

Equity Research

August 11, 2015

**Price: \$33.87** (08/10/2015)

**Price Target: \$45.00**

**OUTPERFORM (1)**

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**Key Data**

Symbol [NASDAQ: CHRS](#)

Market Cap (MM) [\\$1,281.7](#)

Quick Take: Earnings Update

# *Steady Progress Continues; Numerous Disclosures Over The Next 6-12 Months*

## **The Cowen Insight**

Coherus has 3 key biosimilar products in development: (1) CHS-1420 (Humira); (2) CHS-0214 (Enbrel); and (3) CHS-1701, (Neulasta). Our \$45 price target is based on conservative penetration into the RA and psoriasis markets for CHS-1420 and CHS-0214, with modest contribution from CHS-1701. With several disclosures expected over the next 6-12 months, significant value creation could occur.

## **Biosimilar Development Programs Continue To Make Significant Progress**

Coherus held its Q2 earnings call and continues to make steady progress with its robust pipeline. As a reminder, Coherus is one of the leading players in the race to develop biosimilars with three key products in development: (1) CHS-1420, a biosimilar of AbbVie's Humira; (2) CHS-0214, a biosimilar of Amgen's Enbrel; and (3) CHS-1701, a biosimilar of Amgen's Neulasta.

Regarding CHS-1701, Coherus has completed the enrollment of the pivotal PK/PD study and also initiated an immunogenicity study, both of which are being conducted in healthy volunteers. Recall that after recently meeting with the FDA, the Company received guidance to conduct a single-dose PK/PD study of CHS-1701 in 106 healthy patients and a parallel group, two-dose immunogenicity study with 80 healthy patients in each group (CHS-1701 versus its active comparator Neulasta). Importantly, based on the feedback from the Agency, Coherus will not need to conduct Phase III efficacy studies for CHS-1701 in patients with cancer due to the following reasons: (1) pegfilgrastim is a relatively simple molecule to characterize compared to other proteins such as monoclonal antibodies (i.e., smaller molecular weight, no glycosylation, straightforward pegylation, etc.); (2) treatment with the G-CSF analog is on an acute not chronic basis; and finally (3) there is a clear rapid efficacy marker, which is an increase in neutrophil counts that can be observed in both healthy patients and those with cancer. While these three attributes (easier ability to characterize, rapid and measurable effects, acute use versus chronic) are not applicable for all biosimilars, the Agency's willingness to approach each candidate with a degree of flexibility is encouraging for potential current and future targets. The PK/PD and immunogenicity studies for CHS-1701 should support a filing of the 351(k) BLA in Q4:2015/Q1:2016. Management is already in the early stages of formalizing its commercialization and reimbursement strategy, which is encouraging.

For CHS-1420 (biosimilar Humira) – the company's key asset – Coherus continues to make stable progress. Recall that after receiving feedback from the Agency, Coherus has decided to conduct its pivotal Phase III program in plaque psoriasis. Specific for the U.S., the efficacy study will require a 16 week assessment with a PASI 75 endpoint (75% improvement in the Psoriasis Area and Severity Index score) while for the EMA, the regulators have suggested a 12 week assessment with a mean improvement in PASI endpoint. The study is expected to be initiated in mid-2015. Additionally, the Company will also initiate a PK bioequivalence bridging study toward the end of H1:2016 using Phase III drug material. The BLA for CHS-1420 is expected to be filed in H2:2016 and we continue to remain encouraged by the straightforward dialogue and

**Please see addendum of this report for important disclosures.**

clinical guidance that Coherus has received from both the FDA and EMA for this key program.

Finally, regarding CHS-0214 (biosimilar Enbrel partnered with Baxalta and Daiichi Sankyo) enrollment for both the RA and psoriasis Phase III studies was completed in May 2015, for which Coherus received a \$35MM milestone payment from Baxalta. Topline data for the psoriasis study is expected in Q4:2015 with data from the RA study expected in Q1:2016. CHS-0214 remains on-track for regulatory filings in the EU and Japan in mid-2016. The bottom-line is that Coherus continues to make significant progress with its biosimilars pipeline and several disclosures are expected over the next 6-12 months, that could generate significant value for shareholders.

### **Coherus Is A Leader In What Should Be A Significant Biosimilars Market**

By 2017, we estimate the WW sales of Humira for the rheumatoid arthritis (RA) and psoriasis indications alone will be approximately \$10B. For Enbrel, Amgen has U.S. patent protection until 2029 in the U.S., but we estimate the 2017 ex-U.S. sales will still be \$3.2B for just the RA and psoriasis indications. Finally, Neulasta WW sales are expected to be roughly \$4.4B by 2017. Put simply, Coherus is currently developing three lead biosimilar products with an estimated total addressable market of \$18B by 2017. And the Company's impressive development platform is easily transferable to a long list of additional biosimilar opportunities. From a clinician, patient, and overall health care system (government and commercial payors) perspective, there is an escalating, in fact desperate, need for effective and therapeutically equivalent low-cost alternatives. We believe Coherus will be at the forefront of alleviating the massive cost pressures via what should be a successful development of its biosimilar products.

### **Valuation Remains Attractive Here**

Our base-case valuation assumes U.S. approval for CHS-1420 (Humira) in 2017, and peak sales via direct commercialization by Coherus eventually reaching approximately \$1B, assuming a 3% penetration of the U.S. RA and psoriasis markets by 2022. We also assume ex-U.S. approvals of CHS-1420 in 2018 with peak royalty revenues of \$190MM+. For CHS-0214 (Enbrel), we assume ex-U.S. approvals in 2017 with peak royalty revenues of \$200MM+. Finally, we assume a 2017 U.S. approval (which could prove conservative) for CHS-1701 (Neulasta) with peak sales via direct marketing by Coherus of \$260MM+. We also assume ex-U.S. approval of CHS-1701 in 2018 with peak royalty revenues of \$30MM+. We would note, our valuation does not attribute any value to the potential additional indications for CHS-1420 and CHS-0214 that are currently found in the labels for Humira and Enbrel. Our industry checks continue to suggest that physicians are willing to use biosimilars and that managed care will clearly pressure for adoption. As a result, our current assumptions may prove to be conservative. We would note, our valuation does not attribute any value to the potential additional indications for CHS-1420 and CHS-0214 that are currently found in the labels for Humira and Enbrel. The broader utilization could garner significant upside to our base case \$45 valuation since the RA and psoriasis indications only make up 55-60% of Humira's current U.S. sales.

## *Valuation Methodology And Risks*

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### **Valuation Methodology**

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#### **Pharmaceuticals/Specialty**

For our valuation methodology, we arrive at fair value utilizing a discounted cash flow (DCF) approach to derive our 12-month price target.

### **Investment Risks**

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#### **Pharmaceuticals/Specialty**

**Risks include:** (1) growing competitive dynamics in the specialty pharmaceuticals space; (2) the ability of management to execute on external growth by successfully acquiring new strategic, accretive products; (3) the ability to grow organically and keep the product pipeline robust; (4) potential regulatory delays, rejections, or failures of pipeline products; (5) economic sensitivity of any self-pay products or weakening consumer demand; (6) domestic or international pricing pressures for marketed products; and (7) failure to execute on new product launches.

#### **Risks To The Price Target**

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Coherus is a development-stage biosimilar company and while the strategy appears to be risk-mitigated from a clinical efficacy perspective, regulatory and legal hurdles could negatively affect the Company's share price.

# Addendum

## Stocks Mentioned In Important Disclosures

Ticker	Company Name
CHRS	Coherus BioSciences

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**Outperform (1):** The stock is expected to achieve a total positive return of at least 15% over the next 12 months

**Market Perform (2):** The stock is expected to have a total return that falls between the parameters of an Outperform and Underperform over the next 12 months

**Underperform (3):** Stock is expected to achieve a total negative return of at least 10% over the next 12 months

**Assumption:** The expected total return calculation includes anticipated dividend yield

### Cowen and Company Rating System until May 25, 2013

**Outperform (1):** Stock expected to outperform the S&P 500

**Neutral (2):** Stock expected to perform in line with the S&P 500

**Underperform (3):** Stock expected to underperform the S&P 500

**Assumptions:** Time horizon is 12 months; S&P 500 is flat over forecast period

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## Cowen And Company Rating Definitions

### Distribution of Ratings/Investment Banking Services (IB) as of 06/30/15

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	476	59.20%	110	23.11%
Hold (b)	314	39.05%	7	2.23%
Sell (c)	14	1.74%	0	0.00%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions.

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### Coherus BioSciences Rating History as of 08/10/2015

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### Legend for Price Chart:

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | \$xx = Price Target | NA = Not Available | S=Suspended

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