutical company, since 2012. Dr. Freund also serves on the board of directors of two privately held companies, Advion and DiscoverX, and three U.S. registered investment funds managed by Capital Research and Management. He also previously served on the board of directors of four publicly traded companies, Map Pharmaceuticals, a biopharmaceutical company, Hansen Medical, a biotechnology company, Sirtris Pharmaceuticals, a biopharmaceutical company, and Mako Surgical Corp., a medical device company. Dr. Freund is a member of the Advisory Board for the Harvard Business School Healthcare Initiative, and is a member of the Therapeutics Advisory Council of Harvard Medical School. Dr. Freund received a B.A. in history from Harvard College, an M.D. from Harvard Medical School and an M.B.A. from Harvard Business School. We believe that Dr. Freund's extensive finance and investment experience, his experience as an executive and his service on the board of directors of numerous public and privately held companies allows him to be a key contributor to our board of directors.

**Peter Barton Hutt**
Senior Counsel, Covington & Burling LLP

Peter Barton Hutt has served as a member of the board of directors since December 2006. Mr. Hutt has practiced law at Covington & Burling LLP, specializing in food and drug law, since 1960 (except for the period from 1971 to 1975) and currently serves as senior counsel. From 1971 to 1975, he was Chief Counsel for the Food and Drug Administration. Mr. Hutt is a member of the board of directors of Momenta Pharmaceuticals, Inc., a public pharmaceutical company, DBV Technologies SA, Q Therapeutics, Inc. and Xoma Ltd., each of which is a public biotechnology company, as well as numerous private companies. During the last five years, Mr. Hutt also served as a member of the board of directors of Celera Genomics, a public biotechnology company that was acquired by Quest Diagnostics, Inc. in 2011, CV Therapeutics, Inc., a public biotechnology company that was acquired by Gilead Sciences, Inc. in 2009, and Ista Pharmaceuticals, Inc., a public pharmaceuticals company that was acquired by Bausch & Lomb Inc. in 2012. Mr. Hutt received a B.A. from Yale University, an LL.B. from Harvard Law School and an LL.M. from New York University School of Law. We believe Mr. Hutt's extensive knowledge of regulatory and legal issues related to drug development and his service on numerous boards of directors allows him to be a key contributor to our board of directors.

**Wilfred E. Jaeger, M.D.**
Partner, Three Arch Partners

Wilfred E. Jaeger, M.D. has served as a member of the board of directors since May 2006. Dr. Jaeger co-founded Three Arch Partners, a venture capital firm, in 1993 and has served as a Partner since that time. Prior to co-founding Three Arch Partners, Dr. Jaeger was a general partner at Schroder Ventures. He is also a member of the board of directors of Threshold Pharmaceuticals, Inc., a public pharmaceutical company, as well as numerous private companies. Dr. Jaeger received a B.S. in Biology from the University of British Columbia, his M.D. from the University of British Columbia School of Medicine and an M.B.A. from Stanford University. In addition to representing one of our principal stockholders, we believe that that Dr. Jaeger's financial and medical knowledge and experience allows him to be a key contributor to our board of directors.

**Helmut M. Schühsler, Ph.D.**
Managing Partner, TVM Capital

Helmut M. Schühsler, Ph.D. has served as a member of the board of directors since September 2011. Dr. Schühsler has worked for TVM Capital, a group of life science venture capital and healthcare private equity firms, since 1990 and currently serves as its Chairman and Managing Partner. During 2007 and 2008, Dr. Schühsler also served as Chairman of the European Private Equity and Venture Capital Association. Dr. Schühsler currently serves as a member of the board of Enanta Pharmaceuticals, Inc., a public pharmaceutical company, several other healthcare growth companies and Max Planck Innovation, the technology transfer organization of the German Max Planck Society. For several years he was a member of the Selection Committee for the Technology Pioneers program. Prior to joining TVM Capital, Dr. Schühsler worked for Horizonte Venture Management, a venture capital firm, and was an assistant professor for corporate finance at the Institute for Advanced Studies in Vienna. Dr. Schühsler received a Ph.D. in the Social and Economic Sciences from the University of Economics in Vienna. In addition to representing one of our principal stockholders, we believe that Dr. Schühsler's business and financial experience as a director and investor in several companies in our industry allows him to be a key contributor to our board of directors.

*Source: Company SEC filings*

## JMP FACTS AND DISCLOSURES

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The research analyst(s) who prepared this report does/do hereby certify that the views presented in this report are in accordance with my/our personal views on the securities and issuers discussed in this report. As mandated by SEC Regulation AC no part of my/our compensation was, is or will be directly or indirectly related to the specific views or recommendations expressed herein. This certification is made under the obligations set forth in SEC Regulation AC. Any other person or entity may not use it for any other purpose. This certification is made based on my/our analysis on the date of this report's publication. I/We assume no obligation to update this certification to reflect any facts,circumstances or events that may subsequently come to my/our attention. Signed Michael G. King

**JMP Securities Disclosures:**

JMP Securities currently makes a market in the securities of Avanir Pharmaceuticals, Inc., Celgene Corporation and Vertex Pharmaceuticals Incorporated

JMP Securities was manager or co-manager of a public offering, and received compensation for doing so, for Concert Pharmaceuticals, Inc. in the past 12 months.

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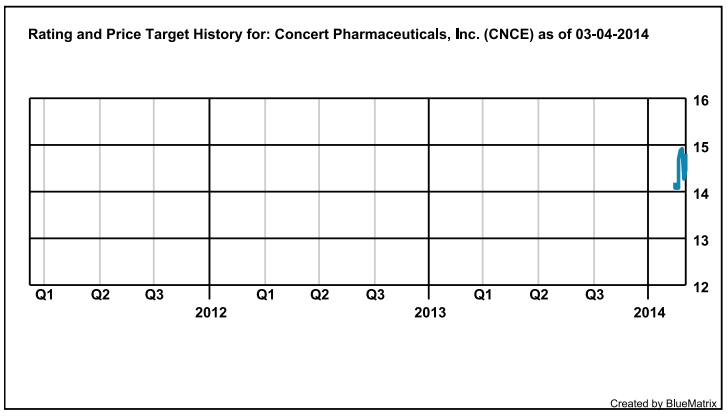
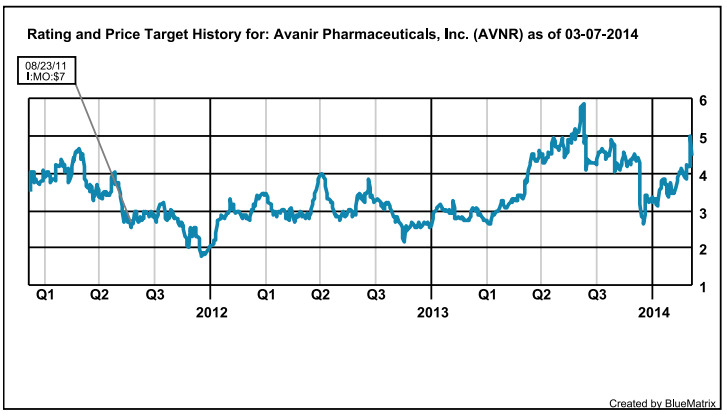
**JMP Securities Research Ratings and Investment Banking Services:** (as of March 9, 2014)

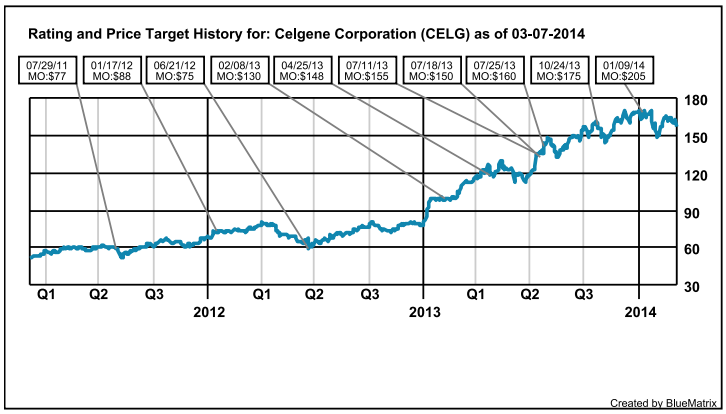
| JMP Rating | Regulatory Equivalent | # Co's Under Coverage | *% of Total* | Regulatory Equivalent | # Co's Under Coverage | *% of Total* | # Co's Receiving IB Services in Past 12 Months | *% of Co's With This Rating* |
|---|---|---|---|---|---|---|---|---|
| MARKET OUTPERFORM | Buy | 247 | *56.52%* | Buy | 247 | *56.52%* | 99 | *40.08%* |
| MARKET PERFORM | Hold | 139 | *31.81%* | Hold | 139 | *31.81%* | 19 | *13.67%* |
| MARKET UNDERPERFORM | Sell | 8 | *1.83%* | Sell | 8 | *1.83%* | 0 | *0%* |
| COVERAGE IN TRANSITION | | 43 | *9.84%* | | 43 | *9.84%* | 0 | *0%* |
| TOTAL: | | 437 | *100%* | | 437 | *100%* | 118 | *27.00%* |

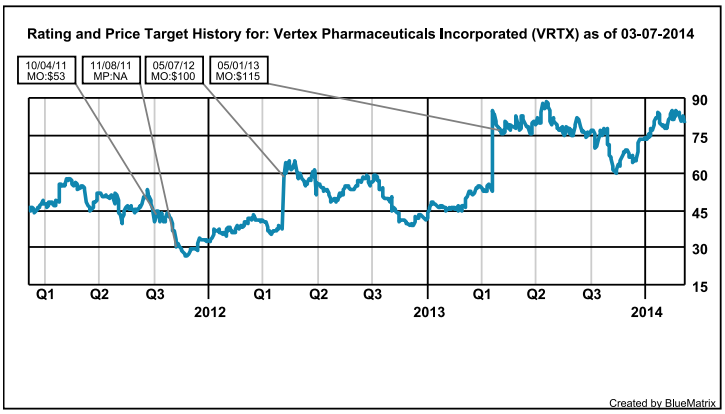
**Stock Price Chart of Rating and Target Price Changes:**

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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