Initiation
**Overweight**

**CCXI, CCXI US**
Price: $10.17

**Price Target: $16.00**

# ChemoCentryx, Inc.

## Good Optionality with Traficet, CCX140; Initiate at OW

We are initiating coverage of ChemoCentryx (CCXI) with an Overweight rating and $16 Dec 2012 target. ChemoCentryx is an early stage biotechnology company with a focus on developing oral drugs targeting the chemokine system, which is involved in autoimmune and inflammatory diseases as well as cancer. The company has a significant and validating partnership with GSK and its pipeline is anchored by Traficet-EN, a unique oral agent for Crohn's disease in phase 3 trials at GSK. In our view, Traficet-EN could be a ~$2B WW opportunity at peak (driving royalties to ChemoCentryx of ~$350M); this is supported by highly positive physician feedback. Beyond Traficet, CCX140 is an unpartnered asset in phase 2 trials for diabetic nephropathy. Trial completion should be YE12 (data in 1H13) and this indication has $1B peak potential, in our view. While ChemoCentryx has many other assets in development and a proven drug discovery platform, our $16 price target is anchored by Traficet royalties and to a lesser extent, CCX140 sales (US only). Hence, we see upside opportunities with further Traficet-EN / CCX140 de-risking as well as progression of earlier stage assets.

- **Key value driver is Traficet-EN in Crohn's.** In the phase 2 PROTECT-1 trial, Traficet-EN significantly induced and maintained remission of Crohn's disease relative to placebo. Importantly, this efficacy was in line with approved biologics, but with improved dosing (oral vs. injection) and a cleaner safety profile. Given similarities in design, we expect the phase 3 trials to confirm PROTECT-1 data and support broad use in Crohn's disease with data in 1H13.
- **CCX140 in diabetic nephropathy (DN) is the second key asset.** Preclinical studies have shown a positive impact of CCX140 on markers / measures of renal function. In addition, in early clinical studies, CCX140 had very good tolerability and a positive efficacy signal in diabetics. Ongoing phase 2 trials in DN should be complete by YE12, which should be a significant de-risking for this indication as well as a leading indicator of activity in other renal indication such as CKD. In DN, our model implies $1B peak potential in the US alone.
- **Robust pipeline validated by a GSK partnership.** ChemoCentryx has a broad pipeline of both partnered and unpartnered assets. GSK has opted in on Traficet-EN and CCX354 (option remains on CCX168), while ChemoCentryx fully owns CCX140 and other preclinical assets.
- **OW; Dec '12 $16 PT.** Our NPV analysis conservatively includes only Traficet-EN in Crohn's (US/EU) with a 70% probability of phase 3 success and CCX140 in DN (US only) with a low 15% probability of clinical success plus net cash.

**US Biotechnology**

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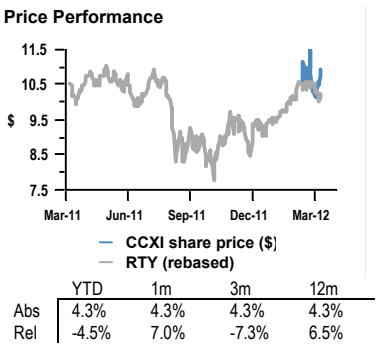
**Price Performance**




| | YTD | 1m | 3m | 12m |
|---|---|---|---|---|
| Abs | 4.3% | 4.3% | 4.3% | 4.3% |
| Rel | -4.5% | 7.0% | -7.3% | 6.5% |

**ChemoCentryx, Inc. (CCXI;CCXI US)**

| FYE Dec | 2010A | 2011E | 2012E | 2013E | 2014E | 2015E |
|---|---|---|---|---|---|---|
| EPS Reported ($) | | | | | | |
| Q1 (Mar) | - | (0.17)A | (0.12) | - | - | - |
| Q2 (Jun) | - | (0.27)A | (0.14) | - | - | - |
| Q3 (Sep) | - | (0.37)A | (0.17) | - | - | - |
| Q4 (Dec) | - | 0.38 | (0.20) | - | - | - |
| FY | (0.11) | (0.44) | (0.64) | (1.06) | (1.53) | (0.23) |

Source: Company data, Bloomberg, J.P. Morgan estimates.

| Company Data | |
|---|---|
| Price ($) | 10.17 |
| Date Of Price | 16-Mar-12 |
| 52-week Range ($) | 12.77 - 10.00 |
| Mkt Cap ($ mn) | 286.90 |
| Fiscal Year End | Dec |
| Shares O/S (mn) | 28 |
| Price Target ($) | 16.00 |
| Price Target End Date | 31 Dec 12 |

**See page 28 for analyst certification and important disclosures.**

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# Investment Thesis

## ChemoCentryx, Inc. (CCXI)

**Overweight**

**Key value driver is Traficet-EN in Crohn's**

Traficet-EN inhibits the CCR9 chemokine receptor and is being developed for Crohn's disease. In the phase 2 PROTECT-1 trial, Traficet-EN successfully induced a clinical response over 12 weeks (≥70 point decline in CDAI of 61% vs. 47% placebo, p=0.039) and maintained remission over 36 weeks (CDAI <150 points of 47% vs. 31% placebo, p=0.011). Importantly, this data is consistent with that of approved biologics (Remicaid, Humira, Cimzia and Tysabri) that have demonstrated responses of 50-60% and maintenance of remission of 40-50%. Traficet-EN is currently in phase 3 trials for moderate-to-severe Crohn's disease with data expected in 1H13. Given the similar design to the phase 2 PROTECT-1 study, we believe that a similar outcome in phase 3 is highly likely. With comparable efficacy to approved biologics and advantages of more convenient dosing (oral vs. IV or SC) and a potentially cleaner safety profile to date, we believe that broad use of Traficet-EN is justified; this is consistent with our feedback from physicians. We project peak WW Traficet-EN sales of nearly $2B (ChemoCentryx receives royalties of ~$350M) and peak US CCX140 sales of $1B+.

**CCX140 in diabetic nephropathy provides another opportunity**

CCX140 inhibits the CCR2 chemokine receptor, selectively inhibiting migration of monocytes and macrophages to the kidneys, preventing inflammation. In phase 1 trials and a phase 2 trial in diabetics, CCX140 was found to be safe and well tolerated with the advantage of improved glycemic control. Preclinical studies have demonstrated that CCX140 has a positive impact on markers of renal function (reduced serum creatinine and blood urea nitrogen levels) as well as renal function (reduced albuminuria and decreased hyperfiltration). These early studies point to the potential of CCX140 in ongoing phase 2 trials for DN, which are expected to be completed by YE12 (data 1Q13). Although still early in development, considering the unmet need and encouraging data to date, we believe CCX140 could be a meaningful treatment option in DN with the potential for success in indications beyond DN such as CKD.

**Productive discovery engine validated by partnerships**

ChemoCentryx is focused on discovering small molecule drugs that target the chemokine system, known to play a role in inflammation. To that end, the company has developed EnabaLink to identify small molecules that inhibit specific chemokines more rapidly. Leveraging this technology, ChemoCentryx has developed a broad pipeline with multiple opportunities in various indications. In fact, in 2006, this approach was validated when ChemoCentryx entered into a partnership with GSK. Under the agreement, GSK has the option for exclusive licenses, which have been exercised on Traficet-EN and CCX354 to date (option remains on CCX168). In return, GSK bears the burden of development in phase 3 and commercialization, while ChemoCentryx will be entitle to milestones and royalties on sales. Beyond these agents, ChemoCentryx has wholly owned assets such as CCX140 and many others in preclinical development.

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# Risks to Rating and Price Target

**Clinical risk**

Predicting the outcome of late stage clinical trials is very difficult. As such, Traficet-EN, currently in four phase 3 trials, may fail to demonstrate a similar outcome to its phase 2 study. Thus, Traficet-EN's ability to demonstrate a meaningful benefit in Crohn's disease is critical to CCXI shares and a key source of clinical risk. Another source of clinical risk is CCX140 in phase 2 clinical trials for DN.

**Regulatory risk**

Assuming Traficet-EN is successful in phase 3 trials in Crohn's disease, the next step would be regulatory approval. Even if Traficet-EN demonstrates a clinical benefit, there is no guarantee that regulators will approve the drug. We see similar risk for CCX140, assuming that it progresses to phase 3 trials. Thus, Traficet-EN and CCX140 could face difficulties obtaining approval from the FDA or EMEA.

**Commercial risk**

ChemoCentryx has no marketed products. For Traficet-EN, the company will rely on partner GSK to market the drug in Crohn's disease. This market is competitive with multiple products and despite advantages, Traficet-EN could fail to gain a meaningful market share. For CCX140, the company intends to market this product on its own in the US for DN. Although this represents more of a niche market, ChemoCentryx has no experience marketing drugs, which could prove challenging.

**Financial risk**

Following completion of its initial public offering and GSKs option exercise on CCX354, we estimate ChemoCentryx has $151M in cash on hand. However, with advancement of a broad pipeline and product revenues not expected until 2015, the company may need to raise additional capital, which could dilute current shareholders.

**Legal risk**

Overall, ChemoCentryx has patents on its pipeline products that expire from 2020-2029. An inability to defend Traficet-EN (expires 2024/2025) or CCX140 (expires 2028) patents in the US or Europe could substantially limit the commercial opportunities. Additionally, Millennium has certain patent claims related to small molecule modulation of CCR9. As a result, ChemoCentryx may need to license or enter in litigation with Millennium in order to commercialize Traficet-EN.

## Company Description

ChemoCentryx is a biotechnology company focused on the discovery, development and commercialization of therapies for the treatment of autoimmune diseases, inflammatory disorders and cancers. The company's primary objective is on the development of oral, small molecule therapeutics that target the chemokine system. Although ChemoCentryx has no marketed products today, it has 4 agents in clinical development. The most advanced of these is Traficet-EN, currently in phase 3 trials for Crohn's disease, with multiple agents in phase 2 (CCX140, CCX354, and CCX168), phase 1, and preclinical testing.

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# Overview

## Background

ChemoCentryx was founded in 1997 and completed its IPO in February 2012, raising $52M, including exercise of the over-allotment option (J.P. Morgan acted as lead manager for the IPO). The company's drug development strategy is focused on the chemokine system. Chemokines and chemokine receptors play a central role in inflammation by targeting specific cells to tissues, which promotes an inflammatory response and ultimately contributes to the pathology of many diseases. As such, the goal of ChemoCentryx's approach is to develop drugs that block specific chemokine or chemo-attractant receptors, preventing inflammation and thus provide a clinical benefit. To that end, ChemoCentryx has developed EnabaLink, a proprietary suite of technologies designed to improve the understanding of the chemokine system and aid in the more rapid identification of small molecules that inhibit specific parts of this system. Leveraging this technology, the company has developed a broad pipeline consisting of many candidates that have been discovered internally.

Although ChemoCentryx has no marketed products, part of the company's strategy is to partner programs that address primary care markets and maintain significant rights to programs that address specialty markets. To that end, in August 2006, ChemoCentryx entered into a strategic alliance with GSK. Under the agreement, ChemoCentryx is responsible for the discovery and development through proof-of-concept for six small molecules targeting CCR9 (Traficet-EN), CCR1 (CCX354), C5aR (CCX168) and two second generation compounds as well as two designated back up compounds for each. Following proof-of-concept for each of these programs, GSK then has the option for an exclusive license. If exercised, GSK will be responsible for further development and commercialization, while ChemoCentryx will receive milestones and royalties on sales of the agent. To date, GSK has exercised its options on Traficet-EN and CCX354 and still has an option remaining on CCX168. Both ChemoCentryx and GSK have decided not to continue development of CCX832 or the two second generation compounds.

## Pipeline

ChemoCentryx currently has a robust pipeline, in our view, with multiple assets in various stages of development (Table 1). The most advanced is Traficet-EN, which is currently in phase 3 trials for Crohn's disease. The next most advanced is CCX140 in phase 2 trials for diabetic nephropathy (DN). Additional products in phase 2 testing include CCX354 for RA and CCX168 for vasculitis. Multiple products are in preclinical testing (CCX662 for glioblastoma multiforme and other unnamed compounds for atopic dermatitis, ulcerative colitis, chronic hepatitis, metabolic complications, and autoimmune disease).

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**Table 1: ChemoCentryx Pipeline Overview**

| Product | Indication | Target | Partner | Preclinical | Ph I | Ph II | Ph III | Marketed |
|---|---|---|---|---|---|---|---|---|
| **Traficet-EN** | Crohn's Disease | CCR9 | GSK | | | | | |
| **CCX140** | Diabetic Nephropathy | CCR2 | None | | | | | |
| **CCX354** | Rheumatoid Arthritis | CCR1 | GSK | | | | | |
| **CCX168** | Vasculitis | C5aR | GSK has option | | | | | |
| **CCX662** | Glioblastoma Multiforme | CXCR7 | None | | | | | |
| **Unnamed** | Atopic Dermatitis | CCR4 | None | | | | | |
| **Unnamed** | Ulcerative Colitis | Next Gen CCR9 | None | | | | | |
| **Unnamed** | Chronic Hepatitis | CXCR6 | None | | | | | |
| **Unnamed** | Metabolic Complications | Next Gen CCR2 | None | | | | | |
| **Unnamed** | Autoimmune Disease | CCR6 | None | | | | | |

Source: Company reports.

## Catalysts and Milestones

### Traficet-EN

Traficet –EN targets the CCR9 chemokine receptor and is being developed for Crohn's disease. In a phase 2 trial (PROTECT-1), Traficet-EN produced a clinical response over a 12 week treatment period and also maintained clinical remission over a 36 week treatment period in moderate-to-severe Crohn's disease. Following these data, GSK exercised its option (Dec 2009) for an exclusive license to develop and commercialize Traficet-EN. GSK has initiated a broad phase 3 program (SHIELD 1, 2, 3, & 4) that began in January 2011 with data expected in 1H13 (Table 2).

### CCX140

CCX140 targets the CCR2 chemokine receptor and is being developed for the treatment of diabetic nephropathy (DN). A phase 2 trial in type 2 diabetics was completed in January 2011 in which CCX140 demonstrated a dose-dependent decline in fasting glucose and was found to be safe and well tolerated. CCX140 is currently in two phase 2 trials in DN, which are expected to be completed by YE12 (Table 2).

### CCX354

CCX354 targets the CCR1 chemokine receptor and is being developed for rheumatoid arthritis (RA). In a phase 2 proof-of-concept study, CCX354 achieved an ACR20 response of 56% (200 mg QD) and 44% (100 mg BID) compared to 30% for placebo. Following this study, GSK exercised its option (Nov 2011) for an exclusive license to develop and commercialize CCX354 and is expected to initiate a phase 2b trial in RA in 2H12 (Table 2).

### CCX168

CCX168 targets C5aR and is being developed for ANCA-associated vasculitis (AVV). In a phase 1 trial, CCX168 dosed up to 100 mg was found to be well

tolerated. A phase 2 proof-of-concept study in AVV was initiated in 4Q11 with completion expected by year-end 2012 (Table 2). Under the collaboration agreement, following the proof-of-concept data, GSK can exercise an option for an exclusive license to develop and commercialize CCX168.

**Early development**

CCX662 targets the CXCR7 chemokine receptor, which plays a key role in the survival of tumor cells. In preclinical studies, CCX662 demonstrated activity against animal models of glioblastoma multiforme (GBM) and a phase 1 trial is expected to begin in 2H13 (Table 2). In addition, other products in preclinical testing target chemokine receptors involved in atopic dermatitis (CCR4), ulcerative colitis (next generation CCR9), chronic hepatitis (CXCR6), metabolic complications (next generation CCR2), and autoimmune diseases (CCR6).

**Table 2: ChemoCentryx Clinical Catalysts**

| Est Timing | Drug | Indication | Event | Significance |
|---|---|---|---|---|
| 2H12 | CCX354 | RA | Initiate a phase 2 trial | Low |
| YE12 | CCX140 | Diabetic Nephropathy | Complete phase 2 trials | High |
| YE12 | CCX168 | Vasculitis | Complete phase 2 proof-of-concept | Medium |
| 2H13 | CCX140 | Diabetic Nephropathy | Initiate phase 3 trial | Low |
| 1H13 | Traficet-EN | Crohn's Disease | Phase 3 SHIELD 1 (induction) data | High |
| 1H13 | CCX662 | Glioblastoma Multiforme | Initiate a phase 1 trial | Low |
| Mid14 | Traficet-EN | Crohn's Disease | Phase 3 SHIELD 2 (maintenance) data | High |
| YE14 | Traficet-EN | Crohn's Disease | Regulatory filing US and EU | High |
| 2015 | Traficet-EN | Crohn's Disease | Approval and launch in US and EU | High |

Source: J.P. Morgan estimates and Company data.

# GSK Strategic Alliance

In August 2006, ChemoCentryx entered into a strategic alliance with GSK worth $1.3B in aggregate and has cumulatively paid ChemoCentryx $248M under the agreement. Given the substantial size of the potential GSK investment, we think the alliance serves as a significant validation of the ChemoCentryx approach and pipeline. Under the agreement, ChemoCentryx is responsible for the discovery and development through proof-of-concept for six small molecules targeting CCR9 (Traficet-EN), CCR1 (CCX354), C5aR (CCX168), ChemR23 (CCX832) and two second generation compounds as well as two designated back up compounds for each. Following proof-of-concept data generated by ChemoCentryx, GSK will then have the option for an exclusive license. If exercised, GSK will be responsible for further development and commercialization, while ChemoCentryx will receive milestones and royalties on sales of the agent.

ChemoCentryx and GSK have decided not to develop the two second generation compounds. Additionally, both have decided not to continue further development of CCX832 following phase 1 data. However, in December 2009, GSK exercised its option on Traficet-EN following positive data from the PROTECT-1 trial and provided an option exercise fee of $35M. More recently, in November 2011, GSK

exercised its option on CCX354 following positive proof-of-concept data and provided an option exercise fee of $25M. Thus, GSK is currently responsible for developing and commercializing Traficet-EN and CCX354. Additionally, GSK has one remaining option on CCX168 and if exercised would owe ChemoCentryx a $25M option exercise fee.

# Traficet-EN for Crohn's Disease

Traficet-EN is currently in phase 3 trials for moderate-to-severe Crohn's disease with data expected in 1H13. Traficet-EN is a small molecule that targets the CCR9 chemokine receptor, selectively inhibiting inflammation in the digestive tract. In phase 2 trials, Traficet-EN was effective in inducing a clinical response over 12 weeks (≥70 point decline in CDAI of 61% vs. 47% placebo, p=0.039) and maintaining a clinical remission over 36 weeks (CDAI <150 points of 47% vs. 31% placebo, p=0.011). Importantly, these data are consistent with that of approved biologics that have demonstrated clinical responses of 50-60% and maintenance of remission of 40-50%. Despite the availability of multiple agents for moderate-to-severe Crohn's disease, we believe an unmet need exists, given the inconvenient dosing (IV and SC) and safety risks associated with current agents. As such, we believe Traficet-EN can fill this need with oral dosing and a potentially clean safety profile. We forecast peak WW sales of nearly $2B in Crohn's disease along with ChemoCentryx receiving $350M in royalties, assuming that the company does not opt into co-promotion in the US.

## Crohn's Disease: A Brief Overview

Crohn's disease is a chronic autoimmune disease that can lead to inflammation of the entire digestive tract. Crohn's is related to ulcerative colitis, which involves inflammation of the colon only, and together these diseases are referred to as inflammatory bowel disease (IBD).[1] Specifically, for Crohn's the cause of disease is currently unknown, but is believed to involve genetic, environmental and immunological factors.[2] The immune system plays an important role in the progression of disease leading to ulcerative lesions. Symptoms can include diarrhea, abdominal pain, nausea, vomiting and rectal bleeding. Over time, scarring leads to stiffness of the bowels and can eventually lead to complications such as obstructions, perforations, abscesses and fistulas, requiring surgery.

Crohn's disease is typically characterized by periods of active disease or flares followed by periods of remission, where the disease is under control. As such, the goal of therapy is to bring the flare-ups under control and then maintain the remission longer term.[3] Currently available therapies for Crohn's disease include antibiotics, anti-inflammatory agents, steroids, immunosuppresants and biologics. Traditionally, treatment with these agents has followed a "bottom up" approach, with less toxic agents being used in early disease, followed by more aggressive agents in later stage disease. However, more recently there has been a trend towards a more aggressive "top down" approach, starting therapy with the more potent and toxic biologics.

[1] Podolsky, *NEJM* 2002, 347:417-429
[2] Fiocchi, *Gastroenterology* 1998, 115: 182-205
[3] Anand Pitadia *et. al., Pharmacological Reports* 2011, 63: 629-642

In mild disease, anti-inflammatory agents such as aminosalicylates and budesonide are preferred and can be administered for years.[4] Oral antibiotics are also used as some believe reducing the bacteria in the intestines indirectly suppress the immune system, but the effectiveness of this approach is unclear. If active disease remains despite the use of anti-inflammatory agents, a short course of oral steroids is often used.

In moderate-to-severe disease, immunosuppressants and steroids are the first choice of therapy and are often used in combination.[4] Steroids are fast acting and thus preferred for active disease, but are not particularly suitable for maintenance given the known risk of long-term exposure. On the other hand, immunosuppressants take more time to have an effect and are preferred for maintenance, but carry their own risk of increased serious infections. In patients not controlled on or intolerant of immunosuppressant or steroids, anti-TNFs have been used to both induce and maintain a remission.[4] More recently, combinations of immunosuppressants and biologics have been explored, resulting in higher responses and remission rates, but at a cost of increased risk of opportunistic infections and malignancies.[5].

## Competitive Treatment Landscape

We expect Traficet-EN to compete with the biologics as these agents similarly block the immune response and are more commonly used in moderate-to-severe Crohn's disease (Table 3). Approved biologics include JNJ's Remicade, Abbott's Humira, and UCB's Cimzia, all of which are anti-TNFs and Biogen/Elan's Tysabri, which is an integrin receptor antagonist. Since all these agents are large molecules, they are administered either intravenously (Remicade and Tysabri) or subcutaneously (Humira and Cimzia). In contrast, Traficet-EN is a small molecule that is administered orally, an attribute we view as a major differentiating factor.

**Table 3: Approved Therapies for Crohn's Disease**

| Drug | Company | Mechanism | Route of administration | Boxed Warning | Crohn's Approval |
|---|---|---|---|---|---|
| **Remicaid** | JNJ | TNF antagonist | Intravenous (every 8 weeks) | Risk of serious infection and malignancy | 1998 |
| **Humira** | Abbott | TNF antagonist | Subcutaneous (every other week) | Risk of serious infection and malignancy | 2007 |
| **Cimzia** | UCB | TNF antagonist | Subcutaneous (every 4 weeks) | Risk of serious infection | 2008 |
| **Tysabri** | Biogen/Elan | Integrin receptor antagonist | Intravenous (every 4 weeks) | Risk of PML | 2008 |

Source: Company reports and product labels.

In terms of efficacy, direct comparisons across clinical trials of biologics are difficult given different time points and endpoints (Table 4). For Cimzia, for example, a more stringent definition of clinical response was used (≥100 vs. ≥70 point decrease in CDAI score) so response rates would be expected to be lower for this agent. Additionally, for Tysabri, maintenance of clinical remission was similarly defined as a CDAI of <150, but was required to be met at all visits (rather than just at the time point tested) and thus represents a higher bar. Despite this, however, the consensus among physicians is that these agents are comparable in terms of efficacy. Among the biologics, clinical responses tend to cluster in the 50-60% range with a range of 40-50% for maintenance of remission.

[4] Cottone *et. al.*, *Expert Opin. Phramacother* 2011, 12: 2505-2525
[5] Colombel JF *et. al., N Engl J Med* 2010, 362: 1383-1395

Table 4: Comparison of Biologics For Moderate-to Severe- Crohn's disease

| | Induction<br>Clinical response (≥70 point decrease CDAI) | Maintenance<br>Clinical remission (<150 CDAI) |
|---|---|---|
| **Remicaid** | n=545, 2 wks<br>**57%**<br>NA | n=545, 7.5 months<br>**46% vs. 25% placebo**<br>p=0.001 |
| **Humira** | n=475, 4 wks<br>**52-58% vs. 34% placebo**<br>p<0.01 | n=342, 6.5 months<br>**40% vs. 17% placebo**<br>p<0.001 |
| **Cimzia** | n=659, 6wks<br>**35% vs. 27% placebo ***<br>p<0.05 | n=425, 6.5months<br>**48% vs. 29% placebo**<br>p<0.05 |
| **Tysabri** | n=896, 10wks<br>**56% vs. 49% placebo**<br>p=0.067 | n=331, 9 months<br>**45% vs. 26% placebo ^**<br>p<0.005 |

**Note:** * Cimzia clinical response defined as ≥100 point decrease in CDAI; ^ Tysabri clinical remission was required at all visits.

Source: Product labels.

Although the biologics are effective in treating moderate-to-severe Crohn's disease, these agents are not without risks. The anti-TNFs carry the risk of severe infection and have been associated with drug induced lupus, reactivation of latent tuberculosis and an increased risk of developing lymphoma or other blood or neurological disorders. Additionally, Tysabri can cause a fatal brain infection known as progressive multifocal encephalopathy (PML). Given these serious risks, we believe there is an opportunity for new more targeted agents, such as Traficet-EN, with the potential for fewer side effects in Crohn's disease.

## Traficet-EN Mechanism of Action

Traficet-EN targets the CCR9 receptor found on a subset of T-cells that play a key role in IBD. During the inflammatory process, CCL25, a chemokine found in the intestines, binds to the CCR9 receptor signaling T-cells to migrate to the intestine and induce an inflammatory response. As such, blocking the interaction of CCR9 with CCL25 specifically prevents inflammation in the intestines. This specificity for the intestines could reduce side effects relative to broader acting agents.

## Phase 3 Program Under Way

In December 2009, GSK exercised its option to obtain an exclusive license for Traficet-EN. GSK initiated the first phase 3 trial (SHEILD-1, induction) in January 2011, which is not yet fully enrolled (Table 5). SHEILD-1 is a randomized, double blind, placebo controlled study expected to enroll approximately 600 patients with moderate-to-severe Crohn's disease. Traficet-EN will be dosed at 500 mg either QD or BID over a 12 week period. The primary endpoint is the proportion of patients that achieve a clinical response, defined as ≥100 point decrease in the Crohn's Disease Activity Index (CDAI). The key secondary endpoint is the proportion of patients that achieve a clinical remission, defined as a CDAI score of <150 points. According to clinicaltrials.gov, this study is expected to be competed in August 2012, with GSK guiding to completion by YE12 and data in 1H13.

The phase 3 program will also include three other trials (Table 5). The SHIELD-2 maintenance study is expected to enroll approximately 750 patients from the SHIELD-1 or other induction studies that have achieved a clinical response. The SHIELD-2 trial has a duration of 52 weeks. The primary endpoint is the proportion of patients in clinical remission, also defined as a CDAI score of <150 points. According to clinicaltrials.gov, this study is expected to be competed in July 2014.

The SHIELD-3 study is an open label extension study with a primary endpoint focused on safety. This study is expected to be completed in July 2015. The SHIELD-4 study is an induction study similarly designed to the SHIELD-1 study. The purpose of SHIELD-4 is to qualify patients for enrollment in to the SHIELD-2 maintenance study. The SHIELD-4 study is expected to be completed in January 2014. We anticipate regulatory filings for Traficet-EN for both induction and maintenance in US and Europe by year-end 2014 with approval in 2015.

Table 5: Design of Traficet-EN Phase 3 Program in Crohn's Disease

| | SHIELD-1<br>Induction | SHIELD-2<br>Maintenance | SHIELD-3<br>Open Label Extension |
|---|---|---|---|
| **N** | 600 | 750 | 800 |
| **Inclusion criteria** | 18 years and older<br><br>Confirmation of current active Crohn's disease<br><br>Moderate to severe Crohn's disease with a CDAI score between 220 and 450 at baseline | 18 years and older<br><br>Achieved a clinical response and/or remission in SHIELD 1 or other induction study<br><br>Subjects on corticosteroids must be willing to undergo a dose taper<br><br>Stable doses of Crohn's Disease medications | 18 years and older<br><br>Previously participated in GSK sponsored study of Traficet-EN |
| **Dosing** | 500 mg QD, 500 mg BID, or placebo | 500 mg QD, 500 mg BID, or placebo | 500 mg QD or 500 mg BID |
| **Duration** | 12 weeks | 52 weeks | 112 weeks |
| **Primary Endpoint** | Clinical response (at least 100 point decrease in CDAI) | Clinical remission (CDAI score of less than 150 points) | Incidence of AEs and SAEs |
| **Secondary Endpoints** | Clinical remission (CDAI score of less than 150 points)<br><br>Change in IBDQ score<br><br>Incidence of AEs and SAEs | Clinical response (at least 100 point decrease in CDAI)<br><br>Corticosteroid-free remission<br><br>Biomarkers (c-reactive protein and faecal calprotein<br><br>Remission in patients that were in remission or not in remission at baseline and remission at the end of treatment<br><br>Incidence of AEs and SAEs | Change in vital signs, hematology and clinical chemistry parameters, and electrocardiogram measurements<br><br>Clinical response (at least 100 point decrease in CDAI)<br><br>Clinical remission (CDAI score of less than 150 points) |
| **Status** | | | |
| **Start** | January 2011 | April 2011 | April 2011 |
| **Estimated End** | 1H 2013 | 2014 | 2015 |

Source: Clinicaltrials.gov.

## Review of PROTECT-1

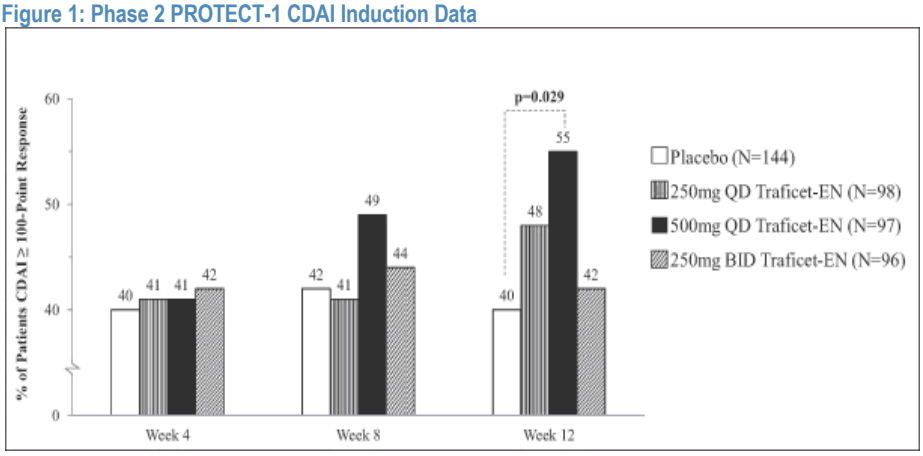
The phase 2 PROTECT-1 study was a double-blind, placebo controlled trial that enrolled 436 moderate-to-severe Crohn's patients with four distinct study periods. The first period evaluated 12 weeks of induction therapy with Traficet-EN (250 mg QD, 500 mg QD, 250 mg BID, or placebo) followed by a 4 week active treatment period (250 mg BID). All patients that experienced a ≥70 point decline in CDAI entered a 36 week maintenance period (250 mg BID, or placebo) and were followed up for 4 weeks after completion of dosing.

### Induction Phase

During the induction period, the clinical response rate for the 500 mg QD consistently improved over time, supporting the selection of this dose for the phase 3 induction study (Figure 1). Importantly, the improvement in CDAI was statistically significant compared to placebo at 12 weeks (≥100 points 55% vs. 40% placebo, p=0.029; ≥70 points 61% vs. 47% placebo, p=0.039). Notably, there wasn't a clear

dose-dependent effect of Traficet-EN over the induction period, but the trial was not designed or powered to compare the Traficet-EN treatment groups. Additionally, only the 500 mg QD dose was significantly different than placebo. This may be related to the plasma concentrations achieved with the 500 mg QD dose that exceeded the critical CCR9 coverage threshold for a longer period of time, related to that achieved with the 250 mg QD or BID doses. As such, the 500 mg QD dose as well as a yet to be tested higher 500 mg BID dose were chosen for phase 3 studies.

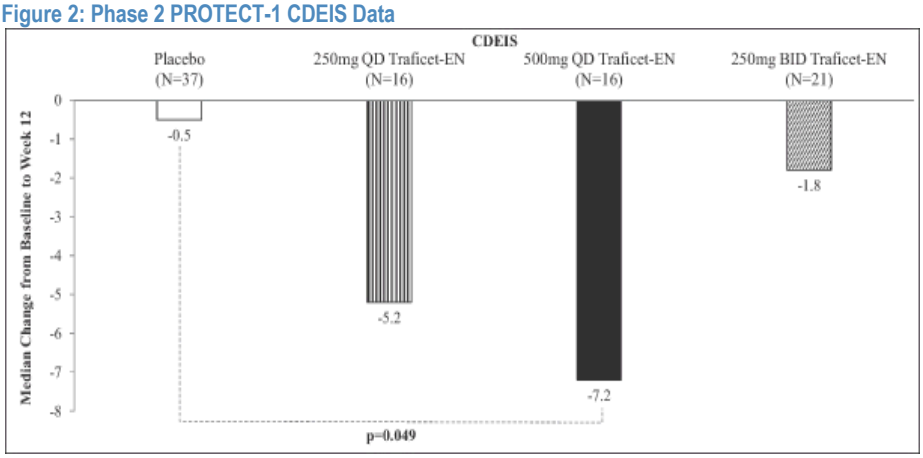
**Figure 1: Phase 2 PROTECT-1 CDAI Induction Data**




Source: Company reports.

In the 500 mg QD arm, significant improvements in the Crohn's disease endoscopic index of severity (CDEIS) was observed (-7.2 vs. -0.5 placebo, $p<0.05$; Figure 2). Although these improvements were statistically significant, not all patients in the study agreed to serial endoscopy. Improvements in c-reactive protein (CRP) were also observed (-6.7 mg/L vs. -2.9 mg/L placebo). Additionally, ~26% of patients had previously received an anti-TNF with 53 of these patients being non-responsive to one or more of these agents. Among this subset of patients, those treated with 500 mg QD of Traficet-EN, 57% (vs. 28% placebo) achieved a clinical response and 21% (vs. 6% placebo) achieved remission.

**Figure 2: Phase 2 PROTECT-1 CDEIS Data**

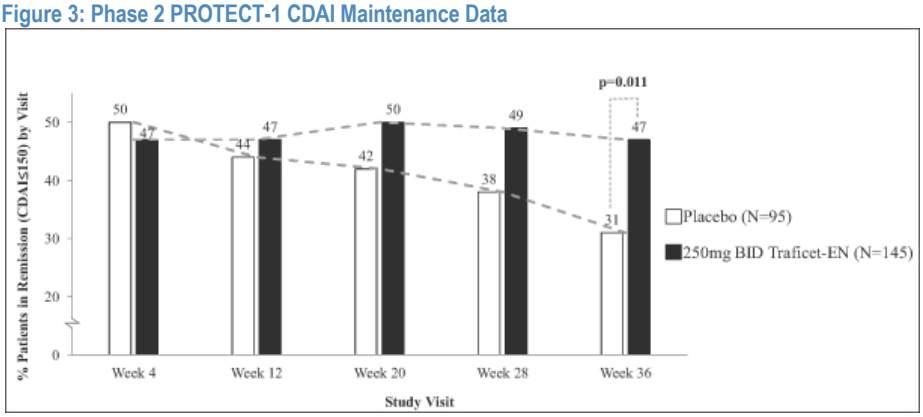



Source: Company reports.

**Maintenance Phase**

During the maintenance period, the less effective 250 mg BID dose was used rather than the 500 mg QD dose. This was based on the fact that to induce a response, more drug is needed for receptor coverage, while less coverage and thus less drug is needed to maintain a response. Indeed, Traficet-EN dosed at 250 mg BID maintained remission (CDAI <150), while the remission rate of those on placebo declined (Figure 3). Specifically, at 36 weeks (52wks of entire study) 47% in the Traficet-EN arm remained in remission compared to 31% on placebo (p=0.011). Additionally, 41% of Traficet-EN patients experienced corticosteroid free remission compared to 28% for placebo (p=0.041). Among Traficet-EN patients, only 11% started or increased corticosteroid use during the maintenance period compared to 21% for placebo (p=0.036). Normalization of CRP during the maintenance period was experienced by 19% of Traficet-EN patients compared to 9% for placebo (p=0.04).

Figure 3: Phase 2 PROTECT-1 CDAI Maintenance Data




Source: Company reports.

**Safety**

Regarding safety, Traficet-EN was found to be safe and well tolerated. During the induction period, the proportion of patients experiencing adverse events (AEs) (60% all doses vs. 63% placebo) and severe adverse events (SAEs) (9% all doses vs. 10% placebo) was similar between Traficet-EN and placebo groups. Additionally, patient discontinuations due to AEs (7% all doses vs. 13% placebo), GI AEs (5% all doses vs. 10% placebo), and Crohn's (1% all doses vs. 4% placebo) were all lower in the combined Traficet-EN arms.

During the maintenance period, the proportion of patients experiencing an AE (62% vs. 61% placebo) and SAE (9% vs. 10% placebo) was also similar, while no patients in any arm experienced serious infections. Patients experiencing GI AEs (41% vs. 43%) were lower for Traficet-EN, while those discontinuing due to AEs (7% vs. 6%) were slightly higher for Traficet-EN.

## Expectations for Phase 3

Overall, the PROTECT-1 study demonstrated that Traficet-EN has a competitive efficacy profile, in our view. Specifically, clinical response and remission rates of 61% and 47% are at the high end of the ranges for biologics of 50-60% and 40-50%, respectively. From a safety perspective, Traficet-EN's clean profile to date is clearly an advantage relative to the biologics, in our view. Given a fairly similar design in

the phase 3 SHIELD 1 & 2 studies, we believe at least a similar outcome is highly likely. Additionally, the higher dose of Traficet-EN (500 mg BID as well as 500mg QD also used in PROTECT-1) could potentially lead to even better efficacy in the SHIELD 1 & 2 studies. Assuming the safety profile remains clean, advantages of oral dosing and improved safety would justify broad use in moderate-to-severe Crohn's disease.

## Physician Perspectives on Traficet-EN

We spoke with specialists in the gastroenterologist arena to gauge some perspective on Traficet-EN (Table 6). The enthusiasm was high based on a similar efficacy profile to the biologics, but with advantages of oral dosing and the potential for a cleaner safety profile. Regarding oral dosing, many Crohn's patients are adverse to needles, so an oral agent was viewed as a significant improvement. However, safety seemed to be the more important attribute relative to convenience. This stems from concerns regarding safety risks such as injection site reaction, antibody formation and serious infections that are often associated with the biologics. The prospect of an agent with a potentially better safety profile, comparable efficacy and more convenient dosing is very appealing among the physicians we spoke with. Overall, the phase 2 data was seen as very encouraging, but we believe safety will be a key focus in the ongoing phase 3 trials. Assuming no safety issues emerge, we believe there is the potential for Traficet-EN to be a first line therapy in naïve patients ahead of biologics and even steroids. Additionally, once there is comfort gained from using Traficet-EN, there is also potential for switching of patients from biologics.

**Table 6: Physician Commentary**

| |
|---|
| "The mechanism of specifically targeting the gut in theory is beautiful." |
| "Traficet's efficacy is similar to that of the biologics." |
| "A key advantage is the potential for better safety." |
| "Oral dosing is another advantage that would improve compliance among my patients." |
| "Once Traficet becomes available I would no longer consider using steroids." |
| "I would use Traficet as soon as it's approved for both induction and maintenance." |
| "Traficet would be my go to drug." |
| "After a few months I would start switching my patients on biologics to Traficet." |
| "I can't wait to see the SHIELD-1 results." |

Source: J.P. Morgan.

## Traficet Market Opportunity

Our model currently includes the opportunity fro Traficet-EN in both the US and Europe (Table 7 and Table 8). In the US, the prevalence of Crohn's disease is estimated to be 400-600k.[6] However, prevalence estimates vary widely and we have assumed a US population of 520k and a slightly smaller 418k population in Europe. We further conservatively assume use will be restricted to an estimated 60% of patients with moderate-to-severe disease, consistent with the phase 3 target population. We assume a price of $15K per year, at the lower end of the range for

[6] Loftus EV, *Gastroenterology*, 2004, 126:1504-1517

anti-TNF therapies. As such, we forecast sales of $852M and $513M in the US and EU in 2021, respectively, with peak combined sales of nearly $2B.

We note that ChemoCentryx has an option to co-develop Traficet-EN with GSK. If exercised, ChemoCentryx would be required to pay GSK 35% of the development costs and could provide up to 50% of the promotional efforts. Additionally, ChemoCentryx would receive a higher royalty rate on worldwide sales. That said, ChemoCentryx has not exercised this option and we believe this is unlikely. As such, we assume 15-20% royalties on US sales and 12-17% royalties on EU sales. This results in 2021 royalties of $170M and $87M in the US and EU, respectively (peak combined royalties of $350M).

**Table 7: Traficet US Market Model**

| US Crohn's Market | 2015E | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E |
|---|---|---|---|---|---|---|---|
| CD patients | 522,839 | 530,682 | 538,642 | 546,722 | 554,922 | 563,246 | 571,695 |
| *% growth* | *1.5%* | *1.5%* | *1.5%* | *1.5%* | *1.5%* | *1.5%* | *1.5%* |
| Treated patients | 365,987 | 371,477 | 377,049 | 382,705 | 388,446 | 394,272 | 400,186 |
| *% treated* | *70%* | *70%* | *70%* | *70%* | *70%* | *70%* | *70%* |
| Moderate to Severe patients | 219,592 | 222,886 | 226,230 | 229,623 | 233,067 | 236,563 | 240,112 |
| % moderate-to-severe | 60% | 60% | 60% | 60% | 60% | 60% | 60% |
| Traficet treated | 5,490 | 17,385 | 27,148 | 34,443 | 40,787 | 46,130 | 50,423 |
| % penetration | 3% | 8% | 12% | 15% | 18% | 20% | 21% |
| Annual cost of Traficet ($) | 15,000 | 15,300 | 15,606 | 15,918 | 16,236 | 16,561 | 16,892 |
| **Total US Sales ($ in millions)** | **$82** | **$266** | **$424** | **$548** | **$662** | **$764** | **$852** |
| | | *223%* | *59%* | *29%* | *21%* | *15%* | *11%* |
| **Royalties on US sales ($ in millions)** | **$12.4** | **$39.9** | **$67.8** | **$93.2** | **$119.2** | **$152.8** | **$170.4** |
| % royalty | 15% | 15% | 16% | 17% | 18% | 20% | 20% |

Source: J.P. Morgan estimates.

**Table 8: Traficet EU Market Model**

| EU Crohn's Market | 2015E | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E |
|---|---|---|---|---|---|---|---|
| CD patients | 418,271 | 424,545 | 430,914 | 437,377 | 443,938 | 450,597 | 457,356 |
| *% growth* | *1.5%* | *1.5%* | *1.5%* | *1.5%* | *1.5%* | *1.5%* | *1.5%* |
| Treated patients | 292,790 | 297,182 | 301,640 | 306,164 | 310,757 | 315,418 | 320,149 |
| *% treated* | *70%* | *70%* | *70%* | *70%* | *70%* | *70%* | *70%* |
| Moderate to Severe patients | 175,674 | 178,309 | 180,984 | 183,698 | 186,454 | 189,251 | 192,090 |
| % moderate-to-severe | 60% | 60% | 60% | 60% | 60% | 60% | 60% |
| Traficet treated | 3,513 | 10,699 | 15,384 | 18,370 | 21,815 | 25,738 | 30,350 |
| % penetration | 2% | 6% | 9% | 10% | 12% | 14% | 16% |
| Annual cost of Traficet ($) | 15,000 | 15,300 | 15,606 | 15,918 | 16,236 | 16,561 | 16,892 |
| **Total EU Sales ($ in millions)** | **$53** | **$164** | **$240** | **$292** | **$354** | **$426** | **$513** |
| | | **211%** | **47%** | **22%** | **21%** | **20%** | **20%** |
| **Royalties on EU sales ($ in millions)** | **$6.3** | **$19.6** | **$31.2** | **$43.9** | **$56.7** | **$68.2** | **$87.2** |
| % royalty | 12% | 12% | 13% | 15% | 16% | 16% | 17% |

Source: J.P. Morgan estimates.

# CCX140 in Diabetic Nephropathy

CCX140 is currently in phase 2 trials for diabetic nephropathy (DN), with completion expected by YE12 (data 1H13). CCX140 targets the CCR2 chemokine receptor, selectively inhibiting migration of monocytes and macrophages to inflamed kidneys and preventing further damage. Clinical development thus far (phase 1 and 2) in diabetics has demonstrated that CCX140 is safe and well tolerated with improved glycemic control. Preclinical studies have demonstrated that CCX140 has a positive impact on markers of renal function (reduced serum creatinine and blood urea nitrogen levels) as well as renal function (reduced albuminuria and decreased hyperfiltration). These early studies suggest that CCX140 has potential in DN, which obviously needs to be confirmed in phase 2 and 3 trials. Considering the unmet need and encouraging data to date, we believe CCX140 could be a meaningful treatment option in DN. We assume ChemoCentryx markets CCX140 in the US and estimate peak sales of $1B+.

## Diabetic Nephropathy: A Brief Overview

Diabetic nephropathy (DN) is a progressive loss of renal function in patients with diabetes and hypertension. The exact cause of DN is unknown, but believed to be related to hyperglycemia, increased glomerular pressure and more recently inflammation. The poor glycemic control results in thickening and scarring of the nephrons, the filtering units of the kidney. This damage occurs slowly over time, eventually leading to a loss of renal function culminating in end stage renal disease (ESRD) where patients require dialysis or a kidney transplant.

DN is characterized by persistent albuminuria (>300 mg.d), progressive declines in glomerular filtration rate (GFR) and increased blood pressure.[7] Given the slow progression of the disease and lack of symptoms early in the disease, diagnosis of DN usually does not occur until 10-20 years after the diagnosis of diabetes. Symptoms do appear later in the disease generally including headaches, nausea, vomiting and swelling of the legs, while those with severe disease tend to have a poor appetite. Diagnosis typically involves a urine test for albumin, while biopsies are reserved in cases where diagnosis of DN is uncertain.

The key goal of treating DN is to prevent continued lose of renal function. This is accomplished through treating the underlying conditions of diabetes and hypertension. The Diabetes Control and Complications Trial (DCCT) demonstrated that intensive glycemic treatment for both Type 1 & 2 diabetics reduces the risk and progression for early DN.[8] Although HbA1c levels should be tailored to individuals, 7% is generally accepted as a reasonable target. Regarding hypertension, angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARB) are used to manage blood pressure (BP). Although there has been debate about the optimal BP, the American Diabetes Association (ADA) recommends a target of < 130/80 mmHg.

However, despite the availability of treatment options and strategies, DN is the leading cause of ESRD.[9] As such, new strategies and treatment options are needed. More recently, inflammation has been identified as playing a role in DN.[10] Specifically, renal biopsy studies have found that monocytes and macrophages tend to accumulate in the glomeruli of DN patients. Additionally, preclinical models have demonstrated that blocking monocyte and macrophage recruitment can delay progression of kidney disease. As such, targeting inflammation could offer a new approach to treating DN that could delay progression of the disease.

## CCX140 Mechanism of Action

CCX140 targets the CCR2 chemokine receptor found on a subset of monocytes and macrophages. In the kidneys of patients with DN, CCL2 is elevated, which binds to the CCR2 receptor and signals monocytes and macrophages to migrate to the inflamed kidneys. As such, blocking CCR2 prevents the migration of monocytes and macrophages and subsequent damage to the kidneys from inflammation.

## Phase 2 Trials Under Way in DN

Two phase 2 trials of CCX140 in DN are ongoing (Table 9). The first study is expected to enroll 135 patients with residual albuminuria despite stable treatment with ACE inhibitors or ARBs. Patients will be treated with 5 mg or 10 mg of CCX140 or placebo for 12 weeks with a 4 week follow up period. The primary endpoint is safety, while the key secondary endpoint is the change in first morning albumin/creatinine ratio, a measure of renal function. According to clinicaltirals.gov, this trial is expected to be completed in September with the company guiding to YE12 (data 1Q13). However, following a preplanned interim analysis, this study could be expanded to include 270 patients and additional dosing groups could be

[7] Adler S, Kidney Int. 2004, 66:2095-2106
[8] DCCT research group, *NEJM* 1993, 329:977-986
[9] Collins A.J. *et. al., Am J Kidney Dis* 2010, 55: S1-S11420
[10] Mora C *et. al.*, *Curr Diab Rep* 2005, 5: 399-401

added. If this occurs, timelines for completion would be extended. Additionally, the preplanned interim analysis does not include a futility assessment so the study will continue to completion.

The second phase 2 study is expected to enroll 20 patients similarly with residual albuminuria despite stable treatment with ACE inhibitors or ARBs. These patients will be treated with 10 mg of CCX140 or placebo for 12 weeks. The primary endpoint is the change in 24 hour urinary albumin excretion. According to clinicaltirals.gov, this trial is expected to be completed in June with the company guiding to YE12 (data 1Q13).

Assuming the results are positive, the company intends to engage the FDA and EMEA in an end of phase 2 meeting to receive feedback on the phase 3 design. The phase 3 program is expected to enroll at least 1,500 patients and will likely be an outcome study rather than an assessment of proteinuria, in our view. We anticipate a phase 3 trial could begin in 2H13 with a potential launch in 2015.

**Table 9: Design of CCX140 Phase 2 Trials**

| | Diabetic Nephropathy | Type 2 Diabetes and Albuminuria |
|---|---|---|
| **N** | 135 | 20 |
| **Inclusion criteria** | 18 to 75 years of age<br>Previously diagnosed with Type 2 diabetes<br>Residual albuminuria despite stable treatment with ACE or ARB<br>Estimated GFR based on serum creatinine of ≥25 mL/min/1.73m<br>HbA1c >6%, but not > 10%<br>Fasting plasma glucose <270 mg/dL | 18 to 75 years of age<br>Previously diagnosed with Type 2 diabetes<br>Albumin:creatinine ratio of 200 to 3000 mg/g creatinine<br>stable treatment with ACE or ARB<br>Estimated GFR based on serum creatinine of ≥25 mL/min/1.73m<br>Fasting plasma glucose <270 mg/dL |
| **Dosing** | 5 mg, 10 mg, and placebo | 10 mg, and placebo |
| **Duration** | 12 weeks | 12 weeks |
| **Primary Endpoint** | Incidence of adverse events | Change from baseline in 24 hour urinary albumin excretion |
| **Secondary Endpoints** | Change in baseline in first morning urinary albumin:creatinine ratio | Incidence of adverse events<br>Change from baseline in HbA1c |
| **Start**<br>**Estimated End** | October 2011<br>1Q 2013 | September 2011<br>1Q 2013 |

Source: Clinicaltrials.gov.

## Phase 2 Data in Type 2 Diabetes

A phase 2 trial of CCX140 was conducted in 159 patients with Type 2 diabetes on stable doses of metformin. Patients were treated with 5 mg or 10 mg of CCX140, pioglitazone, or placebo for a duration of 4 weeks. This study met the primary endpoint demonstrating CCX140 was safe and well tolerated. Specifically, no SAEs were observed related to CCX140 and there were no concerns regarding laboratory hematology, chemistry, or urinalysis. Additionally, no significant changes in plasma MCP-1 (CCL2) or blood monocyte counts were observed, in contrast to other CCR2 antagonists. Importantly, this study confirmed CCX140 was safe in diabetics, paving the way for advancement into phase 2 trials in DN.

CCX140 also demonstrated encouraging activity with statistically significant declines in HbA1C and a dose dependent decrease in fasting plasma glucose (FPG). The change from baseline in HbA1C for 5 mg CCX140, 10 mg of CCX140,

pioglitazone, and placebo were -0.09%, -0.23%, -0.13% and -0.09%, respectively. At the 10 mg dose of CCX140, the decrease in HbA1C was statistically significant compared to placebo (p=0.045), suggesting improved glycemic control, which could be an added benefit when treating DN. Additionally, the change from baseline FPG for 5 mg CCX140, 10 mg of CCX140, pioglitazone, and placebo were -4.3 mg/dL, -16.1 mg/dL, -21.4 mg/dL, and -10.7 mg/dL, respectively. Although, the declines in FPG were not statistically significant compared to placebo, the decline observed for 10 mg CCX140 and pioglitazone were comparable.

## Review of Early Preclinical and Clinical Data

In a phase 1 single ascending dose trial (n=56), CCX140 doses of 0.05 mg, 0.1 mg, 0.3 mg, 0.6 mg, 1 mg, 3 mg, and 10 mg were tested. CCX140 at these doses was well tolerated with no SAEs, while all AEs were mild to moderate. A phase 1 multiple ascending dose trial (n=32) was also conducted, evaluating doses of 0.6 mg and 2 mg for 7 days and 5 mg and 10 mg for 10 days. Similarly, CCX140 was well tolerated with no SAEs, AEs were mild to moderate and no patient discontinued due to AEs. A phase 1 trial evaluating higher doses (5 mg, 10 mg, 12.5 mg and 15 mg) is currently ongoing. Results of this study will support the evaluation of doses higher than 10 mg if needed in the ongoing phase 2 trials.

Preclinical studies have demonstrated that CCX140 has a positive impact on markers of renal function (reduced serum creatinine and blood urea nitrogen levels) as well as renal function (reduced albuminuria and decreased hyperfiltration). In comparison to other CCR2 inhibitors, CCX140 seems to have lower cardiovascular risk, but this needs to be confirmed in phase 3 trials. Additionally, in preclinical studies, CCR2 inhibition has the advantage of reducing protein in the urine compared to Reata's bardoxolone, which has no impact on this parameter.

## CCX140 Market Opportunity

Our model currently includes the opportunity for CCX140 in DN in the US (Table 10). According to the American Diabetes Association (ADA), the prevalence of diabetes in the US is estimated to be 20.8M with approximately 70% of these patients being diagnosed. We further assume an estimated 25% of diabetics will develop nephropathy. We conservatively assume an annual price of $2,500, which represents a premium to BP treatments. We assume ChemoCentryx markets CCX140 on its own in the US with sales reaching $828M in 2021. We forecast peak sales of $1B+ longer term. Although not included in our model, potential upside levers include an OUS partnership and expansion into broader use in CKD.

**Table 10: CCX140 Market Model**

| US | 2015E | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E |
|---|---|---|---|---|---|---|---|
| Diabetic patients ('000) | 22,965 | 23,424 | 23,893 | 24,371 | 24,858 | 25,355 | 25,862 |
| % Type 2? | | | | | | | |
| Diagnosed | 16,075 | 16,397 | 16,725 | 17,059 | 17,401 | 17,749 | 18,104 |
| % diagnosed | 70% | 70% | 70% | 70% | 70% | 70% | 70% |
| Diabetic Neuropathy patients ('000) | 4,019 | 4,099 | 4,181 | 4,265 | 4,350 | 4,437 | 4,526 |
| % w/ neuropathy | 25% | 25% | 25% | 25% | 25% | 25% | 25% |
| CCX140 treated patients ('000) | 32 | 61 | 105 | 149 | 196 | 244 | 294 |
| % penetration | 1% | 2% | 3% | 4% | 5% | 6% | 7% |
| Annual Cost ($) | $2,500 | $2,550 | $2,601 | $2,653 | $2,706 | $2,760 | $2,815 |
| **Total US Sales ($M)** | **$80** | **$157** | **$272** | **$396** | **$530** | **$674** | **$828** |
| *% growth* | | *95%* | *73%* | *46%* | *34%* | *27%* | *23%* |

Source: J.P. Morgan estimates.

# Other Pipeline Assets

**CCX354 in RA**

CCX354 targets the CCR1 chemokine receptor and is being developed for rheumatoid arthritis (RA). High levels of CCR1 expressing monocytes and macrophages are found in the synovium of RA patients. As such, blocking CCR1 reduces the influx of monocytes and macrophages into the joints, reducing inflammation and the resulting joint destruction. In phase 1 single dose and multiple ascending dose studies up to 300 mg, CCX354 was well tolerated with no SAEs or discontinuations due to SAEs. A phase1/2 study (n=24) in RA patients on stable doses of methotrexate confirmed the safety of CCX354 100 mg and 200 mg doses. This study also confirmed there were no drug/drug interactions between CCX354 and methotrexate.

In a phase 2 proof-of-concept study (n=160), CCX354 achieved an ACR20 response of 56% (200 mg QD; p-0.014 vs. placebo) and 44% (100 mg BID) compared to 30% for placebo. CCX345 was well tolerated with no SAEs observed at 200 mg or placebo, while 4 SAEs were reported in the 100 mg dose group, but not considered to be related to CCX345. Following this study, in November 2011, GSK exercised its option for an exclusive license to develop and commercialize CCX354. We anticipate initiation of a phase 2b trial in RA in 2H12.

**CCX168 in ANCA-Associate Vasculitis**

CCX168 targets C5aR and is being developed for ANCA-associated vasculitis (AVV). In AVV, an autoimmune response leads to destruction of neutrophils (type of white blood cells) in the blood that can damage small blood vessels. During the inflammatory response, production of C5a attracts and activates white blood cells. Blocking C5aR prevents recruitment of white blood cells, reducing inflammation and associated damage to the small blood vessels. In a phase 1 trial, CCX168 dosed up to 100 mg was found to be well tolerated with no SAEs or discontinuation due to AEs.

A phase 2 proof-of-concept study (n=60) in AVV with mild-to-moderate renal involvement was initiated in 4Q11. The primary endpoint is safety, while key secondary endpoints include the ability to reduce or eliminate the need for steroids, assessment of the PK profile, and changes in renal function. This study is expected to be completed by year-end 2012. Under the strategic collaboration, following the proof-of-concept data, GSK can exercise an option for an exclusive license to develop and commercialize CCX168.

# Financial Outlook

## P&L Highlights

We project 2012 to 2015 revenues of $35M, $35M, $35M and $134M, respectively. We anticipate a launch of Traficet-EN in Crohn's disease in both the US and Europe in 2015 with 2015-2017 sales of $135M, $430M and $664M with ChemoCentryx receiving associated royalties from GSK of $19M, $60M and $99M, respectively. We also assume a launch of CCX140 in DN in the US in 2015 with 2015-2017 sales of $80M, $157M and $272M, respectively (Table 12).

We expect R&D expense to continue to grow with advancement of the broad pipeline. On the SG&A side, we anticipate continued growth associated with the launch of CCX140 in the US as we assume ChemoCentryx will market this product on its own. We project 2012-2015 GAAP EPS of ($0.64), ($1.06), ($1.53), and ($0.23), respectively.

## Balance Sheet and Cash Flow

At the end of 4Q11, we estimate ChemoCentryx had $91M in cash, including the $25M from GSK in December 2011 associated with the option exercise on CCX354. Including the funds raised from the IPO in February 2012, we estimate ChemoCentryx has $151M in cash on hand. We assume additional equity raises in the outer years (Table 13 and Table 14). However, cash could be raised instead through non-dilutive means such as additional partnerships.

# Valuation

## Sum of the Parts

Our $16 December 2012 price target for CCXI is based on our sum-of-the-parts/NPV analysis, including Traficet-EN in Crohn's and CCX140 in DN (Table 11). We project revenues to 2025 for Traficet-EN and 2028 for CCX140, consistent with IP protection, and assume no terminal value and a 15% discount rate overall. For Traficet-EN, we assume a 70% probability of success given positive phase 2 data in both induction and maintenance and advancement into phase 3. For CCX140, we assume a lower 15% probability of success as we await phase 2 data in DN and given the failure of a number of agents in this indication. Our analysis suggests a value of $8/share for Traficet-EN in the US and EU and a value of $4/share for CCX140 in the US. This taken together with net cash of $4/share supports our December 2012 PT of $16.

Table 11: ChemoCentryx Sum of the Parts Valuation

| Sum Of The Parts Analysis | Total | Value |
|---|---|---|
| Traficet royalty WW | $298 | $8 |
| CCX140 US | $137 | $4 |
| Cash | $150 | |
| LT Debt | $0 | |
| **Net Cash ($ in millions)** | **$150** | **$4** |
| **Total ($ in millions)** | **$586** | **$16** |

Source: J.P. Morgan estimates.

# Management

**Thomas J. Schall, Ph.D., President, CEO and Director**

Founder, president and CEO of ChemoCentryx since its inception in 1996. Prior to starting ChemoCentryx, Dr. Schall led seminal chemokine research at DNAX Research Institute, a division of Schering-Plough Corp, from 1993 to 1996. Prior to 1993, Dr. Schall was at Genentech where he cloned one of the first chemokines. His continued success in the field has led to the discovery of one-third of all known chemokines. Dr. Schall earned his Ph.D. from Stanford University and his B.S. from Northern Illinois University.

**Markus J. Cappel, Ph.D., Chief Business Officer and Treasurer**

Chief business officer and treasurer since 2007 and 2004, respectively. Prior to his role as treasurer, Dr. Cappel was senior vice president of corporate and business development (2001-2003). From 1998-2001, Dr. Cappel held the position of vice president of business development at Alkermes. Additionally, he served as the director of business development at Millennium Pharmaceuticals and held numerous business development roles at Cygnus, Inc. Dr. Cappel earned an M.B.A. from the Harvard Business School and received his Ph.D. from J.W. Goethe University (Germany) and was a fellow at the University of Michigan.

**Susan M. Kanaya, SVP of Finance, CFO and Secretary**

Senior vice president of finance and chief financial officer since 2006. Prior to ChemoCentryx, Ms. Kanaya held similar roles at Kosan Biosciences Inc. from 1999 to 2005. Ms. Kanaya was also vice president of finance and treasurer of at SUGEN, Inc. (1994-1999). Additionally, Ms. Kanaya served as controller to high technology companies, as well as the public accountant for KPMG. Ms. Kanaya received her B.S. from the University of California, Berkeley.

**Juan Jaen, Ph.D., SVP of Drug Discovery and CSO**

Senior vice president of drug discovery and chief scientific officer since 2007 and 2010, respectively, From 1996 to 2006, Dr. Jaen was vice president of chemistry at Tularik and Amgen, which acquired Tularik in 2004. Prior to 1996, Dr. Jaen was the chemistry director at Parke-Davis/Warner-Lambert . Dr. Jaen earned a Ph.D. from the University of Michigan and received his B.S. from the Universidad Complutense (Spain).

**Petrus (Pirow) Bekker, M.D., Ph.D., SVP of Medical and Clinical Affairs**

Senior vice president of medical and clinical affairs since 2009. Dr. Bekker was vice president of clinical and medical affairs from 2005-2009. Prior to ChemoCentryx, Dr. Bekker was at Amgen where he was the senior director of global safety (2004-2005) and the senior director and director of clinical development (1997 to 2004 ). Additionally, Dr. Bekker served as clinical researcher and scientist at Procter & Gamble Pharmaceuticals. Dr. Bekker earned his Ph.D. at Pennsylvania State University and received his M.D. at the University of Pretoria (S. Africa).

# Models

**Table 12: ChemoCentryx Income Statement**

| ($ in millions except per share data) | 2009A | 2010A | 2011E | 2012E | 2013E | 2014E | 2015E | 2016E | 2017E |
|---|---|---|---|---|---|---|---|---|---|
| Revenues | | | | | | | | | |
| Traficet-EN Sales WW | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 135.0 | 429.7 | 663.7 |
| | | | | | | | | | |
| Traficet-EN Royalties WW | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 18.7 | 59.5 | 99.0 |
| US CCX140 sales | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 80.4 | 156.8 | 271.9 |
| Collaborative research and development revenue | 49.7 | 34.9 | 32.5 | 35.2 | 35.0 | 35.0 | 35.0 | 35.0 | 35.0 |
| Grant revenue | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Total Revenues** | **49.7** | **34.9** | **32.5** | **35.2** | **35.0** | **35.0** | **134.1** | **251.3** | **405.9** |
| | | | | | | | | | |
| Operating Expenses | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Cost of sales | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 8.0 | 15.7 | 27.2 |
| Research and development | 27.5 | 33.5 | 36.8 | 46.1 | 57.6 | 72.0 | 90.0 | 111.6 | 137.3 |
| Sales, general and administrative | 6.6 | 7.3 | 8.0 | 14.0 | 23.1 | 37.0 | 49.9 | 59.9 | 68.9 |
| **Total Operating expenses** | **34.0** | **40.8** | **44.8** | **60.1** | **80.7** | **109.0** | **148.0** | **187.2** | **233.4** |
| | | | | | | | | | |
| **Operating Income** | **15.7** | **-6.0** | **-12.3** | **-24.9** | **-45.7** | **-74.0** | **-13.9** | **64.1** | **172.5** |
| Interest Income | 0.3 | 0.4 | 0.0 | 1.0 | 2.0 | 2.0 | 3.0 | 3.5 | 3.5 |
| Interest expense | -0.1 | -0.1 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Other income | 0.0 | 2.4 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Total Other Income** | **0.2** | **2.8** | **0.0** | **1.0** | **2.0** | **2.0** | **3.0** | **3.5** | **3.5** |
| | | | | | | | | | |
| Pretax Income | 15.9 | -3.2 | -12.3 | -23.9 | -43.7 | -72.0 | -10.9 | 67.6 | 176.0 |
| Income tax (benefit) | -0.3 | 0.1 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 23.7 | 61.6 |
| **Net Income (loss)** | **15.6** | **-3.1** | **-12.3** | **-23.9** | **-43.7** | **-72.0** | **-10.9** | **44.0** | **114.4** |
| | | | | | | | | | |
| **Diluted EPS** | **0.27** | **-0.11** | **-0.44** | **-0.64** | **-1.06** | **-1.53** | **-0.23** | **0.90** | **2.28** |
| Fully diluted shares outstanding | 58.5 | 28.2 | 28.2 | 37.6 | 41.1 | 47.1 | 48.1 | 49.1 | 50.1 |

Source: Company reports and J.P. Morgan estimates.

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### Table 13: ChemoCentryx Balance Sheet

| ($ in millions except per share data) | 2009A | 2010A | 2011E | 2012E | 2013E | 2014E | 2015E |
|---|---|---|---|---|---|---|---|
| **Assets** | | | | | | | |
| Cash and cash equivalents | 21.1 | 12.1 | 21.8 | 54.6 | 62.5 | 69.2 | 52.3 |
| Short-term investments | 36.1 | 69.5 | 69.5 | 69.5 | 69.5 | 69.5 | 69.5 |
| Accounts receivable from related party | 35.4 | 12.5 | 14.9 | 17.9 | 21.5 | 25.8 | 31.0 |
| Prepaid expenses and other current assets | 1.0 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 |
| **Total Current Assets** | **93.5** | **94.6** | **106.9** | **142.6** | **154.1** | **165.1** | **153.3** |
| Property and equipment at cost | 6.2 | 7.2 | 7.6 | 8.1 | 8.7 | 9.4 | 10.3 |
| Accumulated depreciation | -4.7 | -5.1 | -5.1 | -5.1 | -5.1 | -5.1 | -5.1 |
| Property and equipment, net | 1.6 | 2.1 | 2.5 | 3.0 | 3.6 | 4.3 | 5.2 |
| Long-term investments | 8.2 | 1.3 | 1.3 | 1.3 | 1.3 | 1.3 | 1.3 |
| Other assets | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 |
| Total Long Term Assets | 9.9 | 3.5 | 4.0 | 4.4 | 5.0 | 5.7 | 6.6 |
| **Total Assets** | **103.5** | **98.1** | **110.8** | **147.1** | **159.1** | **170.8** | **159.9** |
| | | | | | | | |
| **Liabilities and Equity** | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** |
| Accounts payable | 1.0 | 0.9 | 0.9 | 0.9 | 0.9 | 0.9 | 0.9 |
| Accrued liabilities | 6.2 | 7.0 | 7.0 | 7.0 | 7.0 | 7.0 | 7.0 |
| Deferred revenue from related party | 6.8 | 3.6 | 3.6 | 3.6 | 3.6 | 3.6 | 3.6 |
| Current portion of equipment financing obligations | 0.4 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 |
| **Total Current Liabilities** | **14.4** | **11.9** | **11.9** | **11.9** | **11.9** | **11.9** | **11.9** |
| Noncurrent equipment financing obligations | 0.0 | 0.9 | 0.9 | 0.9 | 0.9 | 0.9 | 0.9 |
| Deferred revenue from related party | 11.3 | 8.2 | 8.2 | 8.2 | 8.2 | 8.2 | 8.2 |
| Other non-current liabilities | 0.5 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 |
| Total Long Term Liabilities | 11.8 | 9.5 | 9.5 | 9.5 | 9.5 | 9.5 | 9.5 |
| **Total Liabilities** | **26.2** | **21.4** | **21.4** | **21.4** | **21.4** | **21.4** | **21.4** |
| | | | | | | | |
| Total Shareholders' Equity | 77.3 | 76.8 | 89.5 | 125.7 | 137.8 | 149.5 | 138.6 |
| **Total Liabilities and Equity** | **103.5** | **98.1** | **110.8** | **147.1** | **159.1** | **170.8** | **159.9** |

Source: Company reports and J.P. Morgan estimates.

### Table 14: ChemoCentryx Cash Flow Statement

| ($ in millions except per share data) | 2009A | 2010A | 2011E | 2012E | 2013E | 2014E | 2015E |
|---|---|---|---|---|---|---|---|
| **Cash Flows from Operating Activities:** | | | | | | | |
| Net Income | 15.6 | -3.1 | -12.3 | -23.9 | -43.7 | -72.0 | -10.9 |
| **Adjustments:** | | | | | | | |
| Depreciation of property and equipment | 0.7 | 0.7 | 0.8 | 1.0 | 1.1 | 1.4 | 1.6 |
| Stock-based compensation | 1.8 | 2.3 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Changes in assets and liabilities:** | | | | | | | |
| Changes in operating assets and liabilities: | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Accounts receivable due from related party | -30.4 | 23.0 | -2.5 | -3.0 | -3.6 | -4.3 | -5.2 |
| Prepaids and other current assets | -0.5 | 0.4 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Other assets | 0.1 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Accounts payable | -0.9 | -0.1 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Other liabilities | -4.9 | 0.8 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Deferred revenue | -4.5 | -6.3 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Net change in Working Capital | -41.1 | 17.8 | -2.5 | -3.0 | -3.6 | -4.3 | -5.2 |
| **Net Cash From Operations** | **-23.0** | **17.7** | **-14.0** | **-25.9** | **-46.2** | **-74.9** | **-14.4** |
| **Cash Flows from Investing Activities:** | | | | | | | |
| Purchases of property and equipment, net | -0.2 | -1.2 | -1.2 | -1.4 | -1.7 | -2.1 | -2.5 |
| Purchase of investments | -78.5 | -90.3 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Maturities of investments | 48.8 | 63.8 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Purchase of long-term investment | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Net Cash from Investing** | **-29.9** | **-27.6** | **-1.2** | **-1.4** | **-1.7** | **-2.1** | **-2.5** |
| **Cash Flows from Financing Activities:** | | | | | | | |
| Proceeds from equipment financing | 0.0 | 1.5 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Payments on equipment financing obligations | -0.6 | -0.7 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Payments on line of credit | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Proceeds from issuance of preferred stock, net of issuance costs | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Proceeds from issuance of common stock | 0.1 | 0.1 | 0.0 | 60.1 | 55.8 | 83.7 | 0.0 |
| Payments for repurchase of common stock | -1.1 | 0.0 | 25.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Repayment of capital lease and note obligations | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Net Cash from Financing** | **-1.6** | **0.9** | **25.0** | **60.1** | **55.8** | **83.7** | **0.0** |
| Net Increase (Decrease) in Cash | -54.5 | -9.0 | 9.8 | 32.8 | 7.9 | 6.7 | -16.9 |
| Cash and cash equivalents at beginning of period | 75.6 | 21.1 | 12.1 | 21.8 | 54.6 | 62.5 | 69.2 |
| **Cash and cash equivalents at end of period** | **21.1** | **12.1** | **21.8** | **54.6** | **62.5** | **69.2** | **52.3** |

Source: Company reports and J.P. Morgan estimates.

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J.P.Morgan

# ChemoCentryx, Inc.: Summary of Financials

| Income Statement - Annual | FY10A | FY11E | FY12E | FY13E |
|---|---|---|---|---|
| Revenues | 35 | 33 | 35 | 35 |
| Cost of products sold | - | - | - | - |
| Gross profit | 35 | 33 | 35 | 35 |
| SG&A | 7 | 8 | 14 | 23 |
| R&D | 34 | 37 | 46 | 58 |
| Operating Income | (6) | (12) | (25) | (46) |
| Note: EBITDA | - | - | - | - |
| Net interest income / (expense) | 3 | 0 | 1 | 2 |
| Other income / (expense) | 2 | 0 | 0 | 0 |
| Pretax income | (3) | (12) | (24) | (44) |
| Income taxes | 0 | 0 | 0 | 0 |
| Net income - GAAP | (3) | (12) | (24) | (44) |
| Net income - recurring | - | - | - | - |
| Diluted shares outstanding | 28 | 28 | 38 | 41 |
| EPS - excluding non-recurring | (0.11) | (0.44) | (0.64) | (1.06) |
| EPS - recurring | (0.11) | (0.44) | (0.64) | (1.06) |

| Balance Sheet and Cash Flow Data | FY10A | FY11E | FY12E | FY13E |
|---|---|---|---|---|
| Cash and cash equivalents | 12 | 22 | 55 | 63 |
| Accounts receivable | 12 | 15 | 18 | 22 |
| Inventories | - | - | - | - |
| Other current assets | 1 | 1 | 1 | 1 |
| Current assets | 95 | 107 | 143 | 154 |
| PP&E | 7 | 8 | 8 | 9 |
| Total assets | 98 | 111 | 147 | 159 |
| | | | | |
| Total debt | 0 | 0 | 0 | 0 |
| Total liabilities | 21 | 21 | 21 | 21 |
| Shareholders' equity | 77 | 89 | 126 | 138 |
| | | | | |
| Net income (including charges) | (3) | (12) | (24) | (44) |
| D&A | 1 | 1 | 1 | 1 |
| Change in working capital | 18 | (2) | (3) | (4) |
| Other | | | | |
| Cash flow from operations | 18 | (14) | (26) | (46) |
| | | | | |
| Capex | (1) | (1) | (1) | (2) |
| Free cash flow | 16 | (15) | (27) | (48) |
| Cash flow from investing activities | (28) | (1) | (1) | (2) |
| Cash flow from financing activities | 1 | 25 | 60 | 56 |
| Dividends | - | - | - | - |
| Dividend yield | - | - | - | - |

| Income Statement - Quarterly | 1Q11A | 2Q11A | 3Q11A | 4Q11E |
|---|---|---|---|---|
| Revenues | 2A | 2A | 2A | 27 |
| Cost of products sold | - | - | - | - |
| Gross profit | 2A | 2A | 2A | 27 |
| SG&A | 2A | 2A | 2A | 2 |
| R&D | 5A | 8A | 10A | 14 |
| Operating income | (5)A | (8)A | (10)A | 11 |
| Note: EBITDA | - | - | - | - |
| Net interest income / (expense) | 0A | 0A | 0A | 0 |
| Other income / (expense) | 0A | 0A | 0A | 0 |
| Pretax income | (5)A | (8)A | (10)A | 11 |
| Income taxes | 0A | 0A | 0A | 0 |
| Net income - GAAP | (5)A | (8)A | (10)A | 11 |
| Net income - recurring | - | - | - | - |
| Diluted shares outstanding | 28A | 28A | 28A | 28 |
| EPS - excluding non-recurring | (0.17)A | (0.27)A | (0.37)A | 0.38 |
| EPS - recurring | (0.17)A | (0.27)A | (0.37)A | 0.38 |

| Ratio Analysis | FY10A | FY11E | FY12E | FY13E |
|---|---|---|---|---|
| Sales growth | (29.9%) | (6.7%) | 8.3% | (0.6%) |
| EBIT growth | (138.0%) | 106.9% | 101.9% | 83.6% |
| EPS growth | (141.1%) | 297.6% | 45.7% | 67.4% |
| | | | | |
| Gross margin | 100.0% | 100.0% | 100.0% | 100.0% |
| EBIT margin | (17.1%) | (37.9%) | (70.7%) | (130.6%) |
| EBITDA margin | - | - | - | - |
| Tax rate | (2.3%) | 0.0% | 0.0% | 0.0% |
| Net margin | (8.9%) | (37.9%) | (67.9%) | (124.9%) |
| | | | | |
| Debt / EBITDA | - | - | - | - |
| Debt / Capital (book) | 0.0% | 0.0% | 0.0% | 0.0% |
| Return on assets (ROA) | (3.2%) | (11.1%) | (16.3%) | (27.5%) |
| Return on equity (ROE) | (4.0%) | (13.8%) | (19.0%) | (31.7%) |
| Return on invested capital (ROIC) | - | - | - | - |
| | | | | |
| Enterprise value / sales | 7.4 | 7.6 | 6.1 | 5.9 |
| Enterprise value / EBITDA | - | - | - | - |
| Free cash flow yield | 4.9% | (4.5%) | (8.1%) | (14.1%) |

Source: Company reports and J.P. Morgan estimates.
Note: $ in millions (except per-share data).Fiscal year ends Dec

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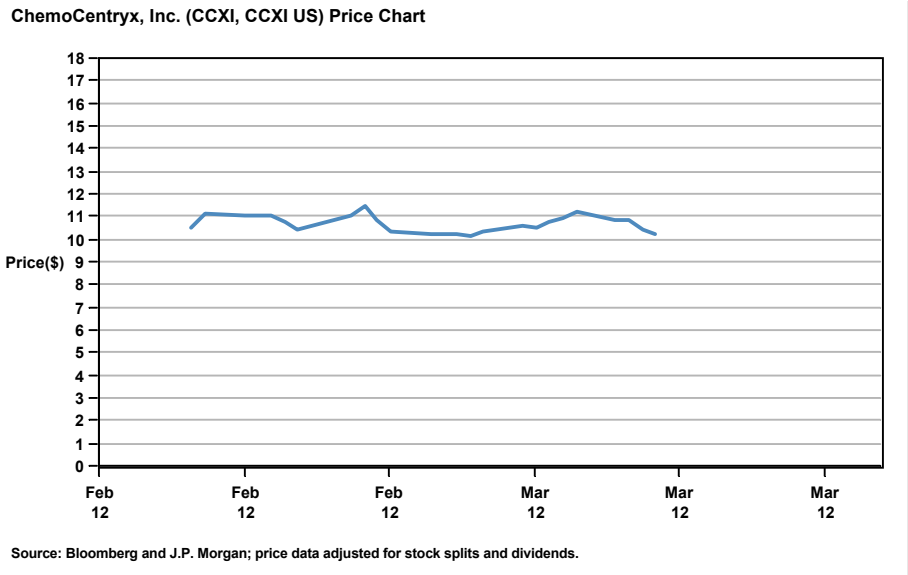


The chart(s) show J.P. Morgan's continuing coverage of the stocks; the current analysts may or may not have covered it over the entire period.
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| IB clients* | 72% | 62% | 58% |

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