Coherus BioSciences

Equity Research

Quick Take: Company Update

November 10, 2015

Price: $29.06 (11/9/2015)

Price Target: $45.00

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: CHRS
Market Cap (MM)	$1,112.9

Continued, Stable, Positive Progress And Execution

The Cowen Insight

CHRS has 3 biosimilar products in development: CHS-1420 (Humira); CHS-0214 (Enbrel); and CHS-1701, (Neulasta). All are progressing according to plan and our $45 target is based on conservative penetration into the RA & psoriasis markets for CHS-1420/CHS-0214, with modest contribution from CHS-1701. With several disclosures over the next 6-12 months, significant value creation could occur.

First CHS-0214 Registration Study Positive Further Validating Platform

Coherus reported third quarter earnings and gave updates on its three key biosimilar development programs. Most notably, Coherus announced that **CHS-0214** (biosimilar Enbrel partnered with Baxalta and Daiichi Sankyo) met both primary efficacy endpoints (12-week PASI score change; proportion of subjects achieving 75% improvement in PASI score) in the Phase III psoriasis clinical study (n=521) demonstrating equivalence to Enbrel. Importantly, no clinically relevant adverse safety signals were observed in either group. Regarding data on antibodies, we await the completion of the 52-week study, which is the most relevant time point. The second Phase III study in RA patients required for registration has results due in Q1:2016, which we continue to assume will be positive. The last component of this clinical program will be additional studies to be initiated in the middle of next year that will provide comparative PK data on the CHS-0214 Phase III drug material, CHS-0214 materials intended for commercial use, and Enbrel manufactured in Europe. If these are successful, the company anticipates filing an MAA in the E.U. later next year.

For **CHS-1701**, the company's biosimilar of Amgen's Neulasta (pegfilgrastim) that demonstrated positive PK/PD results in October, (which we once again review in more detail below), the company remains on track to file a BLA in the first quarter of next year. Worth noting, enrollment (n=300) for the ongoing immunogenicity study has been completed.

Lastly regarding **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 was initiated in August 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 clinical guidance that Coherus has received from both the FDA and EMA for this key program. Furthermore, with the recent positive clinical results for both CHS-1701 and CHS-0214, we remained encouraged by management's execution and their ability to successfully complete the remaining studies for the various programs. 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.

As for the specifics regarding a new development on the intellectual property front, Coherus has filed in the USPTO a petition for Inter Partes Review (IPR) of AbbVie's U.S. Patent No. 8,889,135 entitled "Methods of Administering Anti-TNFalpha antibodies" directed to treating rheumatoid arthritis in a human subject via administration, every 13-15 days, of 40 mg of a human anti-TNFalpha antibody that includes or encompasses adalimumab (Humira). Put simply and without going into greater detail behind their legal strategy (for obvious reasons), Coherus stated that there is prior art from previous clinical trials available that it believes invalidates this patent.

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 we believe 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 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. 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.

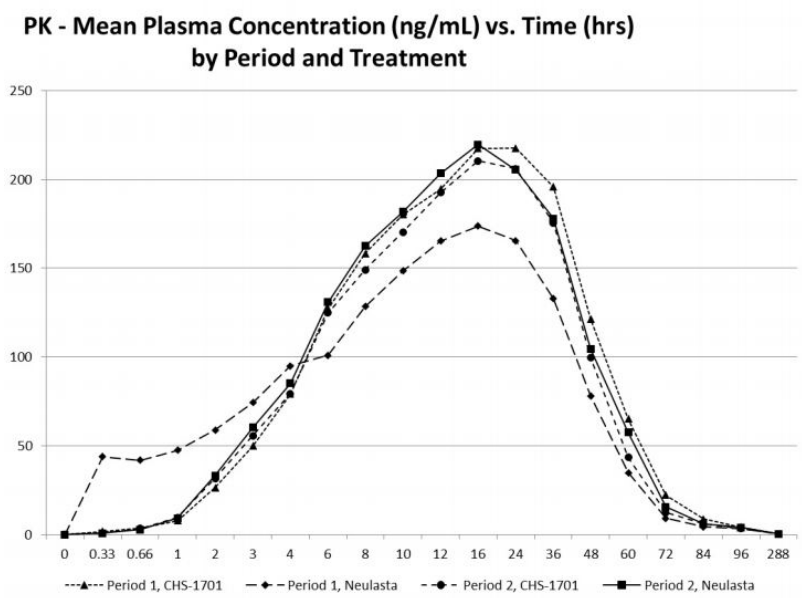
As We've Previously Published, CHS-1701's Profile Appears Consistent, Reproducible And Approvable

In October, Coherus announced the topline PK/PD study results for CHS-1701, the company's biosimilar of Amgen's Neulasta (pegfilgrastim). The bottom-line is that Coherus appears to have a highly consistent formulation of pegfilgrastim that matches the *historical* PK/PD profile of Neulasta. As we will explain within this note, we have italicized "historical" because one of the comparator arms of branded Neulasta in the study had results that were significantly different than the well-established historical profile of the product, as well as the second Neulasta comparator group, which did match the historical profile. This comparator arm anomaly should have no bearing on the key metric of the study, which was the successful and consistent replication of

the PK/PD profile of CHS-1701 compared to a normalized profile of Neulasta. Stated clearly, one of the control arms of the study acted inconsistently, but that does not appear to be a concern of the FDA – especially in light of the CHS-1701 performance. Furthermore, with no neutralizing antibodies being identified during this PK/PD study, we now have greater confidence in the outcome of the ongoing CHS-1701 immunogenicity study (discussed in detail below). This study just recently completed enrollment, and if successful, could allow Coherus to potentially be first-to-market with a biosimilar Neulasta, especially given the ongoing litigation between Amgen and Apotex (also discussed below).

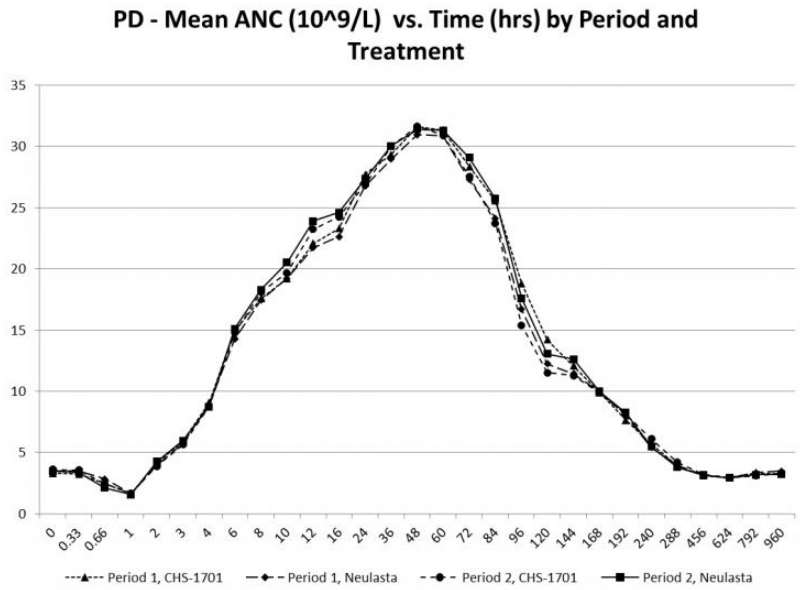
As for the background, recall, Coherus previously received guidance from the FDA regarding the regulatory requirements for CHS-1701, which included two clinical studies for approval: (1) A two-period single-dose PK/PD study in 116 healthy volunteers, and (2) A parallel group, two-dose immunogenicity study with 80 healthy volunteers in each group (CHS-1701 versus Neulasta). Regarding the PK/PD study, during the first period of the trial, subjects received either a single subcutaneous dose of 6mg CHS-1701 or 6mg Neulasta. After a 6-8 week washout, patients were then switched to receive a single dose of the other product during the second period of the study (CHS-1701 then Neulasta or vice versa). As for the data disclosed last night, regarding the PK assessment, CHS-1701 achieved bioequivalence to Neulasta for C_{max}, but did not achieve bioequivalence for Area Under the Curve (AUC). Interestingly, the reason for the "miss" appears to be due to the anomalous performance of the Neulasta control group during the first period of the study (as demonstrated in the graph below). Specifically, management indicated that the Neulasta PK profile seen during the first period was highly inconsistent with the well-established historical profile of the drug, which has been demonstrated in multiple studies by Amgen. The Neulasta PK profile during this first period was also highly inconsistent with the PK profile during the second period of the study, which does match the well-established historical profile of the drug.

Most importantly, CHS-1701 was highly consistent during all phases of the study and achieved bioequivalence with Neulasta during the second period of the trial, which as we indicated above, was when the drug performed in accordance with its historical profile. Although it is unclear what caused the anomalous PK performance of Neulasta during the first period comparator group, given the consistency of CHS-1701 in both phases of the study, the exact cause is likely not meaningful and does not appear to be a concern of the FDA. Specifically, management indicated that the FDA has not recommended initiating a repeat study, which appears due to their comfort in their understanding of the well-established profile of Neulasta. Although we believe it will be unnecessary, if Coherus was asked to conduct another confirmatory PK/PD study, it would likely take roughly five months (from enrollment to data release) and cost approximately $3.5-5.0MM. The bottom-line is, as we indicated above, that Coherus appears to have a highly consistent formulation of pegfilgrastim that matches the historical PK/PD profile of Neulasta. Furthermore, with no neutralizing antibodies being identified during this PK/PD study, we now have greater confidence in the outcome of the ongoing CHS-1701 immunogenicity study. This study just recently completed enrollment, and if successful, could allow Coherus to potentially be first-to-market with a biosimilar Neulasta, especially given the ongoing litigation between Amgen and Apotex.



Source: Coherus

Regarding the PD assessment for CHS-1701, the biosimilar met both primary endpoints of (1) absolute neutrophil count (ANC) C_{max} and (2) absolute neutrophil count Area Under the Curve (AUC). The matched profile of CHS-1701 and Neulasta is clearly demonstrated in the graph below. This PD data provides further positive confirmation of the CHS-1701 profile.



Source: Coherus

CHS-1701 Immunogenicity Study Is Ongoing

Recall that Coherus recently disclosed that it increased enrollment in the ongoing CHS-1701 immunogenicity study to ensure optimal powering. This study enrollment is now complete and the reason for the expansion is what appeared to be an increased aggregate anti-drug antibody rate in the overall study following a blinded preliminary interim look. Of note, the study is still completely blinded, so it is unclear at this point if the CHS-1701 arm, or the Neulasta control arm, is driving the higher aggregate antibody rate observed so far. Although alterations to a study need to be properly

vetted, we believe that this increased enrollment and the suggestion of a higher antibody rate are explainable, and at this point, not overly concerning. We would note that the historical rate of anti-drug antibodies in Neulasta is approximately 3-5%, however, the company believed that the rate in the immunogenicity study would be on the higher end of that range because the latest-generation assays being utilized for detecting antibodies are more sensitive. Nonetheless, in order to pursue the most ethical trial design to minimize the number of healthy volunteers exposed to the Neulasta/CHS-1701 side effects, Coherus powered the study assuming a roughly 5% antibody rate (i.e., initially enrolled a minimum threshold of patients). To compensate for what would likely and potentially occur, Coherus designed into the study a pre-specified allowance of a preliminary blinded look at the aggregate antibody rates, and also included a corresponding pre-specified option to increase the enrollment if higher antibody rates were observed. And indeed, based on this interim analysis, Coherus found that the aggregate rate of antibodies being observed was 1-2% above the historical Neulasta rates (so approximately 6-7%), and in order to ensure optimal powering, decided to increase the enrollment. To reiterate, this was all pre-specified (the interim look and the ability to increase enrollment), which should provide comfort that management was pursuing the most ethical design given the utilization of healthy volunteers. Management indicated that the additional enrollment will place the immunogenicity data disclosure and NDA filing into Q1:2016, which is essentially on track with previous guidance. Although we now must await the final disclosure of the full data set, at this point management's explanation appears sound and the trial design very reasonable and appropriate. We continue to believe that CHS-1701 remains very much on track.

Importantly, regarding the recently issued 8,952,138 manufacturing patent, we do not believe this will pose a legal impediment to Coherus. For background, recall that Apotex submitted the first (and thus far only) application for approval of biosimilar Neulasta to the FDA last year and the application is believed to have an FDA action date in the fall. Amgen and Apotex have engaged in the patent exchange provisions detailed under the Biologic Price Competition and Innovation Act (BPCIA), but have failed to resolve their differences (which is unsurprising to us). Our colleague Eric Schmidt and the Cowen Biotechnology Team indicate a court document in Amgen vs. Apotex (found here) describes that Amgen continues to assert two patents against Apotex. U.S. patent 5,824,784 was previously known to us, and expires October 20, 2015. U.S. patent 8,952,138 is a new patent, issued in February 2015, that is valid until 2030 (a copy can be found here). It covers a method for manufacturing cysteine-containing proteins expressed in non-mammalian cells at high concentrations. Amgen has asked the courts for an injunction to delay the launch of biosimilar Neulasta until 180-days after FDA approval as the Federal Circuit recently ruled that a biosimilar sponsor may only give its 180-day notice once an application has been approved. In theory, this would delay an Apotex biosimilar Neulasta launch until at a minimum the spring of 2016. A court case to rule on the merits of Amgen's patents is scheduled for July 2016. If the courts rule that Amgen's new '138 patent is valid and infringed, the launch of a biosimilar Neulasta via Apotex may be delayed much further.

While the strength of this new patent is still not clear, because Amgen and Apotex have engaged in the patent exchange process wherein Apotex supplied Amgen with a copy of its BLA filing, Amgen likely knows the conditions under which Apotex is manufacturing its biosimilar Neulasta and likely has good reason to believe that Apotex's process infringes the written claims of the '138 patent. With a court date scheduled for July 2016, the question may become whether Apotex would launch at risk. Given the size of the Neulasta franchise (nearly $4B in the U.S. sales) and the risk of treble damages were Apotex found to be in willful infringement of valid manufacturing claims, we suspect an at-risk launch is unlikely. We also note that

Amgen has asked the courts for an injunction to prevent any launch until after the claims of the '138 patent are litigated. Hence, we believe that the '138 patent might at a minimum delay launch of a biosimilar Neulasta until an H2:16 court ruling. Assuming Amgen were to prevail in courts, Neulasta biosimilars might be delayed beyond H2:16.

As this patent issue relates to Coherus, management indicated that the manufacturing method described in the '138 patent is not utilized for the production of CHS-1701. This would suggest that if Apotex's Neulasta biosimilar does in fact infringe the '138 patent, that CHS-1701 could potentially be the first Neulasta biosimilar approved and launched in the U.S., as it would appear that Coherus can circumvent it. This potential first-mover advantage was also aided by the guidance that Coherus received from the FDA that it 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. Management is in the early stages of formalizing its commercialization and reimbursement strategy, which is also encouraging. And to reiterate, Coherus' strategy to formulate and manufacture outside of the known patent estate could (and should) yield significant value as it will likely provide a much clearer legal pathway.

Valuation Methodology And Risks

Valuation Methodology

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

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

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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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

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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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Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	492	59.49%	118	23.98%
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Sell (c)	18	2.18%	0	0.00%

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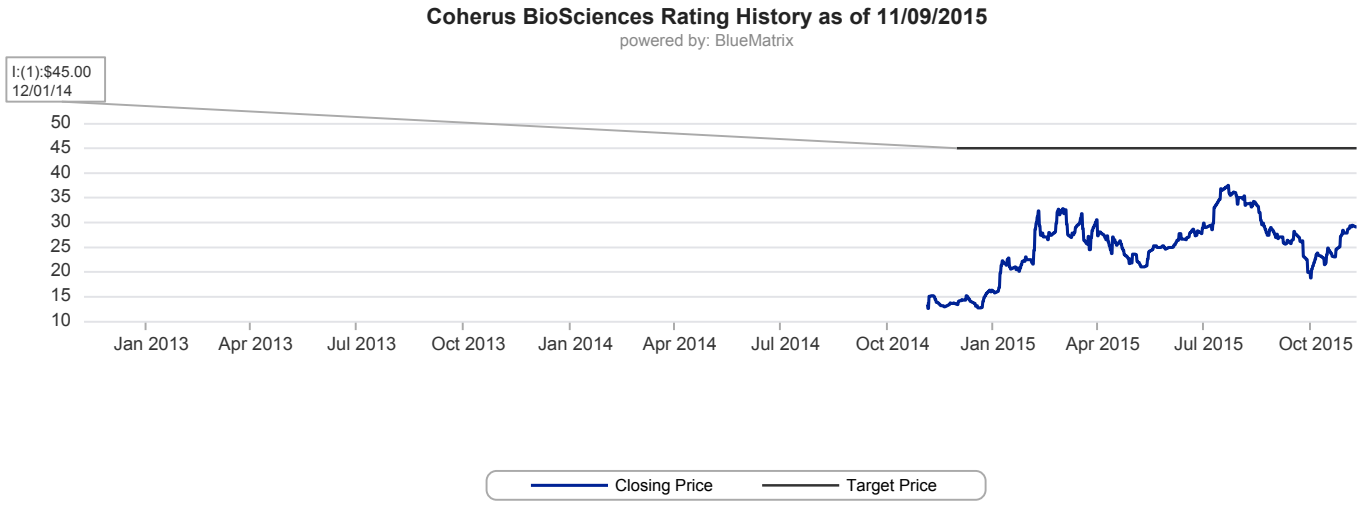

Legend for Price Chart:

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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