

Equity Research

December 1, 2014

**Price: \$13.73** (11/28/2014)

**Price Target: \$45.00**

**OUTPERFORM (1)**

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**Key Data**

Symbol	NASDAQ: CHRS
52-Week Range:	\$16.25 - 12.27
Market Cap (MM):	\$447.0
Net Debt (MM):	\$(35.4)
Cash/Share:	\$13.63
Dil. Shares Out (MM):	32.6
Enterprise Value (MM):	\$461.9
ROIC:	NA
ROE (LTM):	NA
BV/Share:	\$(39.36)
Dividend:	NA

FY (Dec)	2014E	2015E	2016E
<b>Revenue (MM)</b>			
Year	\$10.0	\$0.0	\$0.0
EV/S	46.2x	-	-

**Earnings Per Share**

Year	\$(2.50)	\$(2.90)	\$(3.65)
P/E	NM	NM	NM

Initiating Coverage

# *Initiation: The Leading Pureplay Of The Emerging Biosimilar Opportunity*

**The Cowen Insight**

Coherus is one of the key players in the race to develop biosimilars with three products in development: (1) CHS-1420, (Humira); (2) CHS-0214, (Enbrel); and (3) CHS-1701, (Neulasta). Our price target of \$45 per share is based on conservative penetration into the RA and psoriasis markets for CHS-1420 and CHS-0214, with additional contribution from CHS-1701 in the G-CSF market.

**Coherus Is A Leader In What Should Be A Massive Biosimilars Market**

Coherus is one of the key players in the race to develop biosimilars with three 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. 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 (governments and private payors) viewpoint, 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 Appears 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. 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% of Humira's current U.S. sales.

## At A Glance

### Our Investment Thesis

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 and a 20% price discount to Humira. 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.

### Forthcoming Catalysts

Q1:15 - Initiate Phase III pivotal trial CHS-1420 (Humira) in RA/psoriasis  
2015 - Data readout for CHS-0214 (Enbrel) Phase III trials for RA and psoriasis  
2015 - Initiate Phase III pivotal trial CHS-1701 (Neulasta)

### Base Case Assumptions

\$45 on successful development of Coherus' three lead biosimilar programs

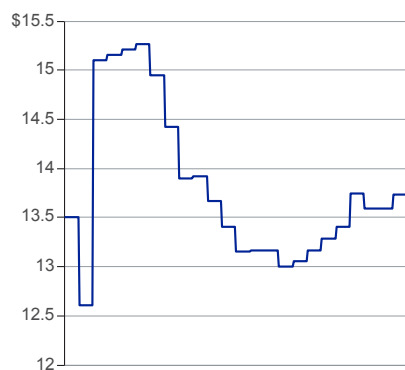
### Upside Scenario

\$60+ in an acquisition scenario

### Downside Scenario

Below \$10 on developmental or regulatory failures of biosimilar programs

### Price Performance



Source: Bloomberg

### Company Description

Coherus is a development-stage biosimilar company. Its three lead programs, biosimilar Humira, Enbrel, and Neulasta, are targeting a total addressable worldwide market of \$18B with other significant opportunities to leverage via its development platform.

### Analyst Top Picks

	Ticker	Price (11/28/2014)	Price Target	Rating
Actavis	ACT	\$270.61	\$350.00	Outperform
Teva Pharmaceutical	TEVA	\$56.98	\$70.00	Outperform
Jazz Pharmaceuticals	JAZZ	\$177.09	\$190.00	Outperform

## Coherus Is A Leader In The Massive Biosimilar Market

Coherus is one of the key players in the race to develop biosimilars with three 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. 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 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 (governments and private payors) viewpoint, there is an escalating need for effective and therapeutically equivalent low-cost alternatives. We believe Coherus will help address this via development of its biosimilar products.

As written by our biotechnology colleagues, based on feedback from physician panelists at our recent Cowen Therapeutics Conference, they underscored what appears to be an increasing willingness from clinicians to adopt biosimilars. Specifically our colleagues wrote: "In their view (physician consultants), a potential game changer could be the introduction of cheaper, biosimilar anti-TNFs. Even though panelists expressed some discomfort with biosimilars, they expect managed care to be able to dictate their utilization to a physician audience that is already frustrated with the daily hassle of prior authorizations." The bottom-line is that U.S. prescriber base already understands that the introduction of well-vetted, therapeutically equivalent biosimilar products could be "a potential game changer."

Our physician consultants have been consistent in their feedback that if a biosimilar anti-TNF is approved by the FDA, the majority of physicians will be willing to use the product. Furthermore, our consultants note that if managed care puts pressure to adopt biosimilars – which they expect will occur – most physicians will likely conform. The cost pressures are simply demanding some form of solution. As written by our biotechnology colleagues, based on feedback from physician panelists at our recent Cowen Therapeutics Conference, they underscored what appears to be an increasing willingness from clinicians to adopt biosimilars. Specifically our colleagues wrote: "*In their [physician consultants] view, a potential game changer could be the introduction of cheaper, biosimilar anti-TNFs. Even though panelists expressed some discomfort with biosimilars, they expect managed care to be able to dictate their utilization to a physician audience that is already frustrated with the daily hassle of prior authorizations.*" The bottom-line is that U.S. prescriber base already understands that the introduction of well-vetted, therapeutically equivalent biosimilar products could be "a potential game changer." Additionally, in Europe, where biosimilars have been available for several years now, we are seeing rapid adoption for some products. As an example, in the five largest European markets, Neupogen (the non-pegylated version of Amgen's Neulasta) has had nearly 80% conversion to biosimilars, even with discounts being offered on the branded product. Granted, the E.U. has been more progressive than the U.S. FDA regarding the development and approval of biosimilars, but the analogue still illustrates the magnitude of the opportunity and the potential for conversion. Furthermore, given the technical hurdles for biosimilar development, we expect only a handful of market entrants, which should help minimize price erosion as we suspect the limited players will be operate rationally.

Coherus offers an interesting combination of a platform with significant technical expertise along with a seasoned management team with decades of experience from leading biologics companies (i.e., Amgen, Genentech, Immunex, etc.). The partnerships that Coherus has established (Baxter, Daiichi Sankyo, Orox) provide further validation on the Company's capabilities. As such, major pharmaceutical companies are beginning to realize that biosimilars pose a real – and impending – threat to some of the most successful franchises, and that competing in this space requires significant expertise that only a handful of companies possess. Additionally, in a recent meeting with Teva management – a leading global generics company – they indicated they would have to acquire additional capabilities to compete in the biosimilars market. This is just another example (among many) of the increasing

demand for these capabilities. These factors provide us with greater confidence and reinforce our belief that this is an exceedingly interesting company. Our base case DCF valuation indicates roughly \$45 per CHRS share, with our takeout scenario suggesting \$60+ and providing considerable upside from current levels.

As for the specifics, CHS-1420, a biosimilar version of Humira will be the key value driver for Coherus. Humira is the largest product in the world by sales and Coherus owns the worldwide rights to CHS-1420. The Company has made steady progress with the development of CHS-1420 including exceedingly positive (tightly matched) Phase I PK/PD clinical results. The study was conducted under a U.S. IND application in healthy volunteers and demonstrated bioequivalence for all prospectively defined endpoints. The positive outcome will allow Coherus to pursue a 351(k) application for CHS-1420, which only requires an additional Phase III confirmatory study for filing. The Company plans to initiate a Phase III study in psoriasis and/or rheumatoid arthritis in H1:15 with a planned U.S. filing in 2016 if successful, and an anticipated launch via Coherus' own direct salesforce in 2017. A potential EU filing could occur in 2017 with a 2018 launch, likely via a commercial partner. Coherus is working with the regulatory agencies in the U.S., E.U., and Japan to develop a Phase III trial design that will allow for filing in all three territories. Based on discussions with these regulatory agencies, Coherus believes it may be possible to extrapolate data from the RA/psoriasis trials to gain approval for CHS-1420 in all of the indications included in the label for Humira. We would note that Novartis/Sandoz is also pursuing a similar strategy with its Humira biosimilar by conducting a single Phase III study for psoriasis.

Specifically, we would note that roughly 60% of all U.S. Humira sales are in the RA and psoriasis indications (~\$6.5B). Utilizing a modest 3% share for CHS-1420 in these two indications alone at a 20% price discount to Humira, would yield \$750MM+. The bottom-line is that small penetration rates could yield significant value creation.

We believe CHS-1420 could be a \$750MM+ product in the U.S. based on conservative penetration rates into Humira's two lead U.S. indications, RA and psoriasis. Specifically, we would note that roughly 60% of all U.S. Humira sales are in the RA and psoriasis indications (~\$6.5B). Utilizing a modest 3% share for CHS-1420 in these two indications alone at a 20% price discount to Humira, would yield this \$750MM+ figure. The bottom-line is that small penetration rates could yield significant value creation. We expect Coherus to partner the ex-U.S. rights for CHS-1420 with peak royalty revenues of \$190MM. The ability for Coherus to capture additional Humira indications on the CHS-1420 label could provide even greater utilization than our current assumptions suggest.

Regarding the CHS-0214 (Enbrel) candidate in development, Coherus is using a partnering strategy and has licensed it to Baxter in Europe, Daiichi Sankyo in Japan, and Orox for certain Caribbean and Latin American countries. The Company has already received \$40MM in cash payments from these partnerships and can receive up to \$220MM in additional milestone payments. Coherus is also entitled to royalty payments that range from the mid-single digits to the high twenties. CHS-0214 is the furthest developed biosimilar asset for Coherus and the Company has recently initiated two Phase III trials for the product: (1) A double blind, multi-center, parallel group RA study will enroll approximately 486 patients with disease-modifying antirheumatic drug (DMARD)-refractory rheumatoid arthritis. Patients will be put on a stable dose of methotrexate and randomized 1:1 to either CHS-0214 50mg or Enbrel 50mg. Both products will be administered subcutaneously on a weekly basis for a period of 24 weeks. The primary endpoint will be a 20% improvement according to American College of Rheumatology Criteria (ACR 20) scores at 24 weeks, which is the same primary endpoint used in the Enbrel registration trial for RA. After 24 weeks, patients in both arms will receive treatment with CHS-0214 for 6 months to evaluate further the safety of the product; (2) For the Phase III psoriasis study, Coherus will enroll approximately 424 patients with active psoriasis. Using a double-blind, parallel group design, patients will be randomized 1:1 to either 50mg subcutaneous CHS-0214 or Enbrel, administered twice-weekly for the first 12 weeks and then switched to

once-weekly for an additional 40 weeks, including 4 weeks of follow-up. The primary endpoint will be the mean Psoriasis Area and Severity Index (PASI), and the percentage of patients achieving a 75% improvement in the score (PASI-75) from baseline, after 12 weeks of treatment.

Our analysis of CHS-0214 suggests partnered peak sales of \$1,000+, yielding peak royalties to Coherus of \$200MM+ (20% royalty rate). This assumes a 20-25% penetration of the ex-U.S. Enbrel market at a 25% price discount relative to Enbrel. Similar to CHS-1420, approval of additional indications in the Enbrel label could provide additional upside for CHS-0214.

If we assume modest market share capture and a 15% price discount, we arrive at peak sales of \$260MM for CHS-1701 via direct Coherus sales in the U.S. and an additional \$30MM of peak royalty revenues for international sales.

Assuming clinical success of these products via the condensed 351(k) regulatory pathway, we arrive at a base valuation of \$45 per share. Our price target of \$45 per share is based on reasonable penetration into the RA and psoriasis markets for CHS-1420 (Humira) and CHS-0214 (Enbrel), with additional contribution from CHS-1701 (Neulasta) in the G-CSF market.

Given the ex-U.S. markets are more advanced than the U.S. regarding the approval and utilization of biosimilars, our analysis of CHS-0214 suggests partnered peak sales of \$1,000+, yielding peak royalties to Coherus of \$200MM+ (20% royalty rate). This assumes a 20-25% penetration of the ex-U.S. Enbrel market at a 25% price discount relative to Enbrel. Similar to CHS-1420, approval of additional indications in the Enbrel label could provide additional upside for CHS-0214.

Finally, Coherus has made progress with CHS-1701 (biosimilar Neulasta), including completion of a Phase I PK/PD study in healthy volunteers, which would support a BLA filing for the product via the standard 351(a) pathway. However, the Phase I study did not meet the strict criteria for bioequivalence required for a 351(k) filing. As a result, Coherus is likely to repeat the critical PK/PD study with adjustments to the study design to address the variability that likely led to the slight miss on bioequivalence. Following a successful Phase I study, Coherus would only need to conduct a confirmatory Phase III safety/efficacy study to file CHS-1701 via the 351(k) pathway. With Neulasta WW sales expected to be \$4.4B by 2017, CHS-1701 provides Coherus with another solid opportunity. If we assume modest market share capture and a 15% price discount, we arrive at peak sales of \$260MM for CHS-1701 via direct Coherus sales in the U.S. and an additional \$30MM of peak royalty revenues for international sales.

Assuming clinical success of these products via the condensed 351(k) regulatory pathway, we arrive at a base valuation of \$45 per share. Our price target of \$45 per share is based on reasonable penetration into the RA and psoriasis markets for CHS-1420 (Humira) and CHS-0214 (Enbrel), with additional contribution from CHS-1701 (Neulasta) in the G-CSF market. Of note, this valuation does not factor in any potential incremental upside such as additional indications for CHS-1420 and CHS-0214 for the treatment of other inflammatory conditions currently in the labels for Humira and Enbrel. Lastly, we feel it is important to note that these biosimilar products are not susceptible to patent cliffs, and should provide considerable duration for Coherus.

#### Upcoming Milestones For Coherus Include:

##### 2015:

- Data readout for CHS-0214 (Enbrel) Phase III trials for RA and psoriasis
- Initiate Phase III pivotal trial CHS-1420 (Humira) in RA/psoriasis
- Initiate Phase III pivotal trial CHS-1701 (Neulasta)

##### 2016:

- Potential MAA filing in the EU for CHS-0214 (Enbrel)
- Data readout for CHS-1420 (Humira) Phase III trial and 351(k) BLA filing
- Data readout for CHS-1701 (Neulasta) Phase III trial and BLA filing

##### 2017:

- Potential launch of CHS-0214 (Enbrel) in the EU in early 2017 – via Baxter
- Potential launch of CHS-1420 (Humira) in the U.S. in mid-2017 – Coherus direct sales force
- Potential launch of CHS-1701 (Neulasta) in the U.S. in mid-2017 – Coherus direct sales force

## Valuation Appears Attractive Here

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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% of Humira's current U.S. sales.

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 and a 20% price discount to Humira. We also assume ex-U.S. approvals of CHS-1420 in 2018 with peak royalty revenues of \$190MM+ and a price discount of 25%. For CHS-0214 (Enbrel), we assume ex-U.S. approvals in 2017 with peak royalty revenues of \$200MM+ and a 25% initial price discount to Enbrel. Finally, we assume a 2017 U.S. approval for CHS-1701 (Neulasta) with peak sales via direct marketing by Coherus of \$260MM+ and a 15% initial price discount to Neulasta. We also assume ex-U.S. approval of CHS-1701 in 2018 with peak royalty revenues of \$30MM+ and also with an initial price discount of 15%. 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. Our base case assumes sales force expansion of approximately 50 reps in 2017 for the launch of CHS-1420 and margins of 85% with SG&A and R&D costs within the range of normal industry standards. 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% of Humira's current U.S. sales.

Below we provide our market models for CHS-1420, CHS-0214, and CHS-1701 to provide a perspective on the size of the product opportunities. On the following pages, we publish our base case DCF scenario as well as an acquisition case DCF scenario to illustrate the potential upside of CHRS shares.



Figure 1 CHS-1420 Rheumatoid Arthritis Market Model

ESTIMATED U.S. RHEUMATOID ARTHRITIS MARKET											
	2013	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	CAGR Comments
Total U.S. Population ('000)	332,000	335,500	338,855	342,240	345,665	349,120	352,610	356,135	359,695	363,295	
Prevalence of Rheumatoid Arthritis (RA)	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	
Total U.S. Patients with RA ('000)	2,490	2,516	2,541	2,567	2,592	2,618	2,645	2,671	2,698	2,725	
% Not Entering Remission	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	- Only 15% of patients enter remission without treatment
% Requiring Add-On Therapy	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	- Including 20% patients failing all treatment & 15-25% failing MTX
Total RA Add-On Therapy Population ('000)	847	858	864	873	881	890	899	908	917	928	- Total number of patients that are candidates for anti-TNF therapy
% Growth		+1%	+1%	+1%	+1%	+1%	+1%	+1%	+1%	+1%	
Remicade Penetration of U.S. RA Add-On Market (JNJ)	10%	8%	8%	5%	4%	3%	3%	3%	2%	2%	
Average Annual Patients ('000)	36	32	29	25	23	20	18	16	14	12	-11%
Annual Cost of Therapy (\$'000)	\$21.8	\$21.8	\$21.8	\$21.8	\$21.8	\$21.8	\$21.8	\$21.8	\$21.8	\$21.8	
Estimated Remicade U.S. RA Sales (\$MM)	\$785	\$700	\$620	\$545	\$480	\$435	\$390	\$360	\$305	\$280	-12%
% Growth		-11%	-11%	-12%	-10%	-11%	-10%	-10%	-13%	-15%	- Simponi cannibalizing sales in RA
Enbrel Penetration of U.S. RA Add-On Market (AMGN/PFE)	31%	30%	29%	27%	26%	24%	23%	23%	23%	23%	
Average Annual Patients ('000)	116	116	117	117	117	117	116	115	114	113	-0.2%
Annual Cost of Therapy (\$'000)	\$22.2	\$22.9	\$23.5	\$24.2	\$25.0	\$25.7	\$26.5	\$27.3	\$28.1	\$29.0	
Estimated Enbrel U.S. RA Sales (\$MM)	\$2,085	\$2,050	\$2,145	\$2,085	\$2,020	\$1,910	\$1,875	\$1,840	\$1,805	\$1,770	+3%
% Growth		+3%	+4%	+3%	+3%	+3%	+2%	+2%	+2%	+2%	
Humira Penetration of U.S. RA Add-On Market (ABBV)	30%	30%	29%	28%	27%	25%	25%	24%	24%	24%	
Average Annual Patients ('000)	120	124	127	130	133	133	132	130	128	126	1%
Annual Cost of Therapy (\$'000)	\$20.7	\$21.4	\$22.0	\$22.7	\$23.4	\$24.1	\$24.8	\$25.5	\$26.3	\$27.1	
Estimated Humira U.S. RA Sales (\$MM)	\$2,490	\$2,650	\$2,795	\$2,945	\$3,105	\$3,200	\$3,270	\$3,315	\$3,385	\$3,410	+4%
% Growth		+6%	+5%	+5%	+5%	+3%	+2%	+1%	+2%	+1%	
Orencia Penetration of U.S. RA Add-On Market (BMY)	10%	10%	11%	11%	11%	10%	10%	11%	11%	11%	
Average Annual Patients ('000)	40	43	47	50	51	51	52	51	50	49	+2%
Annual Cost of Therapy (\$'000)	\$19.9	\$20.9	\$22.0	\$23.1	\$24.2	\$25.4	\$26.7	\$28.1	\$29.5	\$30.9	
Estimated Orencia U.S. RA Sales (\$MM)	\$800	\$900	\$1,020	\$1,155	\$1,235	\$1,300	\$1,375	\$1,430	\$1,475	\$1,515	+7%
% Growth		+13%	+13%	+13%	+7%	+5%	+6%	+4%	+3%	+3%	
Rituxan Penetration of U.S. RA Add-On Market (RHHBY)	0%	0%	5%	5%	4%	4%	4%	4%	4%	4%	
Average Annual Patients ('000)	27	29	28	28	27	26	26	25	25	24	-1%
Annual Cost of Therapy (\$'000)	\$17.1	\$17.6	\$18.1	\$18.6	\$19.2	\$19.8	\$20.4	\$21.0	\$21.6	\$22.3	
Estimated Rituxan U.S. RA Sales (\$MM)	\$460	\$500	\$505	\$510	\$515	\$520	\$525	\$530	\$535	\$540	+2%
% Growth		+9%	+1%	+1%	+1%	+1%	+1%	+1%	+1%	+1%	
Cimzia Penetration of U.S. RA Add-On Market (UCB)	4%	5%	5%	5%	5%	5%	5%	5%	5%	5%	
Average Annual Patients ('000)	17	20	23	25	27	30	30	31	31	31	+7%
Annual Cost of Therapy (\$'000)	\$21.5	\$21.5	\$21.5	\$21.5	\$21.5	\$21.5	\$21.5	\$21.5	\$21.5	\$21.5	
Estimated Cimzia U.S. RA Sales (\$MM)	\$365	\$430	\$485	\$535	\$585	\$635	\$685	\$735	\$785	\$835	+7%
% Growth		+18%	+13%	+10%	+9%	+9%	+2%	+1%	+0%	+0%	
Simponi Penetration of U.S. RA Add-On Market (JNJ)	4%	4%	5%	5%	5%	0%	0%	0%	0%	0%	
Average Annual Patients ('000)	13	15	17	19	22	24	25	25	25	24	+7%
Annual Cost of Therapy (\$'000)	\$26.2	\$27.0	\$27.8	\$28.6	\$29.5	\$30.3	\$31.2	\$32.2	\$33.2	\$34.1	
Estimated Simponi U.S. RA Sales (\$MM)	\$340	\$385	\$400	\$550	\$585	\$730	\$785	\$790	\$810	\$820	+10%
% Growth		+16%	+16%	+20%	+15%	+15%	+5%	+3%	+3%	+1%	
Actemra Penetration of U.S. RA Add-On Market (RHHBY)	4%	5%	5%	5%	5%	5%	5%	5%	5%	5%	
Average Annual Patients ('000)	17	21	23	25	27	29	30	30	30	30	+7%
Annual Cost of Therapy (\$'000)	\$19.7	\$20.1	\$20.5	\$20.9	\$21.3	\$21.7	\$22.2	\$22.6	\$23.1	\$23.5	- Price of 8mg is \$25,500/year and price of 4mg is \$12,700/year
Estimated Actemra U.S. RA Sales (\$MM)	\$325	\$410	\$475	\$525	\$575	\$625	\$685	\$740	\$790	\$840	+9%
% Growth		+26%	+16%	+11%	+10%	+9%	+6%	+2%	+1%	+1%	
Xeljanz Penetration of U.S. RA Add-On Market (PFE)	1%	3%	5%	9%	13%	14%	15%	15%	15%	15%	
Average Annual Patients ('000)	4	10	19	38	56	65	71	71	71	71	+37%
Annual Cost of Therapy (\$'000)	\$25.0	\$25.5	\$26.0	\$26.5	\$27.1	\$27.6	\$28.2	\$28.7	\$29.3	\$29.9	
Estimated Xeljanz U.S. RA Sales (\$MM)	\$105	\$260	\$500	\$1,000	\$1,500	\$1,800	\$2,000	\$2,040	\$2,080	\$2,120	+40%
% Growth		+148%	+92%	+100%	+50%	+20%	+11%	+2%	+2%	+2%	
Baricitinib Penetration of U.S. RA Add-On Market (BMY/INCY)				0%	1%	2%	2%	3%	4%	5%	
Average Annual Patients ('000)				1	4	7	11	16	20	23	+84%
Annual Cost of Therapy (\$'000)				\$27.0	\$27.5	\$28.1	\$28.7	\$29.2	\$29.8	\$30.4	
Estimated Baricitinib U.S. RA Sales (\$MM)				\$15	\$100	\$200	\$325	\$470	\$595	\$700	+90%
% Growth					+567%	+100%	+63%	+45%	+27%	+18%	
CHS-1420 Penetration of U.S. RA Add-On Market (Coherus)					0.5%	1.0%	1.5%	2.0%	2.5%	3.0%	
CHS-1420 Penetration of U.S. Humira RA Sales					1.4%	3.0%	4.5%	6.0%	7.5%	9.0%	
Average Annual Patients ('000)					2	5	8	10	13	16	+45%
Annual Cost of Therapy (\$'000)					\$18.7	\$19.2	\$19.8	\$20.4	\$21.0	\$21.7	- Price Discount of 20% from Humira
Estimated CHS-1420 U.S. RA Sales (\$MM)					\$45	\$100	\$155	\$210	\$275	\$335	+40%
% Growth						+122%	+55%	+35%	+31%	+22%	
Total U.S. RA Market Sales (\$MM)	\$8,235	\$8,895	\$9,805	\$10,615	\$11,705	\$12,555	\$13,195	\$13,810	\$14,590	\$15,325	+6%
% Growth		+8.0%	+8.0%	+10.9%	+10.3%	+7.3%	+5.1%	+3.1%	+2.8%	+2.4%	
Total U.S. RA Patients Treated with Biologics ('000)	389	409	428	457	487	507	518	519	520	518	

ESTIMATED CHS-1420 EX-US RHEUMATOID ARTHRITIS SALES											
	2013	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	CAGR Comments
Total Humira Ex-US RA Market Sales (\$MM)	\$2,710	\$3,025	\$3,305	\$3,500	\$3,600	\$3,400	\$3,200	\$3,000	\$2,800	\$2,600	-0% - RA Sales Compose ~40% of Total Ex-US Sales
% Growth		+12%	+9%	+6%	+3%	-6%	-6%	-6%	-7%	-7%	
CHS-1420 Penetration of Ex-US Humira RA Sales						4.0%	8.0%	12.0%	16.0%	20.0%	
Estimated CHS-1420 Assumed Partner Ex-US RA Sales (\$MM)						\$100.0	\$190.0	\$270.0	\$335.0	\$390.0	- Price Discount of 25% from Humira
% Growth							+90%	+42%	+24%	+16%	
Royalty Revenue to Coherus						\$20.0	\$40.0	\$55.0	\$65.0	\$80.0	+41% - Royalty Rate of 20% including COGS

Source: Cowen and Company; Company Reports

Figure 2 CHS-1420 Psoriasis Market Model

ESTIMATED U.S. PSORIASIS MARKET											
	2013	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	CAGR Comments
Total U.S. Population ('000)	332,000	335,500	338,855	342,240	345,665	349,120	352,610	356,135	359,695	363,295	
Prevalence of Psoriasis	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	
Total U.S. Patients with Psoriasis ('000)	4,980	5,033	5,083	5,134	5,185	5,237	5,289	5,342	5,395	5,449	
Prevalence of Moderate-to-Severe Psoriasis	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	
% Requiring Add-On Therapy	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	
<b>Total Psoriasis Add-On Therapy Population ('000)</b>	<b>365</b>	<b>368</b>	<b>371</b>	<b>375</b>	<b>379</b>	<b>383</b>	<b>387</b>	<b>391</b>	<b>395</b>	<b>399</b>	
% Growth		+1%	+1%	+1%	+1%	+1%	+1%	+1%	+1%	+1%	
<b>Romice Penetration of U.S. Psoriasis Add-On Market (JNJ)</b>	<b>3%</b>	<b>2%</b>	<b>2%</b>	<b>1%</b>	<b>1%</b>	<b>1%</b>	<b>1%</b>	<b>1%</b>	<b>1%</b>	<b>1%</b>	
Average Annual Patients ('000)	4.5	4.5	3.9	3.4	3.1	2.8	2.5	2.3	2.1	1.9	-9%
Annual Cost of Therapy (\$'000)	\$17.7	\$17.7	\$17.7	\$17.7	\$17.7	\$17.7	\$17.7	\$17.7	\$17.7	\$17.7	
<b>Estimated Romice U.S. Psoriasis Sales (\$MM)</b>	<b>\$80</b>	<b>\$80</b>	<b>\$70</b>	<b>\$60</b>	<b>\$55</b>	<b>\$50</b>	<b>\$45</b>	<b>\$40</b>	<b>\$35</b>	<b>\$30</b>	<b>-9%</b>
% Growth		+0%	-13%	-14%	-9%	-9%	-10%	-11%	-13%	+0%	
<b>Enbrel Penetration of U.S. Psoriasis Add-On Market (AMGN/PFE)</b>	<b>30%</b>	<b>37%</b>	<b>37%</b>	<b>30%</b>	<b>35%</b>	<b>35%</b>	<b>34%</b>	<b>34%</b>	<b>34%</b>	<b>35%</b>	
Average Annual Patients ('000)	46	49	52	54	55	56	55	55	55	55	+2%
Annual Cost of Therapy (\$'000)	\$25.9	\$26.7	\$27.5	\$28.3	\$29.2	\$30.1	\$31.0	\$31.9	\$32.8	\$33.8	
<b>Estimated Enbrel U.S. Psoriasis Sales (\$MM)</b>	<b>\$1,185</b>	<b>\$1,285</b>	<b>\$1,415</b>	<b>\$1,815</b>	<b>\$1,805</b>	<b>\$1,870</b>	<b>\$1,705</b>	<b>\$1,785</b>	<b>\$1,855</b>	<b>\$1,930</b>	<b>+8%</b>
% Growth		+8%	+9%	+2%	+0%	+4%	+2%	+3%	+3%	+3%	
<b>Humira Penetration of U.S. Psoriasis Add-On Market (ABBV)</b>	<b>34%</b>	<b>34%</b>	<b>35%</b>	<b>39%</b>	<b>39%</b>	<b>39%</b>	<b>39%</b>	<b>39%</b>	<b>39%</b>	<b>32%</b>	
Average Annual Patients ('000)	42	45	47	50	52	54	55	54	53	52	+2%
Annual Cost of Therapy (\$'000)	\$25.8	\$26.5	\$27.3	\$28.1	\$29.0	\$29.9	\$30.7	\$31.7	\$32.6	\$33.6	
<b>Estimated Humira U.S. Psoriasis Sales (\$MM)</b>	<b>\$1,080</b>	<b>\$1,180</b>	<b>\$1,285</b>	<b>\$1,385</b>	<b>\$1,505</b>	<b>\$1,610</b>	<b>\$1,675</b>	<b>\$1,710</b>	<b>\$1,730</b>	<b>\$1,745</b>	<b>+5%</b>
% Growth		+9%	+9%	+8%	+8%	+7%	+4%	+2%	+1%	+1%	
<b>Stelara Penetration of U.S. Psoriasis Add-On Market (JNJ)</b>	<b>20%</b>	<b>27%</b>	<b>28%</b>	<b>29%</b>	<b>31%</b>	<b>31%</b>	<b>32%</b>	<b>32%</b>	<b>32%</b>	<b>32%</b>	
Average Annual Patients ('000)	36	39	44	48	54	56	58	58	58	58	+5%
Annual Cost of Therapy (\$'000)	\$23	\$24	\$24	\$25	\$26	\$27	\$28	\$28	\$29	\$30	
<b>Estimated Stelara U.S. Psoriasis Sales (\$MM)</b>	<b>\$800</b>	<b>\$925</b>	<b>\$1,075</b>	<b>\$1,210</b>	<b>\$1,400</b>	<b>\$1,495</b>	<b>\$1,605</b>	<b>\$1,645</b>	<b>\$1,685</b>	<b>\$1,745</b>	<b>+9%</b>
% Growth		+11%	+16%	+13%	+16%	+7%	+7%	+3%	+3%	+3%	
<b>CHS-1420 Penetration of U.S. Psoriasis Add-On Market (Coherus)</b>					<b>0.5%</b>	<b>1.0%</b>	<b>1.5%</b>	<b>2.0%</b>	<b>2.5%</b>	<b>3.0%</b>	
<b>CHS-1420 Penetration of U.S. Humira Psoriasis Sales</b>					<b>1.5%</b>	<b>2.4%</b>	<b>3.7%</b>	<b>4.7%</b>	<b>6.0%</b>	<b>7.2%</b>	
Average Annual Patients ('000)					1	2	3	4	5		+44%
Annual Cost of Therapy (\$'000)					\$23.2	\$23.9	\$24.6	\$25.3	\$26.1	\$26.9	- Price Discount of 20% from Humira
<b>Estimated CHS-1420 U.S. Psoriasis Sales (\$MM)</b>					<b>\$20</b>	<b>\$40</b>	<b>\$85</b>	<b>\$95</b>	<b>\$110</b>	<b>\$135</b>	<b>+47%</b>
% Growth					+100%	+100%	+63%	+31%	+29%	+23%	
<b>Total U.S. Psoriasis Market Sales (\$MM)</b>	<b>\$3,185</b>	<b>\$3,480</b>	<b>\$3,845</b>	<b>\$4,180</b>	<b>\$4,685</b>	<b>\$4,825</b>	<b>\$5,020</b>	<b>\$5,100</b>	<b>\$5,265</b>	<b>\$5,385</b>	<b>+8%</b>
% Growth		+9.3%	+10.5%	+8.7%	+9.2%	+5.7%	+4.0%	+2.6%	+2.2%	+2.3%	
Total U.S. Psoriasis Patients Treated with Biologics ('000)	129	137	146	154	164	168	170	169	168	167	

ESTIMATED CHS-1420 EX-US PSORIASIS SALES											
	2013	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	CAGR Comments
Total Humira Ex-U.S. Psoriasis Market Sales (\$MM)	\$1,350	\$1,510	\$1,650	\$1,750	\$1,800	\$1,700	\$1,600	\$1,500	\$1,400	\$1,300	-0% - Psoriasis Sales Compose ~25% of Total Ex-U.S. Sales
% Growth		+12%	+9%	+6%	+3%	-6%	-6%	-6%	-7%	-7%	
CHS-1420 Penetration of Ex-U.S. Humira Psoriasis Sales						4.0%	8.0%	12.0%	16.0%	20.0%	
<b>Estimated CHS-1420 Assumed Partner Ex-U.S. Psoriasis Sales (\$MM)</b>						\$50.0	\$95.0	\$135.0	\$170.0	\$195.0	- Price Discount of 25% from Humira
% Growth							+90%	+42%	+26%	+15%	
<b>Royalty Revenue to Coherus</b>						<b>\$10.0</b>	<b>\$20.0</b>	<b>\$28.0</b>	<b>\$38.0</b>	<b>\$40.0</b>	<b>+41%</b> - Royalty Rate of 20% including COGS

Source: Cowen and Company; Company Reports



Figure 3 CHS-0214 Market Model

ESTIMATED CHS-0214 EX-US INTERNATIONAL SALES											
	2013	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	CAGR Comments
Total Enbrel Ex-U.S. RA Market Sales (\$MM)	\$1,880	\$1,950	\$2,020	\$2,090	\$2,150	\$2,190	\$2,220	\$2,250	\$2,275	\$2,300	+2% - RA Sales Compose ~40% of Total Ex-U.S. Sales
% Growth		+4%	+4%	+3%	+3%	+2%	+1%	+1%	+1%	+1%	
CHS-0214 Penetration of Ex-U.S. Enbrel RA Sales					3.5%	8.0%	12.0%	17.0%	21.0%	24.0%	
Estimated CHS-0214 Ex-U.S. RA Sales (\$MM)					\$55.0	\$130.0	\$200.0	\$285.0	\$360.0	\$415.0	- Price Discount of 25% from Enbrel
% Growth					+136%	+54%	+43%	+26%	+15%		
Royalty Revenue to Coherus					\$10.0	\$26.0	\$40.0	\$66.0	\$70.0	\$86.0	+69% - Royalty Rate of 20% including COGS
Total Enbrel Ex-U.S. Psoriasis Market Sales (\$MM)	\$940	\$975	\$1,010	\$1,045	\$1,075	\$1,095	\$1,110	\$1,125	\$1,140	\$1,150	+2% - Psoriasis Sales Compose ~25% of Total Ex-U.S. Sales
% Growth		+4%	+4%	+3%	+3%	+2%	+1%	+1%	+1%	+1%	
CHS-0214 Penetration of Ex-U.S. Enbrel Psoriasis Sales					3.5%	8.0%	12.0%	17.0%	21.0%	24.0%	
Estimated CHS-0214 Ex-U.S. Psoriasis Sales (\$MM)					\$30.0	\$65.0	\$100.0	\$145.0	\$180.0	\$205.0	- Price Discount of 25% from Enbrel
% Growth					+117%	+54%	+45%	+24%	+14%		
Royalty Revenue to Coherus					\$6.0	\$16.0	\$20.0	\$30.0	\$36.0	\$40.0	+62% - Royalty Rate of 20% including COGS
Total CHS-0214 Ex-U.S. Coherus Royalties (\$MM)					\$16	\$40	\$60	\$86	\$106	\$126	+69%
% Growth						+167%	+50%	+42%	+24%	+19%	

Source: Cowen and Company; Company Reports

Figure 4 CHS-1701 Market Model

ESTIMATED NEULASTA WW SALES											
	2013	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	CAGR Comments
Neulasta WW Sales (AMGN)											
Estimated U.S. Neulasta Sales (\$MM)	\$3,477	\$3,637	\$3,660	\$3,595	\$3,505	\$3,420	\$3,335	\$3,170	\$3,010	\$2,850	-2%
% Growth		+5%	+1%	-2%	-3%	-2%	-2%	-5%	-5%	-5%	
% of Total Neulasta Sales	79.2%	78.8%	79.1%	79.9%	79.7%	79.5%	79.4%	79.3%	79.2%	79.2%	
Estimated Ex-U.S. Neulasta Sales (\$MM)	\$915	\$980	\$965	\$905	\$895	\$880	\$865	\$830	\$790	\$750	-2%
% Growth		+7%	-2%	-6%	-1%	-2%	-2%	-4%	-5%	-5%	
% of Total Neulasta Sales	20.8%	21.2%	20.9%	20.1%	20.3%	20.5%	20.6%	20.8%	20.8%	20.8%	
Total Neulasta WW Sales (\$MM)	\$4,392	\$4,617	\$4,625	\$4,500	\$4,400	\$4,300	\$4,200	\$4,000	\$3,800	\$3,600	-2%
% Growth		+5%	+0%	-3%	-2%	-2%	-2%	-5%	-5%	-5%	
ESTIMATED CHS-1701 WW SALES											
	2013	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	CAGR Comments
CHS-1701 Penetration of U.S. Neulasta Sales					1.0%	2.0%	3.0%	4.0%	5.0%	6.0%	
Estimated CHS-1701 U.S. Market Sales (\$MM)					\$80.0	\$60.0	\$85.0	\$110.0	\$180.0	\$146.0	+87% - Price Discount of 15% from Neulasta
% Growth						+100%	+42%	+23%	+18%	+12%	
CHS-1701 Penetration of Ex-U.S. Neulasta Sales						2.5%	4.0%	6.0%	8.0%	10.0%	
Estimated CHS-1701 Assumed Partner Ex-U.S. Market Sales (\$MM)						\$20.0	\$30.0	\$40.0	\$65.0	\$65.0	+84% - Price Discount of 15% from Neulasta
% Growth							+50%	+33%	+38%	+18%	
Royalty Revenue to Coherus						\$5.0	\$5.0	\$10.0	\$10.0	\$15.0	+82% - Royalty Rate of 20% including COGS
Total CHS-1701 Market Sales (\$MM)					\$80.0	\$65.0	\$90.0	\$120.0	\$140.0	\$160.0	+40%
% Growth						+117%	+38%	+33%	+17%	+14%	

Source: Cowen and Company; Company Reports

Figure 5 Coherus Annual P&L

COHERUS - 2014-2023 ESTIMATED ANNUAL EPS BUILDUP (\$MM)													
2013	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	CGR	Comments	
CHS-1420 (Humira) U.S. Direct Revenue				\$65.0	\$140.0	\$220.0	\$295.0	\$385.0	\$470.0	\$575.0	+16%	- CHS-1420 completed Phase I studies; U.S. launch in mid-2017	
Growth Rate					+115%	+57%	+34%	+31%	+22%	+22%			
CHS-1420 (Humira) Ex-U.S. Royalty Revenue					\$30.0	\$60.0	\$80.0	\$100.0	\$120.0	\$145.0	+9%	- Ex-U.S. launch in mid-2018	
Growth Rate						+100%	+33%	+25%	+20%	+20%			
CHS-0214 (Enbrel) Ex-U.S. Royalty Revenue				\$15.0	\$40.0	\$60.0	\$85.0	\$105.0	\$125.0	\$150.0	+14%	- CHS-0214 conducting Phase III studies; Ex-U.S. launch in early 2017	
Growth Rate					+167%	+50%	+42%	+24%	+19%	+20%			
CHS-1701 (Neulasta) U.S. Direct Revenue				\$30.0	\$60.0	\$85.0	\$110.0	\$130.0	\$145.0	\$175.0	+11%	- CHS-1420 completed Phase I studies; U.S. launch in mid-2017	
Growth Rate					+100%	+42%	+29%	+18%	+12%	+20%			
CHS-1701 (Neulasta) Ex-U.S. Royalty Revenue					\$5.0	\$5.0	\$10.0	\$10.0	\$15.0	\$20.0	+11%	- Ex-U.S. launch in mid-2018	
Growth Rate						+0%	+100%	+0%	+50%	+20%			
Licensing Revenues	\$2.8	\$10.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0		- Daiichi Sankyo, Baxter	
Growth Rate													
Total Coherus Revenues	\$2.8	\$10.0	\$0.0	\$0.0	\$110.0	\$275.0	\$430.0	\$580.0	\$730.0	\$875.0	\$1,065.0	+16%	
% Change					+150%	+56%	+35%	+26%	+20%	+22%			
Cost of Goods	\$0.0	\$0.0	\$0.0	\$0.0	\$15.0	\$40.0	\$65.0	\$85.0	\$110.0	\$130.0	\$160.0		
Gross Profit	\$2.8	\$10.0	\$0.0	\$0.0	\$95.0	\$235.0	\$365.0	\$495.0	\$620.0	\$745.0	\$905.0		
Gross Margin	100.0%	100.0%			85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	- Solid margins; factors in royalty licensing/partnering revenues	
SG&A	\$7.5	\$15.0	\$30.0	\$45.0	\$75.0	\$90.0	\$105.0	\$120.0	\$135.0	\$150.0	\$165.0	+10%	- Salesforce expansion beginning in 2017, in preparation for CHS-1420
% of Revs	NM	NM	NM	NM	68%	33%	24%	21%	18%	17%	15%	- Approximately 50 sales reps, 5 NAMs	
R&D	\$31.3	\$65.0	\$80.0	\$100.0	\$110.0	\$120.0	\$130.0	\$120.0	\$110.0	\$100.0	\$90.0	-9%	- Substantial clinical trial and regulatory costs
% of Revs	NM	NM	NM	NM	100.0%	43.6%	30.2%	20.7%	15.1%	11.4%	8.5%	- CHS-0214, CHS-1420, CHS-1701	
Operating Expenses	\$38.7	\$80.0	\$110.0	\$145.0	\$185.0	\$210.0	\$235.0	\$240.0	\$245.0	\$250.0	\$255.0	+2%	
% of Revenues	NM	NM	NM	NM	76.4%	54.7%	41.4%	33.6%	28.6%	23.9%			
Operating Income	(\$36.0)	(\$70.0)	(\$110.0)	(\$145.0)	(\$90.0)	\$25.0	\$130.0	\$255.0	\$375.0	\$495.0	\$650.0	- Operating profit expected in 2018	
% Operating Margin	NM	NM	NM	NM	NM	30.2%	44.0%	51.4%	56.6%	61.0%			
Non-Operating Income													
Interest Income	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0		
Interest Expense	(5.3)	(7.8)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
Other Income	(12.3)	(14.6)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
Non-Operating Income	(\$17.6)	(\$22.4)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0		
Pretax Income	(\$53.6)	(\$92.4)	(\$110.0)	(\$145.0)	(\$90.0)	\$25.0	\$130.0	\$255.0	\$375.0	\$495.0	\$650.0	NM	
% of Revs	NM	NM	NM	NM	NM	30.2%	44.0%	51.4%	56.6%	61.0%			
Income Taxes						\$45.5	\$89.3	\$131.3	\$173.3	\$227.5		NM	
Income Tax Rate						35.0%	35.0%	35.0%	35.0%	35.0%			
Net Income - Operations	(\$53.6)	(\$92.4)	(\$110.0)	(\$145.0)	(\$90.0)	\$25.0	\$84.5	\$165.8	\$243.8	\$321.8	\$422.5	NM	
% Net Margin	NM	NM	NM	NM	NM	19.7%	28.6%	33.4%	36.8%	39.7%			
Extraordinary Items	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0		
Reported Net Income	(\$53.6)	(\$92.4)	(\$110.0)	(\$145.0)	(\$90.0)	\$25.0	\$84.5	\$165.8	\$243.8	\$321.8	\$422.5	NM	
Interest Add-Back	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0		
EPS (Non-GAAP) - Before Ex. Item:	(\$2.19)	(\$2.50)	(\$2.90)	(\$3.65)	(\$2.15)	\$0.55	\$1.85	\$3.45	\$4.90	\$6.20	\$7.80	NM	- Profitable in 2018 following Ex-US launches of CHS-1420/1710
Growth	NM	NM	NM	NM	NM	NM	NM	+42%	+27%	+26%			
EPS - Extraordinary Items	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00		
EPS - Reported	(\$2.19)	(\$2.50)	(\$2.90)	(\$3.65)	(\$2.15)	\$0.55	\$1.85	\$3.45	\$4.90	\$6.20	\$7.80	NM	
Shares - Fully Diluted (MM)	24.5	37.3	38.0	40.0	42.0	44.0	46.0	48.0	50.0	52.0	54.0	- Diluted shares; assuming some onward dilution from options	

Source: Company Reports; Cowen and Company

Source: Company Reports; Cowen and Company

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## Coherus Has An Impressive Biosimilar Development Platform

Coherus BioSciences is a leading biosimilars company 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.

While larger biosimilar players have greater resources to work with, Coherus has a level of experience that provides differentiation and cannot be easily replicated. This has been validated through large pharma partnerships (Daiichi Sankyo, Baxter, etc).

The range of acceptability for pharmacokinetic equivalence is 80% to 125% with the target at 100%, and in the Phase 1 study for CHS-0214, Coherus achieved a geometric ratio of 98% indicating pharmacokinetic equivalence. Thus, rapid development did not impact the quality of the product produced.

Based out of Redwood City, California, Coherus BioSciences is a leading biosimilars company 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. By 2017, we estimate the WW sales of Humira for just the rheumatoid arthritis (RA) and psoriasis indications will be approximately \$10.0B. For Enbrel, Amgen has U.S. patent protection until 2029, so biosimilar penetration will only be made ex-U.S., but still, we estimate the 2017 ex-U.S. sales will still be \$3.2B for just the RA and psoriasis indications. Finally, we estimate Neulasta WW sales will be roughly \$4.4B by 2017. This results in an estimated combined addressable market size of \$18B in 2017 for Coherus' three lead programs. While the massive opportunity in the biosimilars market is obvious, the hurdles for entry are also significant. To increase the likelihood of success, Coherus has established a clear biosimilar development strategy, which pairs a seasoned management team, with decades of experience at the leading biologics companies (Amgen, Genentech, Immunex, etc.), with differentiated technical expertise consisting of the following elements:

**Advanced Proprietary Analytics:** In order to get regulatory approval, a biosimilar must demonstrate robust comparability to the originator molecule. This requires sophisticated analytical techniques and substantial capital investment (e.g., mass spectrometry, which measures the structure and composition of individual molecules). The people at Coherus have extensive technical expertise based on years of experience and the Company has made the necessary capital investment to be competitive in the biosimilars space. While larger biosimilar players have greater resources to work with, Coherus has a level of experience that provides differentiation and cannot be easily replicated. This has been validated through large pharma partnerships (Daiichi Sankyo, Baxter, etc.).

**Molecular Refinement:** Protein modifications can vary significantly. For example, glycosylation occurs when sugar molecules are added to the backbone of a protein. For a highly glycosylated molecule such as Enbrel (etanercept), accurately reproducing the glycosylation pattern of the originator protein is critical as this can substantially impact pharmacokinetics, pharmacodynamics and biologic activity. With CHS-0214 (biosimilar Enbrel), Coherus was able to complete the molecular tuning in an extremely short period of time by conducting a number of steps in parallel, which include making adjustments to cell growth conditions and process conditions while conducting *in vivo* and *in vitro* testing simultaneously. The same parallel process is being utilized for the Company's other biosimilar product candidates to facilitate timely development. Moreover, the range of acceptability for pharmacokinetic equivalence is 80% to 125% with the target at 100%, and in the Phase 1 study for CHS-0214, Coherus achieved a geometric ratio of 98% indicating pharmacokinetic equivalence. Thus, rapid development did not impact the quality of the product produced.

**Process Science:** Biologic originators are required by regulators to manufacture a product consistent with the one that was originally approved. Often times this means using the same decade-old protocols even though numerous technological advancements have been made since. Coherus is not limited to the same restrictions and has put in place state-of-the-art growth media, chromatography resins, filters and other techniques for protein production. These processes are highly scalable and easily automated, resulting in consistent product quality, and robust yield. Additionally, the efficiency of these modern processes allows for production at a much lower cost than previous generations.

The originator formulations for Humira and Enbrel have patents that specify use of various formulation ingredients for stabilizing the protein. Coherus has developed proprietary formulations for both their Enbrel and Humira biosimilar products which do not require these ingredients.


**Formulation Technologies:** Originator companies have pursued a strategy of establishing intellectual property around specific formulations for their biologic products. Coherus has made considerable investments in proprietary formulation technology that will potentially allow the Company to innovate around certain patent protected formulations. For example, the originator formulations for Humira and Enbrel have patents that specify use of various formulation ingredients for stabilizing the protein. Coherus has developed proprietary formulations for both their Enbrel and Humira biosimilar products which do not require these ingredients.

**Global Regulatory And Clinical Development:** Coherus' clinical/regulatory teams have extensive experience with product development and approvals. The global biosimilar regulatory environment is rapidly evolving and Coherus has made extensive efforts to meet with key regulatory authorities in the U.S., E.U. and Japan to gain insight into regulatory rationale and specific feedback on the Company's development plans for each of its biosimilar candidates.

#### A Seasoned Management Team And Solid Foundation Of Investors

Coherus has a seasoned management team with significant experience from the leading biologics companies. Denny Lanfear (Chief Executive Officer), Dr. Alan Herman (Chief Scientific Officer) and Dr. Peter Watler (Chief Technical Officer) all previously worked at Amgen. Dr. Barbara Finck, led the global development of Enbrel during her time at Immunex. We believe this management team should be well-equipped to deal with the complex challenges associated with biosimilar development.

Figure 8 Coherus Management Team

Name	Prior Experience
<b>Denny Lanfear</b> President and CEO	 
<b>Jean Viret Ph.D.</b> Chief Financial Officer	  
<b>Alan Herman, Ph.D.</b> Chief Scientific Officer	  
<b>Barbara Finck, M.D.</b> Chief Medical Officer	 
<b>Peter Watler, Ph.D.</b> Chief Technical Officer	  
<b>Michael Fleming</b> SVP, Commercial Strategy	  

Source: Company Reports; Cowen and Company

## The Biosimilar Market Opportunity And Strategy

By 2020, at least 24 blockbuster drugs that are currently generating more than \$100B in sales are expected to lose patent exclusivity in at least one major market. As increasing healthcare costs continue to amass, governments and payors are aggressively looking for avenues to help reduce spend without sacrificing quality of care.

By 2020, at least 24 blockbuster drugs that are currently generating more than \$100B in sales are expected to lose patent exclusivity in at least one major market. As increasing healthcare costs continue to amass, governments and payors are aggressively looking for avenues to help reduce spend without sacrificing quality of care. Hence there is considerable interest from numerous stakeholders to bring high-quality, lower-cost biologic products to market.

Figure 9 Blockbuster Drugs Coming Off Patent By 2020

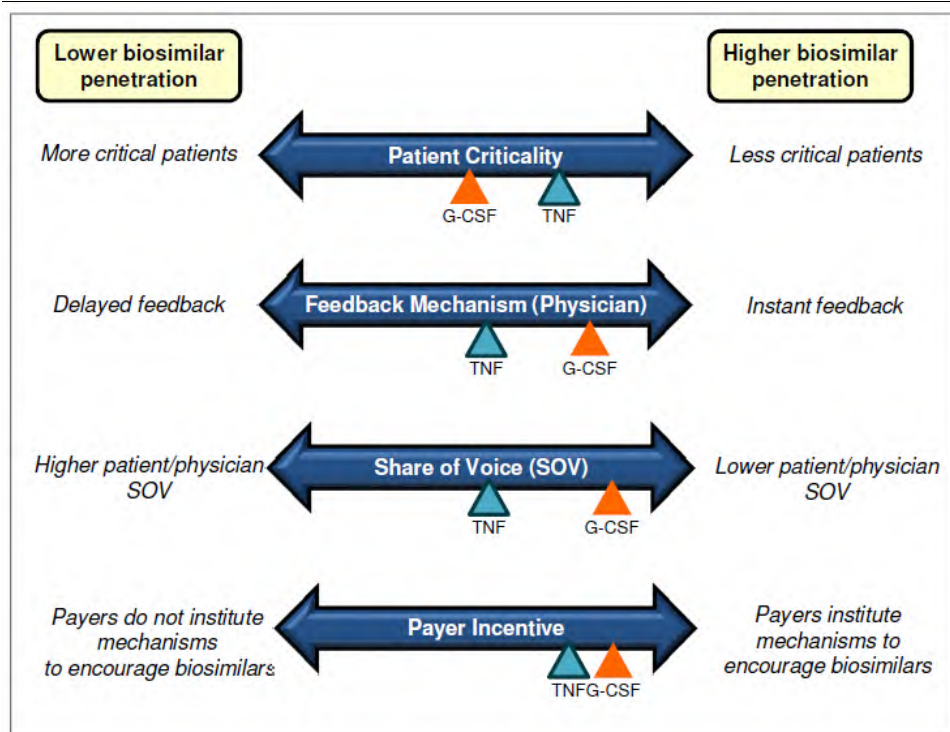
Brand	Generic	Company	2013 Sales (\$M)
Humira	adalimumab	AbbVie	\$ 11,014
Enbrel	etanercept	Amgen	\$ 8,778
Remicade	infliximab	Johnson & Johnson	\$ 8,367
Lantus	insulin glargine recombinant	Sanofi	\$ 7,592
Rituxan	rituximab	Roche	\$ 7,503
Avastin	bevacizumab	Roche	\$ 6,751
Herceptin	trastuzumab	Roche	\$ 6,562
Neulasta	pegfilgrastim	Amgen	\$ 4,392
Lucentis	ranibizumab	Roche / Novartis	\$ 4,206
Avonex	interferon beta-1a	Biogen Idec	\$ 3,005
NovoRapid	insulin aspart	Novo Nordisk	\$ 3,001
Humalog	insulin lispro recombinant	Eli Lilly	\$ 2,611
Rebif	interferon beta-1a	Merck KGaA	\$ 2,513
Botox	onabotulinumtoxinA	Allergan	\$ 2,201
Levemir	insulin detemir	Novo Nordisk	\$ 2,057
Advate	factor VIII (procoagulant)	Baxter International	\$ 1,967
Epogen	epoetin alfa	Amgen	\$ 1,953
Erbix	cetuximab	Bristol-Myers Squibb / Merck KGaA	\$ 1,868
NovoMix 30	insulin; insulin aspart	Novo Nordisk	\$ 1,738
Kogenate	octocog alfa	Bayer	\$ 1,597
Xolair	omalizumab	Roche / Novartis	\$ 1,466
Synagis	palivizumab	AstraZeneca / AbbVie	\$ 1,444
Pegasys	peginterferon alfa-2a	Roche / Chugai	\$ 1,416
Tysabri	natalizumab	Biogen Idec	\$ 1,413
Neupogen	filgrastim	Amgen	\$ 1,398
Pediarix	DTP, hepatitis B & polio vaccine	GlaxoSmithKline	\$ 1,349
Procrit	epoetin alfa	Johnson & Johnson	\$ 1,349
Forteo	teriparatide recombinant human	Eli Lilly	\$ 1,245
Actemra	tocilizumab	Roche / Chugai	\$ 1,116
Norditropin Simplexx	somatropin recombinant	Novo Nordisk	\$ 1,089
Orencia	abatacept	Bristol-Myers Squibb	\$ 1,003

Source: Company Reports; Cowen and Company

To maximize the commercial opportunity, Coherus has put in place strict criteria for product selection. Coherus believes that biosimilar adoption and penetration rates in each market will be determined by four key factors: (1) severity of the patient's condition; (2) rapidity of feedback on the safety and efficacy of the drug; (3) physician and patient influence on the prescribing decision; and (4) managed care's ability to drive substitution. As highlighted in the figure below, Coherus believes there will be strong uptake of biosimilar anti-TNFs and G-CSFs due to the relative lack of disease severity and payor incentives. These expectations were further corroborated by our physician consultants. They even noted that for anti-TNFs, the treatment of psoriasis would likely have more rapid uptake as it aligns with these factors a bit more closely than RA.



Figure 10 Key Market Factors For Biosimilar Adoption



Source: Company Reports; Cowen and Company

### Biosimilars Could Soon Be A Threat For TNF Inhibitors

Half of our physician consultants believe that the first biosimilar TNF inhibitor will receive FDA approval as early as 2016. At least two companies are in Phase III with a biosimilar of Humira (Novartis/Sandoz for psoriasis and Amgen/Actavis for psoriasis and RA; Coherus will be initiating a Phase III trial in 2015), which represents a significant risk to AbbVie.

38% of the surveyed specialists from our October 2014 Therapeutics Conference would be ready to prescribe a biosimilar in the U.S. market for any indication, were it approved on a similar clinical package.

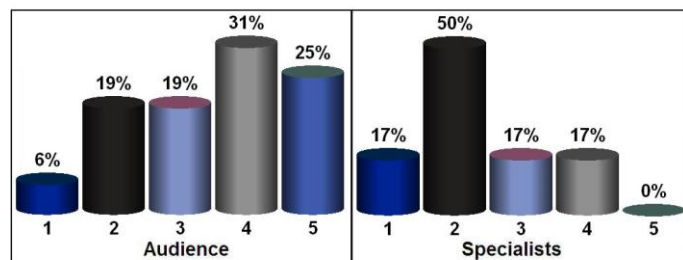
Our consultants indicate that the possibility of biosimilar anti-TNFs entering the market is a matter of increasing discussion among rheumatologists, particularly given the availability of biosimilar Enbrel and Remicade in China, India, and South America. They expect that price and perceived quality will be the major determinants of uptake. Half of our physician consultants believe that the first biosimilar TNF inhibitor will receive FDA approval as early as 2016. At least two companies are in Phase III with a biosimilar of Humira (Novartis/Sandoz for psoriasis and Amgen/Actavis for psoriasis and RA; Coherus will be initiating a Phase III trial in 2015), which represents a significant risk to AbbVie.

Interestingly, 38% of the surveyed specialists from our October 2014 Therapeutics Conference would be ready to prescribe a biosimilar in the U.S. market for any indication, were it approved on a similar clinical package, with another 15% of surveyed doctors satisfied with the efficacy data, but wanting to see more safety data.

## Physicians More Optimistic About Biosimilar TNF Inhibitors

4) The FDA is likely to approve the first biosimilar TNF inhibitors in:

1. 2015
2. 2016
3. 2017
4. 2018
5. 2019 or beyond

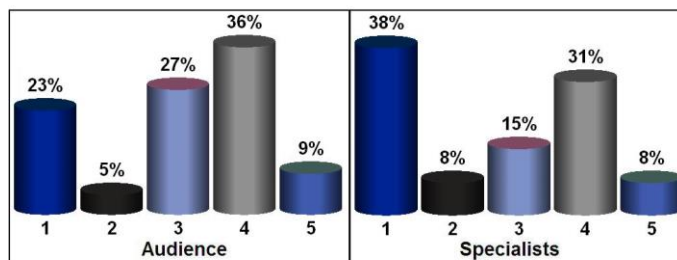


Source: Cowen and Company March 2014 Health Care Conference

## Opinions Are Divided On Biosimilar TNF Inhibitors

5) Celltrion's Inflectra, a biosimilar infliximab, was approved by the EMA following demonstration of non-inferiority to Remicade, with comparable safety and tolerability, in a 580-patient Phase III trial for RA and a 230-patient Phase I trial for ankylosing spondylitis. If biosimilars eventually become available in the U.S., what would you want to see to feel comfortable prescribing the biosimilars?

1. A clinical efficacy and safety data package similar to Inflectra's would suffice to prescribe the biosimilar in all labeled indications
2. Safety is adequate, but I would want efficacy trials for each specific indication in question before prescribing
3. Efficacy is adequate to prescribe for all indications, but I would want more safety data
4. Both more efficacy data and more safety data would be needed for me to feel comfortable
5. Price is the most important factor



## Product Targeting Strategy

Along with these key factors, Coherus is also focusing its efforts on therapeutic categories with high levels of current promotional spend and anticipated growth. As noted in the figure below, inflammation and oncology are two categories that place a significant burden on payors for cost management. Moreover, with the aging U.S. population, these categories are expected to continue to grow and make up an even larger portion of future drug spend. We believe Coherus' thoughtful product selection will help further increase the likelihood of success.

Figure 11 Managed Care Drug Spend By Therapeutic Category

Class	PMPY Spend	2013 Trend			Projected Trend		
		Utilization	Unit Cost	Total	2014	2015	2016
Diabetes	\$84	2.4%	11.6%	14.0%	11%	12%	11%
<b>Inflammatory</b>	<b>\$63</b>	<b>6.8%</b>	<b>15.0%</b>	<b>21.8%</b>	<b>23%</b>	<b>22%</b>	<b>21%</b>
High Cholesterol	\$52	-2.1%	-12.3%	-14.4%	-12%	-12%	-14%
Multiple Sclerosis	\$46	1.0%	14.7%	15.7%	13%	12%	12%
High BP / Heart Disease	\$40	0.4%	-9.1%	-8.7%	-12%	-11%	-11%
<b>Cancer</b>	<b>\$36</b>	<b>10.5%</b>	<b>13.6%</b>	<b>24.1%</b>	<b>24%</b>	<b>25%</b>	<b>24%</b>
Ulcers	\$36	0.9%	-4.1%	-3.2%	-15%	-7%	-6%
Asthma	\$35	1.0%	-15.1%	-14.1%	-5%	-0%	1%
Attention Disorders	\$33	5.3%	-1.3%	4.0%	7%	5%	5%
Depression	\$32	1.5%	-10.5%	-9.1%	-15%	-12%	-12%

Source: Company Reports; Cowen and Company

Most protein-based therapeutic agents, including all monoclonal antibodies, are glycosylated to some degree. This glycosylation can be critical to the half-life, safety and efficacy of the product and is therefore a key consideration for biosimilarity. Analyzing and replicating the variability in an originator molecule requires significant skill in cell biology, protein purification and analytical protein chemistry.

## The Biosimilar Development Process

While the potential market opportunity is significant, biosimilar development is also complex and poses a number of challenges that distinguishes it from the development of small-molecule generics. The physicochemical complexity of biologics results in heterogeneity that requires significant technical and scientific expertise to replicate a product. As previously discussed, one example of this variability is glycosylation, or the attachment of sugar molecule to certain amino acids. Most protein-based therapeutic agents, including all monoclonal antibodies, are glycosylated to some degree. This glycosylation can be critical to the half-life, safety and efficacy of the product and is therefore a key consideration for biosimilarity. Analyzing and replicating the variability in an originator molecule requires significant skill in cell biology, protein purification and analytical protein chemistry.

Furthermore, biologic products manufactured in one production facility can differ from those produced in another facility. In fact, considerable variability can also exist among different lots of the same product within a single facility. Hence, inherent variation is a key consideration for establishing biosimilarity and regulatory agencies have issued guidelines that require demonstration of biological similarity and functional equivalence. This is in contrast to small molecules, which are relatively homogeneous and therefore easier to replicate. This simplicity often allows multiple market entrants and ultimately, rapid price erosion upon loss of exclusivity. We believe the challenges of biosimilar development will limit the number of entrants and should help maintain stable pricing in these markets.

The specific steps for developing a biosimilar product include the following:

- 1. Cell Line Development And Manufacturing:** The amino acid sequence of the biosimilar and originator molecules must precisely match. Publicly available data on originator molecules can be unreliable; therefore, Coherus individually validates all potential biosimilars prior to developing clones. While all clones will produce proteins with the same primary sequence, the challenge is in selecting the clone that most closely matches the glycosylation profile of the originator. As noted above, the glycosylation profile has a significant impact on the pharmacokinetics and

pharmacodynamics, as well as the safety and efficacy of the molecule. Coherus is using its technical expertise and working with several experienced contract manufacturing organizations (CMOs) to produce the necessary product at scale. Specifically, Coherus is working with Cook Pharmica, Rentschler Biotechnologie GmbH, and Cytovance Biologics to manufacture its lead products candidates.

2. **Analytical Characterization And *In Vitro* Comparability:** Once the biosimilar product has been manufactured, Coherus' analysts use sophisticated analytical methods and equipment to detect, analyze and interpret the chemical and structural similarity between the biosimilar and the originator. To test for comparability of biologic activity, the Company uses a battery of sensitive *in vitro* pharmacology assays that demonstrate binding characteristics, functionality and mechanism of action. These measures may be predictive of clinically relevant differences in PK, PD, efficacy, safety and immunogenicity between the two products.
3. ***In Vivo* Animal Comparability:** Once *in vitro* biosimilarity has been demonstrated, Coherus then compares the biosimilar to the originator in relevant animal models. PK/PD and safety observations from these studies may be predictive of the human clinical trial experience and provide rationale to advance to a pivotal Phase 1 clinical study.
4. **Phase I PK/PD Study:** Once preclinical animal studies are complete, human studies are necessary to directly evaluate the PK/PD similarity between the biosimilar and the originator. Based on requirements from the U.S. and E.U. regulatory agencies, the biosimilar must demonstrate bioequivalence based on: (1) the maximum measured serum concentration ( $C_{max}$ ); (2) how much of the drug is in a patient's system over a given time period (Area under the curve, AUC). For AUC, the specific measurements are  $AUC_{0 \rightarrow t}$ , which ranges from the first time point measured (0) to the last time point measured (t); (3) and  $AUC_{0 \rightarrow \infty}$ , which ranges from the first time point measured (0) and then extrapolated to infinity to determine when the concentration would be below the level of detection or zero. In order to be deemed bioequivalent, for all three parameters individually, the ratio of the originator product and the biosimilar must fall within 80% to 125%, with the identical match being 100%.
5. **Phase III Confirmatory Safety And Efficacy Clinical Trials:** The final step to support approval of the biosimilar is a single Phase III confirmatory safety and efficacy study in a therapeutic indication for which the originator has been approved. The design of the study, including the indication being pursued and the clinical endpoints are subject to discussion and agreement with the appropriate regulatory body.

#### Partnership Agreements Are Validating And Give Coherus Access To Larger Platforms

To maximize potential value, Coherus has retained the U.S. rights for all of its products. Coherus also plans to partner the ex-U.S. rights for its products with companies that have an established infrastructure and can provide the competitive scale required to address the global biosimilar market opportunity.

To maximize potential value, Coherus has retained the U.S. rights for all of its products. Coherus also plans to partner the ex-U.S. rights for its products with companies that have an established infrastructure and can provide the competitive scale required to address the global biosimilar market opportunity. The Company already has several partnership agreements in place for CHS-0214 (Enbrel), including Baxter in Europe and Brazil, and Daiichi Sankyo in Japan. Coherus has also partnered all three of its products (CHS-0214, CHS-1420 and CHS-1710) to Orox Pharmaceuticals for certain Caribbean and Latin American countries.

Coherus' partnership with Baxter included an upfront cash payment of \$30MM and entitles Coherus to tiered royalties based on the manufacturing cost as a percentage

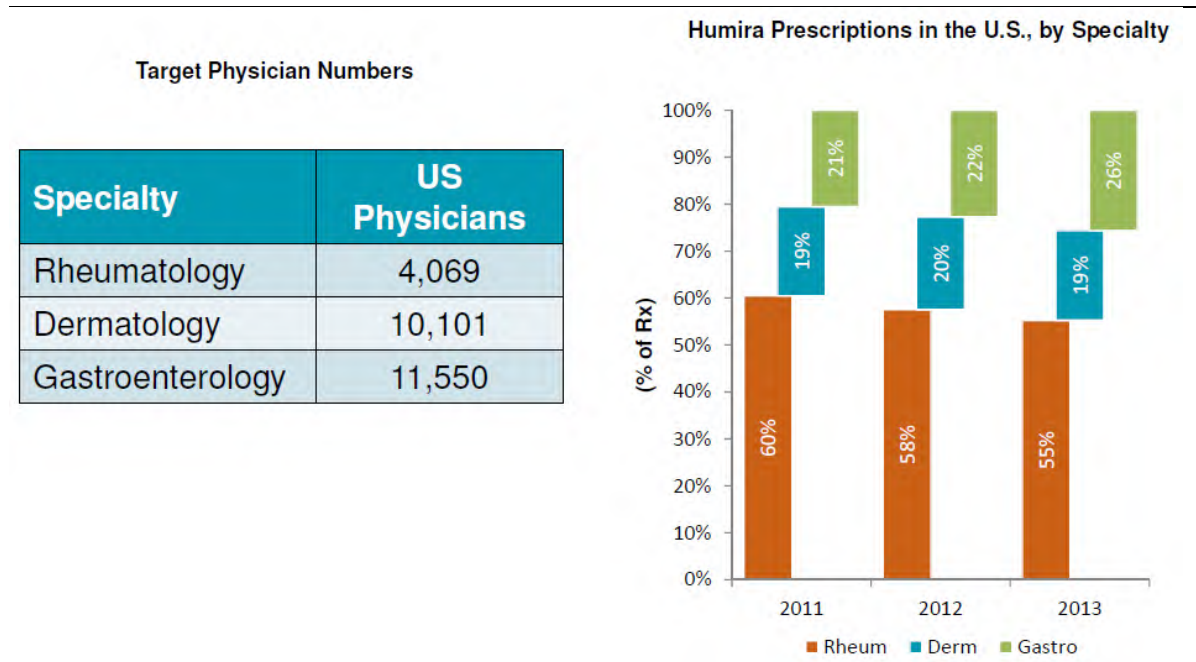
of net sales ranging from the mid-single digits to high teens. Importantly, Coherus is also entitled to milestone payments up to \$221MM. The agreement with Baxter is valid for 10 years from August 2013.

The partnership agreement with Daiichi Sankyo included an upfront cash payment of \$10MM and an equity investment of \$20MM and entitles Coherus to tiered royalties based on a percentage of net sales ranging from the low double digits to high teens. If Coherus manufactures the product, they are then eligible to receive an incremental royalty which, when combined with the base royalty, will result in a total royalty rate ranging from the low- to high-twenties. The agreement with Daiichi Sankyo is on a product-by-product and country-by-country basis for 10 years after regulatory approval for each product in each country.

Finally, the Company's agreement with Orox Pharmaceuticals entitles Coherus to a share of gross profits in the low 20% range. The agreement with Orox is also on a product-by-product and country-by-country basis for 10 years after regulatory approval for each product in each country.

For U.S. commercialization, the sales call points for Coherus' development products are highly concentrated and addressable by a relatively small commercial organization. This should allow the Company to build out a commercial infrastructure in a cost-effective manner. As an example, the majority of Humira prescriptions flow through rheumatology physicians, which are the smallest subset of prescribing physicians (see figure below).

Figure 12 Distribution Of Humira Prescribers By Specialty



Source: Company Reports; Cowen and Company



## Intellectual Property

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One of the key benefits of generic and biosimilar products are the limited dependency on intellectual property, including steep drop-offs in revenue resulting from product patent cliffs. In theory, once approved, Coherus could have indefinite duration on its biosimilar assets.

One of the key benefits of generic and biosimilar products are the limited dependency on intellectual property, including steep drop-offs in revenue resulting from product patent cliffs. In theory, once approved, Coherus could have indefinite duration on its biosimilar assets. That being said, Coherus is still developing extensive patent protection for its products to further increase the barriers for entry for its competitors. Specifically, Coherus has 104 pending patent applications in the U.S. and other countries for CHS-0214 regarding various formulations and manufacturing processes. If granted, these patents are expected to expire in 2032 and 2033. The Company also has eight pending patent applications (U.S. and international) for CHS-1420, which if granted, will expire in 2033.

## Coherus' Humira Biosimilar Program CHS-1420: A Major Opportunity

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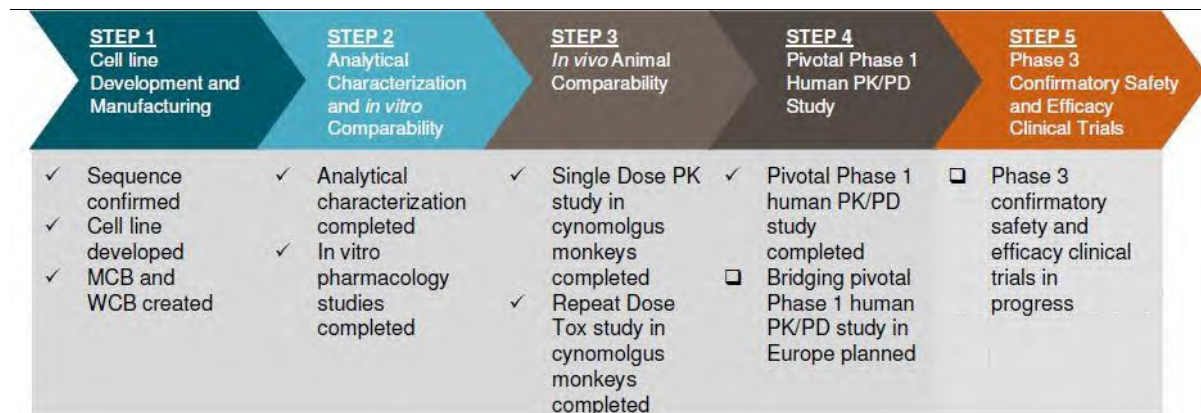
CHS-1420, a biosimilar version of Humira will be the key product for Coherus. Humira is the largest product in the world by sales, and therefore provides Coherus with a significant commercial opportunity. Moreover, the Company owns the worldwide rights to CHS-1420 and will commercialize it in the U.S. retaining full economics and likely partner the ex-U.S. rights.

CHS-1420, a biosimilar version of Humira will be the key product for Coherus. Humira is the largest product in the world by sales, and therefore provides Coherus with a significant commercial opportunity. Moreover, the Company owns the worldwide rights to CHS-1420 and will commercialize it in the U.S. retaining full economics and likely partner the ex-U.S. rights. Our physician consultants continue to note that while the inflammatory conditions treated with anti-TNFs are certainly debilitating, they are not life-threatening and physicians would be willing to use a biosimilar if validated and approved by the FDA.

Coherus continues to make steady progress with CHS-1420 including the completion of 4 of the 5 key steps for biosimilar development as highlighted below. Importantly, the Phase I PK/PD clinical study, which was conducted under a U.S. IND application in healthy volunteers, met the primary endpoint and demonstrated bioequivalence for all prospectively defined endpoints. This study outcome will allow Coherus to pursue a 351(k) application for CHS-1420, which requires only an additional Phase III confirmatory study along with the positive Phase I findings. The Company plans to initiate a Phase III study in psoriasis and/or rheumatoid arthritis in H1:15 with a potential U.S. filing in 2016 if successful, and an anticipated launch via Coherus' own direct salesforce in 2017. A potential EU filing could occur in 2017 with a 2018 launch, likely via a commercial partner. Coherus is working with the regulatory agencies in the U.S., E.U., and Japan to develop a Phase III trial design that will allow for filing in all three territories. Similar to the strategy Novartis/Sandoz is pursuing with its Humira biosimilar (conducting a single Phase III study for psoriasis), Coherus plans to extrapolate to additional indications in the Humira label with the data it generates from its Phase III trial (psoriasis or rheumatoid arthritis), without conducting additional full-scale Phase III studies.



Figure 13 CHS-1420 (Humira) Development Progress



Source: Company Reports; Cowen and Company

Specifically, Coherus has achieved the following development milestones for CHS-1420:

- 1. Cell Line Development and Manufacturing.** Coherus successfully identified and matched the amino acid sequence of CHS-1420 to Humira and demonstrated it to be identical. The Company has also developed Master Cell Banks (MCBs) and Working Cell Banks (WCBs) and transferred the manufacturing process to a U.S. contract manufacturing organization (CMO) to produce the clinical trial supplies used for the Phase 1 study that will also be used for the Phase 3 study.
- 2. Analytical Characterization and *In Vitro* Comparability.** By utilizing multi-dimensional biochemical, biophysical and biological analyses, Coherus has demonstrated that CHS-1420 has a structure and *in vitro* activity similar to that of Humira. Specifically, CHS-1420 has similarity with respect to: (1) the primary sequence of the amino acids in the protein; (2) protein folding attributes; (3) electrical charge; and (4) glycosylation profile and potency. Furthermore, based on *in vitro* receptor binding studies, including Fc receptors, complement (C1q) and Fc-mediated functional activities, CHS-1420 has shown similar pharmacological activity to Humira. These Fc-mediated functional activities include antibody-dependent cell-mediated cytotoxicity (ADCC), and complement-dependent cytotoxicity (CDC), which are biological mechanisms that facilitate the body's ability to use its immune system to target and destroy specific cells.
- 3. *In Vivo* Animal Comparability.** By utilizing nonclinical studies in monkeys, Coherus also demonstrated a similar PK and safety profile for CHS-1402 based on repeat dosing over a month.
- 4. Pivotal Phase I Human Pharmacokinetic and Pharmacodynamic Study.** In April 2014, Coherus conducted a Phase I PK study in human subjects. Using a double-blind, single dose, parallel group study, CHS-1420 demonstrated bioequivalence to Humira based on the three prospectively defined PK endpoints mentioned earlier ( $C_{max}$ ,  $AUC_{0 \rightarrow t}$  and  $AUC_{0 \rightarrow \infty}$ ). Furthermore, CHS-1420 was well-tolerated and did not demonstrate any concerns regarding its safety profile. Based on the bioequivalent Phase I data, Coherus will pursue the 351(k) biosimilar regulatory pathway for CHS-1420, which only requires an additional confirmatory Phase III study.

Importantly, our consultants note that many physicians view Humira and Enbrel to be relatively interchangeable, which would allow CHS-1420 to potentially capture share from both products. They highlight that this trend is especially common among dermatologists for the treatment of psoriasis.

Sales of \$10.6B in 2013 make Humira the largest-selling therapeutic on the market today. Globally about 35-40% of sales are in rheumatoid arthritis and 20-22% in Crohn's. Psoriasis ranks third in the U.S., contributing about 15% of sales, and a similar percentage OUS.

**5. Phase III Confirmatory Safety and Efficacy Clinical Trials.** Coherus plans to initiate a Phase III pivotal trial in either psoriasis or rheumatoid arthritis in H1:15. The randomized, double-blind, active-controlled study will be conducted across multiple global sites and is expected to support all global regulatory filings.

Importantly, our consultants note that many physicians view Humira and Enbrel to be relatively interchangeable, which would allow CHS-1420 to potentially capture share from both products. They highlight that this trend is especially common among dermatologists for the treatment of psoriasis. Furthermore, our consultants provided feedback that for most physicians, if they were forced by managed care to treat a patient with a biosimilar anti-TNF before using a branded version, they would likely provide little pushback.

## Humira Is The Top Selling Drug In The World

Humira (adalimumab) is a fully human monoclonal TNF antibody that has FDA approval for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, Crohn's disease, ulcerative colitis, moderate to severe plaque psoriasis and axial spondyloarthritis (SpA; E.U. only). Sales of \$10.6B in 2013 make Humira the largest-selling therapeutic on the market today. Globally about 35-40% of sales are in rheumatoid arthritis and 20-22% in Crohn's. Psoriasis ranks third in the U.S., contributing about 15% of sales, and a similar percentage OUS. Ulcerative colitis is a very small contributor of Humira sales globally.

Figure 14 Humira Sales By Indication And Geography

	U.S.	Foreign
Rheumatoid Arthritis	40%	35%
Crohn's	22%	20%
Psoriasis	15%	15%
AS/PsA*	20%	25%
Ulcerative Colitis	5%	1%

\*Includes Axial SpA in foreign markets.

Source: Cowen and Company

Our physician consultants consider Humira to be as safe and effective as Enbrel in RA and modestly more efficacious than Enbrel in psoriasis. Humira's main differentiating features are less frequent injectable dosing (40mg subcutaneously every other week vs. once weekly 50mg injection with Enbrel). Humira can also be dose-escalated to 40mg weekly (another benefit over Enbrel). In Crohn's disease, Humira is viewed as having more modest efficacy than Remicade but with a better safety profile and more convenient administration.

AbbVie has conducted a number of trials to broaden Humira's label in Spondyloarthritis (SpA) beyond the AS indication enjoyed by other anti-TNFs. In July 2012, the EMA approved Humira for severe axial spondyloarthritis (axSpA), a condition that includes both AS and also non-radiographic axial spondylitis (nr-axSpA; a disease state similar to AS, but with no radiographic evidence of structural damage). Humira thus became the first anti-TNF approved for nr-axSp. Spondyloarthritis refers to a collection of related disorders with common clinical features including ankylosing spondylitis, psoriatic arthritis, undifferentiated spondyloarthritis, reactive arthritis, and arthritis associated with IBD. The disease can be further classified as axial or

peripheral, depending on region of involvement. SpA is distinct from other forms of arthritis by its involvement of the entheses (attachments of ligaments and tendons to bones). Expanding Humira further, at EULAR 2012, Abbott reported Phase III success for Humira in active peripheral spondylitis patients who have not been diagnosed with PsA or AS. In addition, in September 2014, AbbVie announced positive pivotal data for Humira in hidradenitis suppurativa, a chronic inflammatory skin disease characterized by persistent abscesses and sores, most commonly affecting areas with apocrine sweat glands, with no FDA-approved treatments. Over the next few years, we expect Humira to continue its growth in RA, IBD, and psoriasis, as well as the smaller indications. AbbVie is also developing Humira in five additional indications, which include: pediatric Crohn's disease (approved in E.U.; Phase III in U.S.), uveitis, peripheral and axial spondyloarthropathies (axial approved in E.U.), and hidradenitis suppurativa. Management estimates the WW incremental sales opportunity of these new indications at \$1B+ by 2016.

Figure 15 Humira Indications Summary And Market Projections

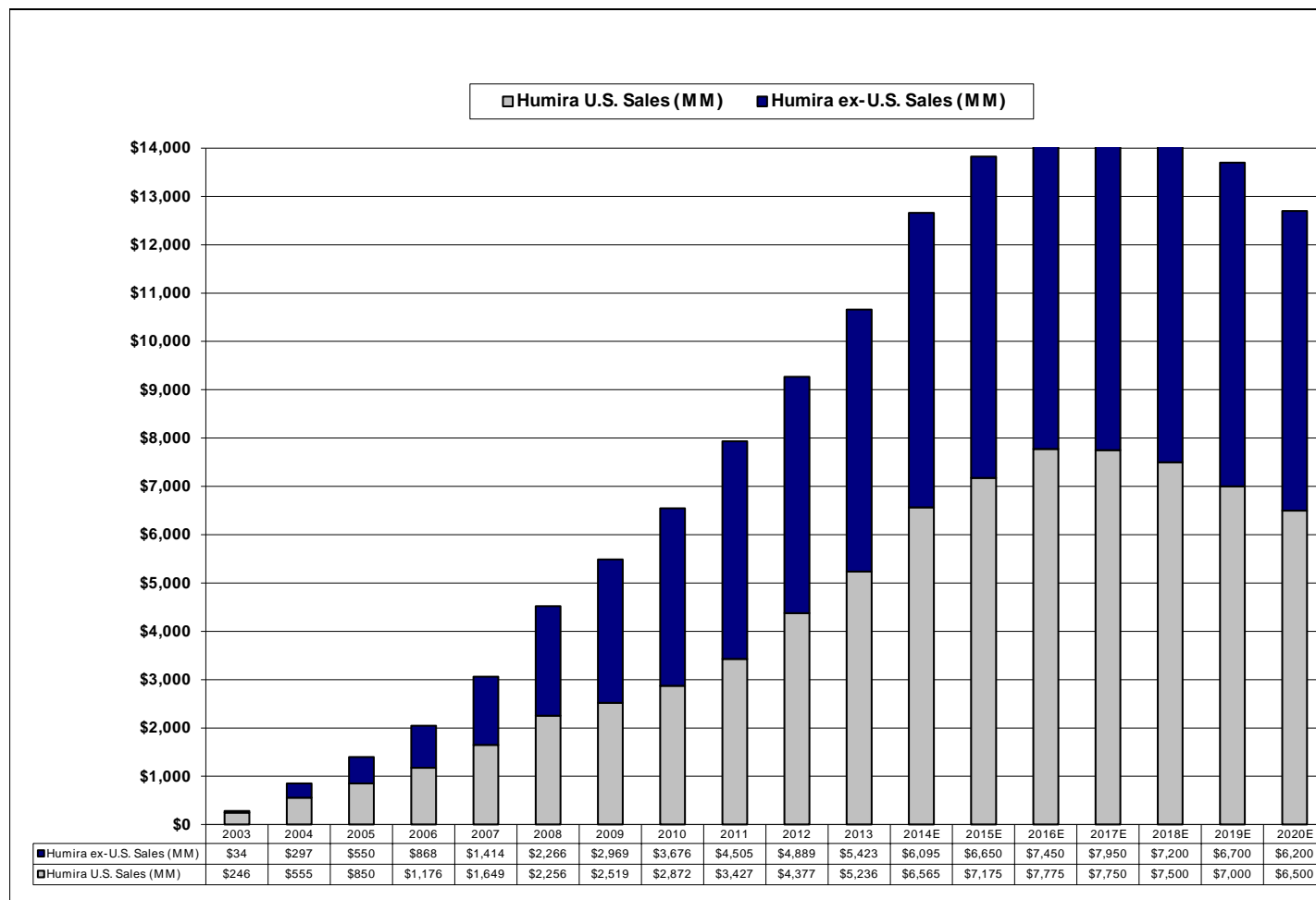
Disease Category	Indications	Timing	Potential WW Market Opportunity
Rheumatology	Rheumatoid Arthritis (RA)	Approved in 2002	~\$15B
	Psoriatic Arthritis (PsA)	Approved in 2005	~\$1.5B
	Ankylosing Spondylitis (AS)	Approved in 2006	~\$1.2B
	Juvenile Idiopathic Arthritis (JIA)	Approved in 2008	~\$2.0B
	Peripheral Spondyloarthropathies	Evaluating next steps	\$100-150MM
	Axial Spondyloarthropathies	EU approved 2012; evaluating next steps in U.S.	\$100-150MM
Gastroenterology	Crohn's Disease (CD)	Approved in 2007	~\$1.0B
	Ulcerative Colitis	Approved in Q4:12	\$300-400MM
	Pediatric Crohn's Disease	Approved September 2014	\$100-150MM
Dermatology	Psoriasis (Ps)	Approved in 2008	~\$1.5B
	Hidradenitis Suppurativa	Expect filing H2:14; approval in 2015	\$25-50MM
	Fingernail Psoriasis	Phase III started Q2:14	\$50-100MM
Ophthalmology	Uveitis	Expect filing 2015; approval in 2106	\$50-100MM

Source: Company Reports; Cowen and Company

**We estimate Humira sales at \$12.66B (+19%) in 2014, \$13.825B in 2015, \$15.225B in 2016, \$15.7MM in 2017, and then declining to \$14.7B in 2018, \$13.7B in 2019, and \$12.7B in 2020.**

Humira became the world's top selling drug in 2012, with Pfizer's Lipitor and Sanofi's/Bristol's Plavix having gone off-patent. Humira revenues, across all indications, in 2013 were \$10.7B. We estimate WW Humira revenues of \$12.5B in 2014, rising to \$13.7B in 2019. Humira sales growth in the OUS markets has outpaced U.S. growth over the past few years, yet the TNF inhibitor penetration of international RA, Crohn's, and psoriasis treatment markets remains relatively low, at less than 30%. AbbVie continues to focus its OUS Humira sales efforts on the rapidly-growing biologics markets in Brazil, Japan, China, and Russia. We estimate Humira sales at \$12.66B (+19%) in 2014, \$13.825B in 2015, \$15.225B in 2016, \$15.7MM in 2017, and then declining to \$14.7B in 2018, \$13.7B in 2019, and \$12.7B in 2020.

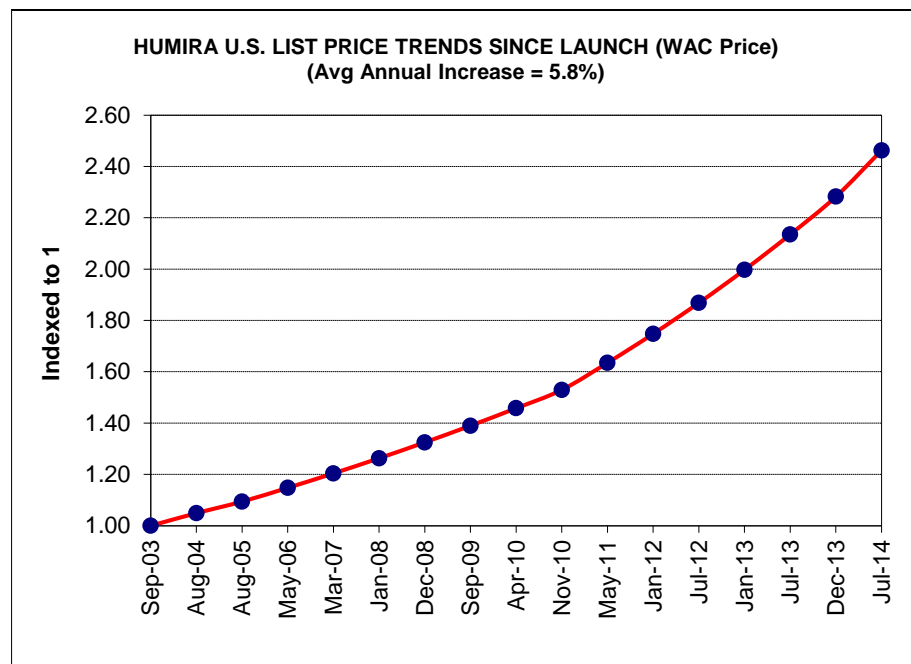
Figure 16 Humira WW Sales Growth Since Launch



Source: Cowen and Company

The key U.S. composition-of-matter patent covering Humira (#6,090,382: Human antibodies that bind human TNF $\alpha$ ) expires December 31, 2016 and the equivalent EU patent expires in February 2018. These patents claim high affinity antibodies for human TNF $\alpha$  with a slow off-rate for dissociation both *in vitro* and *in vivo*. Methods for expressing and synthesizing recombinant human antibodies that directly relate to Humira or related antibodies are also covered by the composition of matter patents. AbbVie continues to prosecute new intellectual property around Humira, and has many granted or pending patents. The Company has over 100 patents beyond the substance patent protecting Humira and we have very little visibility on these patents (although NVS claims they have been following the patent filings closely); ABBV pays a 10% royalty on sales of Humira which ceases with the expiration of certain patents, substantially bolstering ABBVs profits in a few years, by up to an estimated \$1.5B annually.

Figure 17 Humira's U.S. Price Has Doubled Since Launch



Source: Walters Kluwer Health

Humira has 27% patient share, followed by Enbrel with 20% patient share. Remicade leads with 32% share. The next five drugs (RoActemra, MabThera/Rituxan, Orencia, Simponi, and Cimzia) combined hold a 20% patient share.

Figure 18 Anti-TNFs And Other Biologics Approved In The U.S. For The Treatment Of RA

Drug	Company	Description/ Class	Indications (U.S. and/or International)	Route of admin	Dose in RA	Annual cost of therapy	Initial U.S. approval
Remicade (infliximab)	JNJ/MRK	TNF antagonist	RA w MTX, AS, PsA, Ps, CD, UC, pCD	IV infusion	3mg/kg at 0,2 & 6 weeks, then every 8 weeks	\$15-30K	1998
Enbrel (etanercept)	AMGN/PFE	TNF antagonist	RA, JIA, AS, PsA, Ps, pPs	S/C injection	50mg once weekly	\$29K	1998
Humira (adalimumab)	ABBV	TNF antagonist	RA, JIA, AS, PsA, Ps, CD, UC, aSpA; Ph III for HS, Uvt, pSpA, pCD, pPs	S/C injection	40mg every other week; 40mg every week in MTX non-responders	\$28-57K	2002
Simponi (golimumab)	JNJ/MRK	TNF antagonist	RA, AS, PsA; Filed for UC	S/C injection; sBLA filed for IV form	50mg every 4 weeks	\$29K	2009
Cimzia (certolizumab pegol)	UCB	TNF antagonist	RA, CD; Ph III in JIA, aSpA, PsA, pCD	S/C injection	400mg at 1, 2 & 4 weeks, then 200 mg every other week or 400mg every 4 weeks	\$27K	2008
Orencia (abatacept)	BMJ	T cell costimulation modulator	RA but not w TNF antagonist, JIA	IV infusion or S/C injection	500-1,000mg at 0,2 & 4 weeks, then every 4 weeks; or 125 mg S/C weekly	\$16K-31K (IV); \$27K (S/C)	2005
Actemra (tocilizumab)	Roche/Chugai	IL-6 inhibitor	RA; SJIA	IV infusion	4-8mg/kg every 4 weeks	\$19-37K	2010
Rituxan (rituximab)	BiIB/Roche	Anti CD20 antibody	RA but only in TNF non-responders	IV infusion	two-1000 mg IV infusions separated by 2 weeks (one course) every 24 weeks	\$26K	2006
Kineret (anakinra)	SOBI	IL-1 antagonist	RA but not w TNF antagonist	S/C injection	100mg daily	\$25K	2001
Xeljanz (tofacitinib)	Pfizer	JAK inhibitor	RA but not w other biologics; Ph III for UC, pPs, JIA	Oral	5 mg twice daily	\$25K	2012

RA- Rheumatoid arthritis, JIA- Juvenile idiopathic arthritis, AS- Ankylosing spondylitis, PsA- Psoriatic arthritis, UC- Ulcerative colitis, CD- Crohn's disease, Ps- Psoriasis, aSpA- axial spondyloarthritis, pSpA- peripheral spondyloarthritis, pPs- plaque psoriasis, pCD- pediatric Crohn's disease, Uvt- uveitis, HS- hidradenitis suppurativa

Source: Cowen and Company, Company data

## Coherus' Enbrel Biosimilar Program CHS-0214: Another Significant Opportunity

**While the commercial potential for CHS-0214 is more limited than CHS-1420 due to the U.S. patents, Enbrel sales are still estimated to be roughly \$4.4B in these markets by 2017, and provide a significant opportunity.**

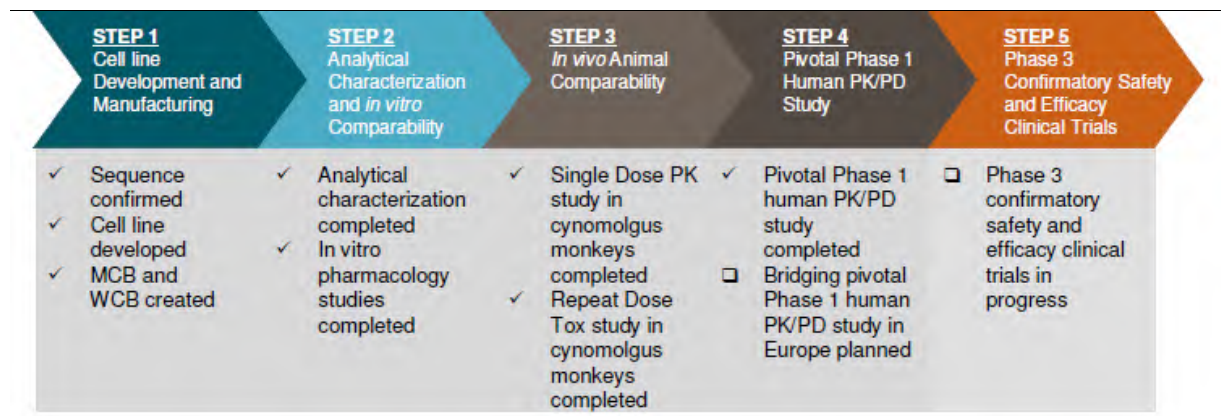
Coherus is also developing CHS-0214, a biosimilar version of Enbrel (etanercept). Due to the recent U.S. patent extensions for Enbrel, which cover the product until 2029, Coherus is focusing its efforts on the European and Japanese markets. The Company has licensed CHS-0214 to Baxter in Europe, Daiichi Sankyo in Japan, and Orox for certain Caribbean and Latin American countries. While the commercial potential for CHS-0214 is more limited than CHS-1420 due to the U.S. patents, Enbrel sales are still estimated to be roughly \$4.4B in these markets by 2017, and provide a significant opportunity.

CHS-0214 is the most developed biosimilar asset for Coherus. The Company has completed 4 of the 5 key development steps as highlighted below and has also initiated two Phase III trials for the Enbrel biosimilar. One trial is being conducted in rheumatoid arthritis and the other in psoriasis. The double-blind, multicenter, parallel group RA trial was initiated in June 2014, with an IND application (or equivalent) filed in the U.S., Argentina, Belarus, France, Germany, Hungary, Israel, Japan, Poland, Russia, South Africa and the United Kingdom. For psoriasis, a double-blind, multicenter, parallel group trial was initiated in July 2014, with an IND application (or equivalent) filed in the U.S., Canada, Australia, Chile, Germany, Israel, Poland, Russia, South Africa and the United Kingdom. Data from the studies are expected in 2015 with a potential EMA filing in 2016 and a subsequent launch in 2017. Based on



discussions with regulatory agencies, Coherus believes it may be possible to extrapolate data from the RA and psoriasis trials to gain approval for CHS-0214 in all the indications included in the label for Enbrel.

Figure 19 CHS-0214 (Enbrel) Development Progress



Source: Company Reports; Cowen and Company

Coherus has achieved the following specific development milestones for CHS-0214:

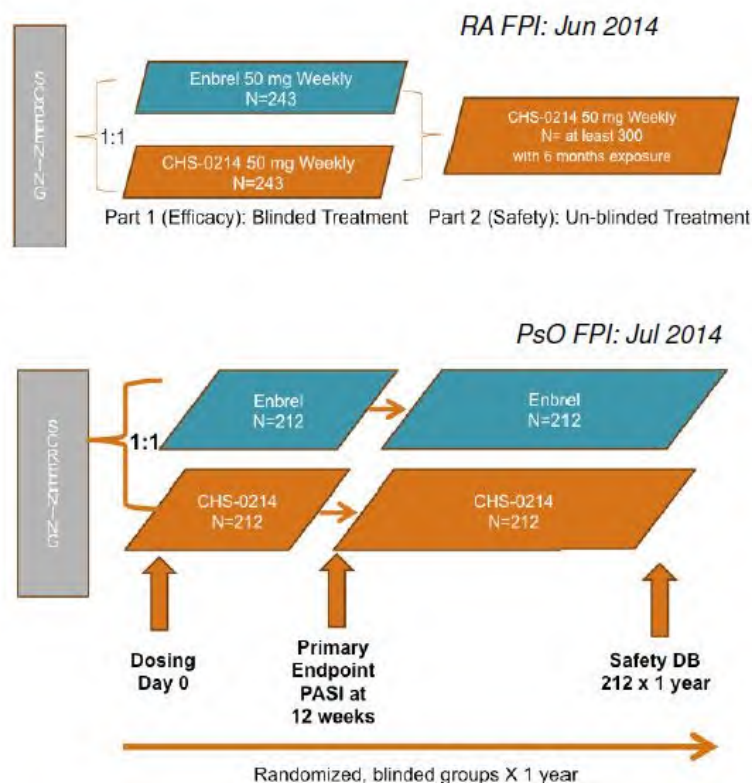
- 1. Cell Line Development and Manufacturing.** Coherus successfully identified and matched the amino acid sequence of Enbrel and CHS-0214 and demonstrated them to be identical. The Company has developed MCBs and WCBs for the product and produced toxicology materials in Q3:12. Coherus has also produced Phase I study materials at a U.S. CMO and transferred the manufacturing process to a European CMO for the product being evaluated in the Phase III studies.
- 2. Analytical Characterization and *In Vitro* Comparability.** Coherus has used multi-dimensional analyses to demonstrate that CHS-0214 has similarity to Enbrel with respect to key physiochemical properties that determine the safety, efficacy and PK/PD of both products. *In vitro* receptor binding studies, including Fc receptors, complement (C1q) and Fc-mediated functional activities (ADCC and CDC), have shown CHS-0214 to have similar pharmacological activity to Enbrel.
- 3. *In Vivo* Animal Comparability.** CHS-0214 was compared to Enbrel in a single-dose PK study and a 28-day PK/toxicity study in cynomolgus monkeys, with no appreciable differences found.
- 4. Pivotal Phase I Human Pharmacokinetic and Pharmacodynamic Study.** In October 2013, Coherus announced the findings from a Phase I PK study of CHS-0214 in 60 healthy adult volunteers. CHS-0214 met the primary endpoint of PK similarity to Enbrel with a 98% correlation between the two products along with a similar safety profile. Additionally, due to the transfer in manufacturing from the U.S. to the E.U., Coherus will be conducting an additional PK study to compare CHS-0214 to a lot of Enbrel manufactured in Europe. The single-dose, cross-over study will be similar to the first PK study and will be initiated by year-end.
- 5. Phase III Confirmatory Safety and Efficacy Clinical Trials.** The Phase III RA and psoriasis studies described above were designed based on feedback from key regulatory agencies. The double blind, multi-center, parallel group RA study will

enroll approximately 486 patients with disease-modifying antirheumatic drug (DMARD)-refractory rheumatoid arthritis. Patients will be put on a stable dose of methotrexate and randomized 1:1 to either CHS-0214 50mg or Enbrel 50mg. Both products will be administered subcutaneously on a weekly basis for a period of 24 weeks. The primary endpoint will be a 20% improvement according to American College of Rheumatology Criteria (ACR 20) scores at 24 weeks, which is the same primary endpoint used in the Enbrel registration trial for RA. After 24 weeks, patients in both arms will receive treatment with CHS-0214 treatment for 6 months to evaluate further safety.

The Phase III double blind, multi-center, parallel group psoriasis study will enroll approximately 424 patients with active psoriasis. Patients will be randomized 1:1 to either 50mg subcutaneous CHS-0214 or Enbrel, administered twice weekly for the first 12 weeks and then switching to once weekly additional 40 weeks, including 4 weeks of follow-up. The primary endpoint will be the mean Psoriasis Area and Severity Index (PASI), and the percentage of patients achieving a 75% improvement in the score (PASI-75) from baseline, after 12 weeks of treatment.

Both Phase III studies for CHS-0214 will be conducted in parallel with data expected to readout in 2015 and a potential Marketing Authorization Application (MAA) filing in 2016.

Figure 20 CHS-0214 (Enbrel) Development Progress



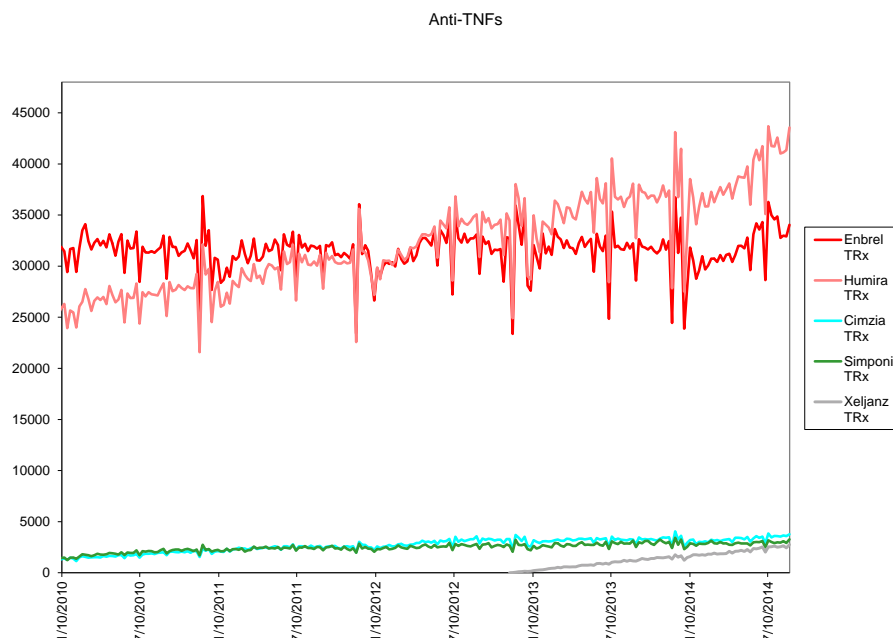
Source: Company Reports; Cowen and Company

## Enbrel: A Cash Cow That Has Become Even More Valuable

Enbrel's patent life was extended to 2028 by a new composition patent issued in 2011. As a result, Amgen has been promoting the drug more heavily, leading to volume increases.

Enbrel (etanercept) is a soluble tumor necrosis factor receptor linked to the Fc portion of human IgG<sub>1</sub>. Enbrel's long-term established safety profile and convenient subcutaneous administration have made it one of the favored anti-TNF therapies. In 2004, the company announced the launch of a once-a-week, 50 mg self-injectable pre-filled syringe, which has narrowed the convenience gap versus Abbott's Humira (once every week or once every two weeks). Competition in the anti-TNF market is fierce. Although Enbrel remains the market leader by dollar value in the U.S. in rheumatology and dermatology segments, Humira continues to perform well in rheumatoid arthritis, psoriatic arthritis, psoriasis, and other inflammatory arthritides. In addition, UCB's Cimzia and J&J's Simponi (once-monthly anti-TNFs) have been launched. Other potential competition comes from other classes of RA drugs (Roche's Actemra, Bristol's Orencia, and more recently, Pfizer's Xeljanz) and psoriasis drugs (J&J's Stelara). Nevertheless, the U.S. pricing environment remains permissive. Multiple price increases (a combined 31% increase since 2012) have supported sales upside. Moreover, Enbrel's patent life was extended to 2028 by a new composition patent issued in 2011. As a result, Amgen has been promoting the drug more heavily, leading to volume increases. In addition, in February 2013, a 3% royalty that had been payable to Sanofi expired, which will directly increase Enbrel's profitability. Most significantly, co-promote payments to Pfizer began declining in November 2013. Amgen expects this to add \$800MM to annual operating income in 2014. We estimate Enbrel sales of \$4.6B in 2014 and \$5.3B in 2019.

Figure 21 IMS Reported SubQ Anti-TNF Prescription Trends



Source: Cowen and Company, IMS Health

### Enbrel Still #1 In Dermatology

Enbrel continues to lead the biologic market for moderate-to-severe psoriasis (38% share as of YE:12). However, Abbott's Humira has experienced strong uptake by

Our consultants, who work at academic centers, typically use Humira or Stelara as their first-line drug and Enbrel as their second-line therapy. This preference is attributed to Humira's superior efficacy when compared to Enbrel's payor-mandated step-down dosing regimen.

dermatologists and JNJ's Stelara represents an emerging threat. Nonetheless, Enbrel sales in psoriasis are likely to remain relatively stable as (1) patients who are well cared for on Enbrel are unlikely to switch; (2) Enbrel still benefits from the perception of superior safety among dermatologists who treat moderate-to-severe psoriasis less frequently; (3) the market for biologics will continue to grow modestly with greater promotional support and awareness surrounding complications associated with poorly controlled psoriasis; and (4) Amgen reports that its share of biologics-naïve patients has grown over 2011-12, reaching leading 37% share by YE:2012, a positive leading indicator, and as of YE:13, Amgen remained the value share leader in dermatology and rheumatology.

Our consultants, who work at academic centers, typically use Humira or Stelara as their first-line drug and Enbrel as their second-line therapy. This preference is attributed to Humira's superior efficacy when compared to Enbrel's payor-mandated step-down dosing regimen. Physicians note that they are forced to use 50mg twice weekly for 12 weeks followed by 50mg once weekly. Unfortunately, the step down is problematic for up to half of patients who do not perform as well on the lower dose.

In terms of safety, while many dermatologists still tend to view Enbrel as having a modestly better safety profile than Humira, our consultants believe that any safety differences are clinically modest and trumped by Humira's superior efficacy. Over time and with more experience, it is clear that physicians are viewing Enbrel's and Humira's safety profile as more and more similar.

### Enbrel Clinging To Market Leadership In RA

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First approved in the U.S. in 1998, Enbrel is indicated for the treatment of RA, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and psoriasis. Numerous studies evaluating combination therapy of Enbrel with methotrexate early in the disease course have demonstrated that the combination of Enbrel + methotrexate is statistically superior in preventing disease and radiographic progression versus either methotrexate or Enbrel monotherapy. A review of the available clinical data suggests that the Enbrel/methotrexate combination is as effective as Humira/methotrexate and Remicade/methotrexate combinations. Humira's share has been steady over the last few years, and Enbrel remains the market leader in RA in terms of value share, according to Amgen. Enbrel sales in the U.S. and Canada, across all indications, were \$4.55B in 2013 (+7%), and we model U.S./Canadian sales growing to \$5.3B in 2019. Pfizer's ROW Enbrel sales were \$3.8B in 2013, and we model 2019 ROW sales of \$4.5B.

### Amgen Has Regained Full Enbrel Rights In North America

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In November 2013, Amgen's and Pfizer's co-promotion agreement surrounding Enbrel expired. During the following three years the royalty Amgen pays Pfizer will decline from 12% to 10% until November 2016, when Amgen will regain essentially 100% of North American rights. Amgen expects these changes to result in approximately \$800MM additional operating income in 2014 and 2015 vs. 2010. However, based upon Amgen disclosures that annual profit sharing payments to Pfizer were running in excess of \$1.6B; we view the \$800MM in cost savings as a low estimate. With these payments now declining, and scheduled to go away by November 2016, we believe Amgen's margin expansion should exceed the consensus expectations.

## Patent Extends Enbrel's IP To 2028

In November 2011, Amgen was issued a new composition patent on Enbrel describing the protein. Previously Amgen held patents on the DNA encoding the protein, expiring in 2012, and method of use patents in arthritis and psoriasis. The new protein patent was originally filed prior to 1995 and has been in prosecution since that time. The patent will extend IP protection for 17 years from the date of issue. (Patent law was changed in 1995 so that patents last for 20 years from the date of *filing*.) The new patent does not alter the terms of the rights return from Pfizer described above.

Our consultants admit that the bar is high for proving inequitable conduct and the challenger would have to find compelling evidence of intent to deceive during the discovery process, adequate evidence of which is seemingly not present in the publicly available record. Thus, it would appear Enbrel is likely secure from direct biosimilar competition for some time.

Legal experts believe that Enbrel's issued U.S. composition patent is strong and defensible. Our consultants could think of only one potentially viable approach a challenger to the patent could take (but thought it unlikely to succeed). Specifically, a challenger could assert that the patent is unenforceable due to inequitable conduct stemming from procedural irregularities during the long (16 year) prosecution. One possible such procedural issue our consultants identified was a reconstruction of claims in 2004 that might have been more usually re-filed as a continuation (thus losing the pre-GATT exclusivity). However, our consultants admit that the bar is high for proving inequitable conduct and the challenger would have to find compelling evidence of intent to deceive during the discovery process, adequate evidence of which is seemingly not present in the publicly available record. Thus, it would appear Enbrel is likely secure from direct biosimilar competition for some time.

## Rheumatoid Arthritis Disease Background

Rheumatoid arthritis (RA) affects about 1% of the U.S. population, with a female to male ratio of 2:1. The exact etiology is unknown, but there appears to be a genetic predisposition. Smoking, the presence of autoantibodies (RF and anti-CCP), hormonal imbalances, and environmental and infectious exposure may all play a synergistic role in triggering RA disease activity. The pathophysiology of RA is complicated and involves the interplay of T and B lymphocytes, cytokines (TNF alpha), growth factors and ligands, the complement system, and other proteins and reactive agents.

Patients present to their physician with complaints of morning stiffness >1 hr relieved with activity and red, hot, swollen, painful hands/wrists/feet/ankles. Symptoms typically develop slowly over time and if they continue over a period of 6 weeks or more, become "typical" for RA. While smaller joints are usually involved on presentation, almost any joint can be affected over time. Rheumatologists diagnose RA by the patient's history, physical examination, laboratory testing, and diagnostic imaging and procedures. Patients, especially those with positive autoantibodies (RF and anti-CCP), can have manifestations other than joint inflammation. These include hematologic, cutaneous, pulmonary, cardiac, ocular, vascular, and renal disease. Patients with RA also have a decreased life expectancy from infection, cancer (especially lymphoma), and accelerated vascular disease.

## Aggressive Medical Therapy Is The Standard of Care

Over the last decade, several new disease-modifying anti-rheumatic drugs (DMARDs) have been approved for the treatment of RA. The main attribute of DMARDs is their ability to slow or stop disease progression and radiographic bony destruction. American College of Rheumatology (ACR) guidelines from 2008 and 2012 recommend that physicians target low disease activity or remission in all patients. Therefore,



Despite the convenience of oral administration and a FDA label for methotrexate-failure RA, Xeljanz use has thus far been largely limited to the anti-TNF failure setting. Other medications, such as sulfasalazine, minocycline, azathioprine, Cytoxan, Kineret, and cyclosporine are rarely used.

rheumatologists aggressively scale up therapy, as many rheumatoid arthritis patients are able to achieve a clinical remission on a combination of two or more DMARDs. Most of the medical literature concludes that the earlier combination therapy is started, including utilizing anti-TNF agents, the quicker patients are able to achieve clinical disease and radiographic remission. The 2012 ACR guidelines acknowledge this by suggesting more aggressive therapy than the 2008 guidelines in early RA, with the thoughts being that (1) earlier treatment leads to better outcome; and (2) prevention of (irreversible) joint damage is important.

Initial therapy includes NSAIDs, methotrexate, and possibly Plaquenil, depending on disease severity and number of joints involved. Prednisone is prescribed as an initial therapy for those patients with severe symptoms since it can provide immediate relief (within 24 hrs) vs. methotrexate and Plaquenil, which can take up to 3-6 months to exert a maximum effect. If after 2-3 months the disease is still active, rheumatologists will often maximize the dose of methotrexate and consider additional therapies such as anti-TNF injectables, leflunomide, Plaquenil (if not already prescribed), or low-dose prednisone. Enbrel (Amgen/Pfizer) and Humira (AbbVie) are often the first-line biologic agents after methotrexate failure. Remicade (JNJ, MRK), Simponi (JNJ, MRK), and Cimzia (UCB) represent additional anti-TNF options. Once started on an anti-TNF agent, most rheumatologists wait 3-6 months to evaluate its efficacy (including the option to dose escalate Humira/Remicade). After 3-6 months, if a patient continues to have break-through disease activity, specialists then will either change to a second anti-TNF or switch classes to Orencia (Bristol-Myers), Actemra (Roche), or Rituxan (Biogen Idec/Roche). The newest class of DMARDs for RA are the JAK inhibitors. The first marketed JAK inhibitor approved for RA was Pfizer's Xeljanz (tofacitinib), which won FDA approval in November 2012. Despite the convenience of oral administration and a FDA label for methotrexate-failure RA, Xeljanz use has thus far been largely limited to the anti-TNF failure setting. Other medications, such as sulfasalazine, minocycline, azathioprine, Cytoxan, Kineret, and cyclosporine are rarely used.

### TNF Inhibitors Are Entrenched As The Go-To Biologic Agents...

Tumor necrosis factor alpha (TNF  $\alpha$ ), a cytokine produced by T-lymphocytes and macrophages, is a central player in the inflammatory cascade and a primary mediator of immune reactions. TNF  $\alpha$  inhibitors (anti-TNFs) block TNFs' ability to attach to cell receptors. The net result is a dramatic decline in inflammation. Anti-TNF agents are highly effective in treating a multitude of inflammatory diseases including: RA, juvenile idiopathic arthritis, ankylosing spondylitis, psoriatic arthritis, inflammatory bowel diseases, psoriasis, and spondyloarthritis.

Evidence-based clinical trials support the use of anti-TNFs as an early second-line therapy. Anti-TNFs can be used as monotherapy or in combination with traditional disease-modifying antirheumatic drugs (DMARDs) in treatment naïve or treatment failure patients. Issues with anti-TNFs include their high cost and their contraindication in patients with CHF, old/latent tuberculosis, or a history of cancer or demyelinating disease. All anti-TNF labels were updated in 2008 to include a black box for fungal infections and TB reactivation. In 2009, the FDA announced that anti-TNFs in children and adolescents lead to "an increased risk of lymphoma and other cancers" (e.g., leukemia) and is associated with new-onset psoriasis. Black-box warnings and medication guides associated with all biologics from this class were updated to reflect these safety concerns. According to the ACR, the FDA's analysis was based on reports of 48 malignancies (including lymphoma) in children and adolescents, 147 cases of leukemias (primarily in adults, few in children), and 69 cases of new-onset psoriasis. In April 2011, the FDA issued an additional warning indicating



that it continues to receive reports of cases of Hepatosplenic T-Cell Lymphoma (HSTCL), primarily in adolescents and young adults being treated with anti-TNFs. In September 2011, the FDA updated the black box on all anti-TNFs to reflect increased risk of infection by *Legionella* and *Listeria*.

Although the FDA has become more aggressive in detailing the risks associated with anti-TNFs, specialists remain eager to use these drugs for the following three reasons: (1) Anti-TNFs have demonstrated robust efficacy in halting or slowing disease progression (clinically and radiographically); (2) The serious adverse events associated with these drugs are very rare; and (3) Evidence-based medicine suggests that anti-TNFs lead to a decrease in associated co-morbidities (i.e. acute coronary syndrome, stroke). Thus, rheumatologists believe the benefits of TNF inhibitors continue to far outweigh the risks and expect these agents to remain the dominant therapy in RA. In fact, TNF inhibitors are so well-entrenched and highly regarded that doctors usually try a second anti-TNF in patients who fail on initial therapy.

#### ...That Leaves Little Unmet Need...

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Over the last several years, surveyed specialists have generally recognized little clinical need in RA. They opine that it would be hard to imagine how a new drug could beat methotrexate and anti-TNFs in efficacy for patients with early RA. Instead, lower cost is most often cited as the greatest unmet need.

Indeed, consultants continue to marvel at the impact that TNF inhibitors have had on moderate-to-severe RA, transforming it from a progressive, debilitating condition to one that can, in most cases, be quite well controlled. Over the last several years, surveyed specialists have generally recognized little clinical need in RA. They opine that it would be hard to imagine how a new drug could beat methotrexate and anti-TNFs in efficacy for patients with early RA. Instead, lower cost is most often cited as the greatest unmet need. Nevertheless, anti-TNF's have enjoyed a fairly open pricing environment, with their cost having been increased by nearly 70% over the past five years. Consultants note that prescribing physicians are mostly concerned about the cost to patients, not to insurers. As the costs of anti-TNF meds continue to increase, they note that patient access to the drugs is becoming more difficult. The consultants add that they see no imminent halting to the rising prices of anti-TNF meds.

Interestingly, none of our experts view convenience as a major drawback to the current (primarily injectable) armamentarium. One of our consultants remains puzzled as to the reasons why companies were so focused on improving convenience. The consultant added that, in his view, the greatest unmet need is the ability to predict which patients would benefit from different types of anti-TNF therapies.

#### ...Anti-TNFs Likely Won't Be Replaced Anytime Soon

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According to consultants, TNF-inhibitors (Enbrel, Humira, Simponi, Cimzia, and Remicade) penetrate over 50% of the U.S. moderate-to-severe RA market. Experts believe that these biologics are used early in the course of the disease by nearly all rheumatologists, based on excellent long-term efficacy and safety data. Our consultants believe that market growth has been driven by (1) increased diagnosis; (2) increased patient awareness of anti-TNFs through "responsible advertising"; and (3) treatment guidelines calling for early and aggressive treatment of RA, increasingly leading PCPs to refer patients to rheumatologists for treatment with injectable anti-TNFs. However, the consultants expect the overall number of RA patients treated with anti-TNFs to stay about the same over the next three years, with RA patient population growth offset by increased competition resulting from (1) novel oral agents and (2) comparative effectiveness studies of current later line agents. Doctors identify payor pushback as an increasingly important hassle. Much physician time and effort are spent in prior authorizations, and the doctors are seeing increasing attempts at step

Humira and Enbrel remain far and away the market leaders, with Humira having steadily gained on Enbrel in recent years. Our consultants do not expect these two to cede market leadership within the foreseeable future, given physicians' long experience and familiarity with Enbrel and Humira.

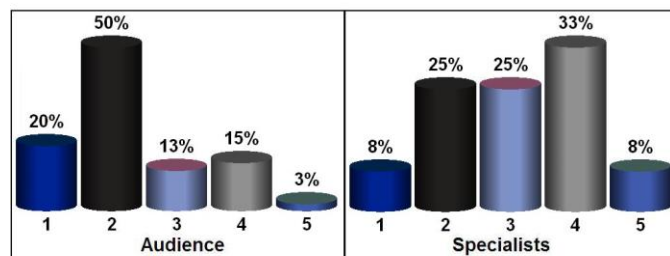
therapy and/or differential tiering of the anti-TNFs by payors. However, groups like the ACR have had some success in fighting off these efforts.

Of the five anti-TNFs on the market today (AMGN/PFE's Enbrel, ABBV's Humira, JNJ's Simponi, UCB's Cimzia, and JNJ's Remicade), Humira and Enbrel remain far and away the market leaders, with Humira having steadily gained on Enbrel in recent years. Our consultants do not expect these two to cede market leadership within the foreseeable future, given physicians' long experience and familiarity with Enbrel and Humira. One expert suggested that the choice of first-line TNF is largely driven by when and where a doctor first trained, as physicians feel comfortable continuing to prescribe the agent with which they have had the most experience.

#### The Number Of RA Patient On TNF Inhibitors May Increase Slightly

2) All things considered (population growth, penetration gains, competition, etc), in 3 years' time the number of RA patients in the U.S. on TNF inhibitors will be:

1. 15%+ higher than today
2. 0-15% higher than today
3. unchanged
4. 0-15% lower than today
5. 15%+ lower than today

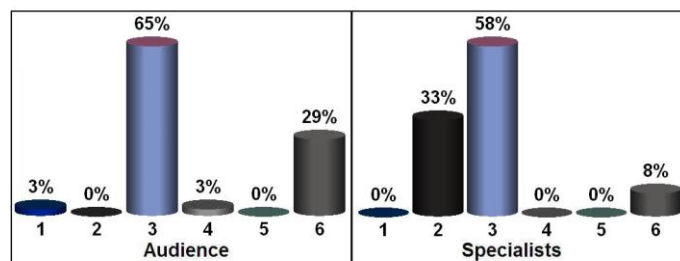


Source: Cowen and Company Health Care Conference; Vistacom; March 2014

#### Humira Is The Preferred TNF Inhibitor

3) The TNF inhibitor I prescribe most often is:

1. Cimzia (UCB)
2. Enbrel (Amgen)
3. Humira (AbbVie)
4. Remicade (JNJ)
5. Simponi (JNJ)
6. Whichever one is dictated by managed care



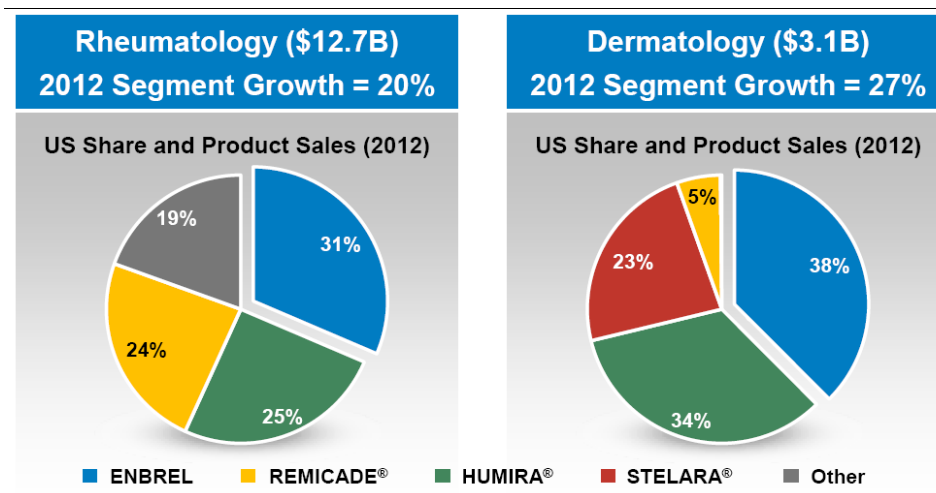
Source: Source: Cowen and Company Health Care Conference; Vistacom; March 2014

Patients tend to prefer Humira over Enbrel due to the former's more convenient dosing schedule. UCB's Cimzia and JNJ's Simponi were late to market, and their labeled once-monthly dosing has not as yet enabled them to gain significant share from the leaders. Moreover, consultants do not believe that either of these two agents effectively control patients on their once-monthly dosing schedule, and prefer Cimzia as a third choice anti-TNF (after Enbrel and Humira) because of the option to dose biweekly. Physicians we surveyed in 2013 expect Humira and Cimzia to gain the most new patients among the anti-TNFs near-term. The consultants attributed increasing enthusiasm for Cimzia to UCB's data demonstrating that responders can be identified based on the presence or absence of an ACR20 response at 12 weeks. This limited-period "treat-to-target" approach has resonated well with physicians and insurers alike. Our doctors express limited enthusiasm for Simponi. They say that Simponi's clinical efficacy is sub-par because (1) despite being a "monthly" medication, patients' symptoms tend to return by the fourth week and (2) Simponi's data on delaying structural progression, an important measure of disease-modifying ability, are the weakest of the class. Remicade remains relegated to use in certain geographies where economic incentives are more prevalent.

## Remicade Retains A Strong Presence In Rheumatology...

Remicade (infliximab) is a chimeric anti-TNF monoclonal antibody approved for the treatment of RA (signs and symptoms, inhibition of disease and radiographic progression), ankylosing spondylitis, psoriasis and psoriatic arthritis, Crohn's disease (acute and maintenance use; fistula closure or prevention), and ulcerative colitis. In RA, Remicade's share of new and total patients has eroded due to competition from Enbrel and Humira. We estimate that Medicare represents about 20% of RA patients, and that Remicade will maintain a modest presence in this patient population, due to legacy reimbursement considerations. Worldwide Remicade sales, across all indications, in 2013 were \$8.8B, largely from IBD sales. Remicade was the #2 therapeutic product by global sales in 2013 (behind Humira), and we model 2019 revenue of \$8.2B.

Figure 22 RA & Dermatology Biologic Market Share



Source: Cowen and Company, Amgen's February 2013 Business Review Day

## ...But Simponi Likely To Cannibalize Some Sales

Simponi (golimumab), a fully human monoclonal anti-TNF antibody that is administered once monthly subcutaneously, was approved by the FDA and EMA in 2009 for the treatment of moderate-to-severe RA, psoriatic arthritis, and ankylosing spondylitis. In September 2010, JNJ submitted a sBLA seeking expansion of Simponi's label to include inhibition of structural damage, induction of major clinical response, and improving physical function in RA, but received a Complete Response Letter in July 2011. In May 2013, the drug was approved by FDA for the treatment of moderate to severe UC.

Although consultants believe that Simponi has an efficacy/safety profile similar to other anti-TNFs, adoption will likely continue to be modest for several reasons, including: there are now five anti-TNFs approved for the same indications; Enbrel and Humira are entrenched; and consultants do not believe the drug truly controls disease symptoms for a full month.

JNJ has also developed an intravenous formulation of Simponi, with the potential for every 8 week dosing. Data from the Phase III GO-FURTHER trial presented at EULAR

and ACR 2012 compared IV Simponi vs. placebo, both on background methotrexate, in 592 methotrexate-failure RA patients. Patients received a 30-minute infusion at week 0, 4, and then every 8 weeks through 100 weeks. Proportion of patients achieving ACR20 at week 14 was the primary endpoint. At week 14, 59% of patients achieved ACR20 (vs. 25% on placebo), and 30% achieved ACR50 (vs. 9% on placebo). Results were similar at 24 weeks, and maintained through one year. Patients also saw significant improvements on disease activity (DAS28) and physical function (HAQ), as well as a significant inhibition of radiographic structural progression through week 24 that was maintained through one year. Consultants have noted in the past that subQ Simponi has weak data on inhibition of structural progression, so it is a positive that the IV formulation appears to have clear benefit in this regard. Nevertheless, we believe Simponi will continue to struggle to compete with entrenched competitors that combine subQ convenience with strong structural data. In July 2013, the FDA approved the IV formulation of Simponi for the treatment of moderate to severe RA in combination with methotrexate.

Following a settlement with Merck in April 2011, JNJ will solely distribute Remicade and Simponi in the U.S., Canada, Central and South America, the Middle East, Africa, and Asia Pacific. Merck will sell the drugs in Europe, Russia, and Turkey, but will relinquish 50% of profits to JNJ. Simponi revenues, across all indications, in 2013 were \$932MM (+54%), and we estimate growth to \$2.2B in 2019.

#### UCB's Cimzia Expected To Remain A Minor Player

Cimzia (certolizumab pegol), a once monthly anti-TNF (pegylated anti-TNF $\alpha$  antibody fragment), is FDA and EMA approved for patients with moderate to severe RA (every two weeks or every four weeks in the U.S.; every two weeks only in the EU). Open-label extension data from two Phase III trials presented at EULAR 2010 showed sustained benefits in RA over 2 and 3 years as a monotherapy and in combination with methotrexate, respectively. Cimzia is also FDA-approved for the treatment of moderate to severe Crohn's disease patients who have not responded to conventional medications. Positive Phase III data for Cimzia in PsA and axSpA (including AS) were reported in 2012. The data enabled FDA and EMA approval for these indications in 2013. Cimzia achieved 2013 net sales of close to €500MM.

We expect Cimzia to struggle in the U.S. Crohn's market, as Humira's and Remicade's profiles will likely hinder Cimzia's potential. In RA, Cimzia will face the same issues Simponi has. In addition, while consultants believe that Cimzia has a safety profile similar to other anti-TNFs, they are not convinced that it is equally efficacious, or that it is a true once-monthly therapy.

We expect Cimzia to struggle in the U.S. Crohn's market, as Humira's and Remicade's profiles will likely hinder Cimzia's potential. In RA, Cimzia will face the same issues Simponi has. In addition, while consultants believe that Cimzia has a safety profile similar to other anti-TNFs, they are not convinced that it is equally efficacious, or that it is a true once-monthly therapy. (To address these issues, in late 2011 UCB began a Phase III head-to-head trial of Cimzia vs. Humira in methotrexate-refractory RA, with data expected in 2016. In addition, the company presented Phase IIIb trial data at EULAR and ACR 2012 arguing that 200mg q2week maintenance dosing produced comparable efficacy to 400mg q4week maintenance dosing, each after a 4-month biweekly dosing induction period.) Nevertheless, consultants have become somewhat more positive on Cimzia as a result of UCB's post-hoc analysis showing that response at 12 weeks is predictive of response at 52 weeks. Consultants find it appealing to be able to definitively identify responders by using only a relatively short 3-month trial.

#### Pfizer's Xeljanz Not Gaining Much Traction In RA

There had been some investor concern that Pfizer's oral JAK inhibitor Xeljanz (tofacitinib), which was launched in the U.S. in December 2012, might represent a new source of competition for Enbrel. Xeljanz is labeled for methotrexate-failure RA

patients, a broad indication which in theory would permit use ahead of TNF-inhibitors and other injectable biologics. Notably, however, we are finding that many payors have limited Xeljanz reimbursement to patients who have failed both methotrexate and one or more anti-TNFs. We note that our consultants have also indicated they are using Xeljanz only in anti-TNF failures. These views combined with lackluster initial prescribing trends suggest limited competitive risk to Enbrel. Cowen's Pharma Team models Xeljanz estimated 2014 sales at just \$260MM.

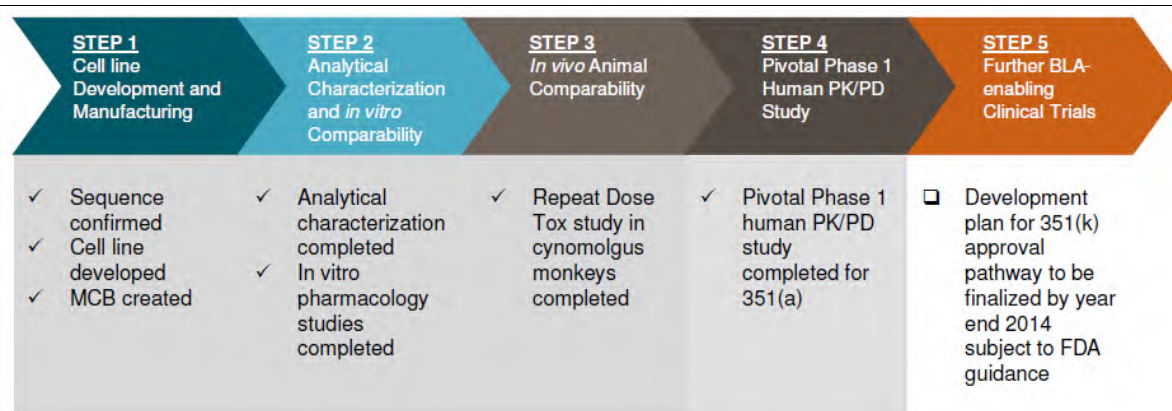
## Coherus' Neulasta Biosimilar Program CHS-1701 Also Meaningful

Patent expirations for Neulasta offer a near-term opportunity for biosimilars in the U.S. after October 2015 and in Europe after February 2018. With \$4.4B in WW sales expected by 2017, a biosimilar of the G-CSF product provides Coherus with another solid opportunity.

Patent expirations for Neulasta offer a near-term opportunity for biosimilars in the U.S. after October 2015 and in Europe after February 2018. With \$4.4B in WW sales expected by 2017, a biosimilar of the G-CSF product provides Coherus with another solid opportunity. Coherus has conducted extensive analytical characterization of CHS-1701 and determined that its basic and higher-order structures are similar to Amgen's Neulasta. The biological effect of CHS-1701 on neutrophils was assessed by measuring the biosimilar's effect on the proliferation of NFS-60 cells, a common test for evaluating G-CSF products. Specifically, CHS-1701 binds to G-CSF receptors expressed on NFS-60 cells, which activates the receptor and induces proliferation. NFS-60 cells are stimulated using varying concentrations of CHS-1701 and proliferation is then evaluated by adding a dye that induces a luminescent signal and measuring the light emission which is directly proportional to the number of living cells. Luminescence is emission of light caused by chemical reactions.

Coherus has completed 3 of the 5 key development steps for CHS-1701 as highlighted below. The Company has also completed a Phase I PK/PD study in healthy volunteers, which would support a BLA filing for CHS-1701 via the standard 351(1) pathway, but did not meet the strict criteria for bioequivalence required for a 351(k) filing. As a result, Coherus is likely to repeat the critical Phase I PK/PD study with adjustments to the study design to address the variability that was observed and likely led to the lack of bioequivalence.

Figure 23 CHS-1701 (Neulasta) Development Progress



Source: Company Reports; Cowen and Company

Specific details on the development milestones of CHS-1701 include:



1. **Cell Line Development and Manufacturing.** The amino acid sequence of CHS-1701 has been confirmed to be the same as Neulasta. Regarding the pegylation of CHS-1701, Coherus has confirmed that the polyethylene glycol molecule and the site of attachment are the same as Neulasta. Like CHS-1420, CHS-1701 will be manufactured using a U.S.-based CMO.
2. **Analytical Characterization and *In Vitro* Comparability.** Based on extensive analytical characterization of CHS-1701, Coherus has determined that the basic and higher-order structures of the product are similar to Neulasta. Using a luminescence assay to evaluate the *in vitro* activity of CHS-1701, Coherus established that the product stimulated the proliferation of NFS-60 cells in a concentration-dependent manner, consistent with the activity of Neulasta.
3. ***In Vivo* Animal Comparability.** Coherus conducted a 2-week preclinical study in rats to evaluate the pharmacodynamics and toxicity of CHS-1701. The biosimilar product was administered every 4 days for 2 weeks (doses ranged from 0.1-1.0 mg/kg), with a recovery period of one week compared to Neulasta. No signs of systemic toxicity that could be attributed to treatment were seen during the study, including no mortalities. Dose-proportional increases in absolute neutrophil count (ANC), and total white blood cell count were observed at all dose levels of CHS-1701 and were consistent with the treatment effects of Neulasta.

A second preclinical study in monkeys was conducted to characterize the PK and PD profiles of CHS-1701 and evaluate the potential for antibody responses to the product. Both CHS-1701 and Neulasta were administered at dose levels of 0.075, 0.25 and 0.75 mg/kg once weekly for 4 weeks. Both products performed similarly with increased production of white blood cells in the bone marrow and resulting increases in WBCs in the blood, bone marrow and lymphoid tissues such as the spleen and thymus. Furthermore, no differences were seen between the two products in terms of antibody response or the PK/PD profile.

4. **Pivotal Phase I Human Pharmacokinetic and Pharmacodynamic Study.** Starting in November 2012, Coherus conducted a Phase I randomized, double-blind, single-dose, two-period crossover study to evaluate the PK and safety profile of 6mg CHS-1701 and Neulasta. 79 healthy patients were evaluated with bioequivalence measured based on  $C_{max}$ ,  $AUC_{0 \rightarrow t}$ , and  $AUC_{0 \rightarrow \infty}$ , including a 28-day washout period after each drug administration. Mean exposure and standard deviation of these three measures overlapped; however, the study did not meet bioequivalence based on geometric mean values, which ranged slightly above the allowed upper confidence interval (125%) on all three variables.

Importantly, with respect to the absolute neutrophil count (ANC) mean exposure ( $AUC_{0 \rightarrow t}$ ), the conducted study did demonstrate that CHS-1701 mobilization of neutrophils was comparable to Neulasta. And while Coherus did not power the Phase I study to define bioequivalence for this endpoint, a post-hoc analysis of the secondary endpoint determined that the endpoint would have met bioequivalence criteria.

Under the standard biologic 351(a) regulatory pathway, demonstration of bioequivalence to Neulasta is not required and the FDA has indicated to Coherus that they can proceed to Phase III via this track if they choose. However, to maintain optionality for CHS-1701 and pursue a 351(k) biosimilar filing, the Company will likely conduct another Phase I PK/PD study in healthy volunteers for the purpose of demonstrating bioequivalence to Neulasta. Importantly, with respect to the absolute neutrophil count (ANC) mean exposure ( $AUC_{0 \rightarrow t}$ ), the conducted study did demonstrate that CHS-1701 mobilization of neutrophils was comparable to Neulasta. And while Coherus did not power the Phase I study to define bioequivalence for this endpoint, a post-hoc analysis of the secondary endpoint determined that the endpoint would have met bioequivalence criteria. This suggests that the variations seen in the study that resulted in missing PK bioequivalence had little to no effect on the PD response (i.e., the mean increase in ANC over time) and that CHS-1701 functioned similarly to Neulasta.



Regarding safety and tolerability, CHS-1701 and Neulasta demonstrated a similar profile in the Phase I study. Adverse events in both treatment groups included upper respiratory infections, back pain, extremity pain, arthralgia, musculoskeletal chest pain, neck pain and headache. Of note, anti-drug antibodies were similar between CHS-1701 and Neulasta and did not appear to affect drug exposure. Neutralizing antibodies were not evaluated in the study.

Coherus also plans to conduct a single-dose, dose-proportionality study to evaluate the PK and ANC profile over time for CHS-1701 relative to Neulasta. The approved 6mg dose of Neulasta and an additional dose below 6mg will be evaluated. This additional study will be conducted in parallel with the Phase 3 trial for CHS-1701. The Company also plans to conduct a multi-dose PK study for the 6mg dose as part of the Phase III program described below.

5. **Phase III Confirmatory Safety and Efficacy Clinical Trials.** Currently, Coherus is planning to initiate two Phase III clinical trials for CHS-1701 in 2015. In both studies, the primary endpoint will be the number of days of severe neutropenia (a surrogate marker for febrile neutropenia), following the first dose of CHS-1701 and Neulasta. For each trial, Coherus plans to enroll approximately 369 patients with advanced breast cancer that are receiving chemotherapy. Patients will be randomized 2:1 to CHS-1701 or Neulasta, which will be administered 24 hours after each dose of chemotherapy for the first four cycles. The studies will also evaluate the safety profile of both products and may explore additional efficacy measures. If successful, Coherus is planning for a U.S. filing in early 2016 with a potential 2017 launch and also a potential E.U. filing in 2017 with a 2018 launch.

### Modest Growth Expected For Neulasta

Neulasta is approved in the United States and Europe and is indicated to reduce the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving chemotherapy. Launched in 2002, Neulasta is a sustained-duration form of Neupogen (G-CSF) created by attaching a polyethylene glycol (PEG) molecule to the N-terminus of Neupogen. Neulasta's longer half-life permits once-per-cycle dosing to control chemotherapy-induced neutropenia (CIN). Neulasta's dosing advantage translated into rapid market acceptance, and allowed the long-acting product to quickly capture two-thirds of the G-CSF market from Neupogen. Neulasta is sold in 10-day doses instead of Neupogen's single day doses. Because patients tend to receive Neupogen therapy for an average of 6.5 days, Amgen captures significantly more revenue per Neulasta patient. Following rapid initial adoption, the conversion rate from Neupogen to Neulasta has slowed, and Neupogen still represents over 20% of the franchise, including use to treat more temporary forms of CIN.

Amgen expects modest growth of its Neulasta/Neupogen franchise driven by pricing, geographic expansion, and expanded first-cycle use (prophylaxis of neutropenia). Data from a randomized, double-blind, placebo-controlled study of 928 breast cancer patients show that first and subsequent-cycle administration of Neulasta resulted in a 94% reduction in the incidence of febrile neutropenia, a 93% reduction in the incidence of hospitalization, and an 80% reduction in the incidence of intravenous anti-infective use in patients receiving myelosuppressive chemotherapy previously considered at moderate risk for neutropenic complications. In 2005, Neulasta's label was expanded to cover this indication. In January 2012, Amgen reported success in the 845-patient Phase III PAVES study of Neulasta in mCRC patients receiving FOLFOX or FOLFIRI, each with Avastin. The study succeeded on the primary endpoint of

reduced Grade 3/4 febrile neutropenia (2.4% in drug group vs. 5.7% placebo,  $p=0.014$ ). Overall Grade 3+ AEs were similar between drug and placebo arms.

Neulasta's penetration as a "first cycle" agent in patients on myelosuppressive therapies is approximately 75%, and could still grow modestly. Moreover, in October 2013, Amgen announced that it had acquired the rights to Neupogen and Neulasta in 100 ex-US markets from Roche, effective January 1, 2014 (the franchise generated \$200MM sales in these territories in 2012). Amgen's G-CSF franchise produced sales of \$5.79B WW in 2013, +8% Y/Y, with modest global volume declines offset by U.S. price increases. We project a decline to \$5.64B in sales for the franchise in 2014, with a further decline to \$5B in 2019 as competition from new market entrants begins to erode sales.

### Neupogen Encounters E.U. Biosimilars...

Amgen has reduced the price of Neupogen in certain territories in order to limit market share loss, but nevertheless, in mid-2013 Sandoz' Zarzio surpassed Neupogen in market share. Within the five largest European markets, total biosimilar conversion of Neupogen is nearly 80% as of 2013.

Several biosimilar versions of G-CSF (Ratiopharm's Ratiograstim, CT Arzneimittel's Biograstim, and Teva's TevaGrastim, Hexal's Filgrastim Hexal, Sandoz's Zarzio) have been launched in the E.U. Such introductions appear to be competing for share in Neupogen's \$300MM ex-U.S. market, but have had minimal impact on Neulasta. Amgen has reduced the price of Neupogen in certain territories in order to limit market share loss, but nevertheless, in mid-2013 Sandoz' Zarzio surpassed Neupogen in market share. Within the five largest European markets, total biosimilar conversion of Neupogen is nearly 80% as of 2013.

Meanwhile, the EMA approved Teva's Lonquex (peg-filgrastim) in August 2013. Because Amgen's E.U. Neulasta patent (expiring 2017) cites a different site of pegylation than Lonquex, Teva believes it does not infringe Amgen's patent and has launched Lonquex in Europe, starting with Germany in November 2013. Amgen believes otherwise and is suing Teva for infringement.

Figure 24 Biosimilar Conversion Of Neupogen In The EU5

filgrastim (EU5, Q3 2013)	
	Sales Unit Doses (Thousands)
NEUPOGEN	215.8
BIOSIMILAR FILGRASTIM	703.9
<b>Total</b>	<b>919.7</b>

	Unit Share of filgrastim Market
NEUPOGEN	23%
<b>BIOSIMILAR FILGRASTIM</b>	<b>77%</b>

Source: Company Reports; Cowen and Company

### ...Neupogen Is Also Experiencing U.S. Competition

Neupogen-like molecules are also now entering the U.S. market. In late 2009, Teva filed a BLA for the approval of Granix (a.k.a. tbo-filgrastim/XM02, sold as TevGrastim in several EU markets), a G-CSF that is similar to Neupogen, though not a true biosimilar. Granix's regulatory filing was based on data from five clinical trials (in BRCA, lung cancer, and NHL) that enrolled more than 680 patients. In August 2012, the FDA announced approval of Granix. Launch was delayed until November 2013, per

a prior legal settlement with Amgen on the G-CSF patent. Granix launched at a 23% discount to Neupogen. However, it has a narrower label than Neupogen (one indication to Neupogen's five). Amgen reports that Teva appears to be focusing on the hospital market and characterizes competitive sales efforts as "modest". Thus far, IMS sales data indicate that Granix has taken less than 10% of the U.S. market.

Meanwhile, Teva is also developing a long-acting version of G-CSF, called Neugranin (balufilgrastim). Notably, Neugranin is a fusion of G-CSF with albumin, rather than PEG, and is therefore not a true biosimilar version of Neulasta. Balufilgrastim is in principle free to launch as of November 2013, per a legal settlement with Amgen, but the drug has not been FDA approved. Teva filed a BLA, but withdrew the filing in November 2013 after the FDA requested additional confirmatory data, possibly including new clinical trials.

Teva also filed a BLA for its pegylated long-acting filgrastim, Lonquex (a.k.a. XM22/lipegfilgrastim). However, Amgen's U.S. patents protecting pegylated filgrastim do not expire until 2015, and Amgen filed a U.S. lawsuit in August 2013 seeking to establish that any attempted U.S. Lonquex launch would infringe its patents. In October 2013, Teva withdrew the Lonquex BLA, so Amgen discontinued the lawsuit. Amgen believes that Lonquex has on average a 3% uptake in EU markets where the drug has launched since TEVA received EMA approval in August 2013.

As Teva reported at the MASCC meeting in June 2012, both balugrastim and lipegfilgrastim have successfully completed Phase III trials showing noninferiority to treat neutropenia in breast cancer patients receiving myelosuppressive therapy, with efficacy and safety comparable to Neulasta.

Separately, in early 2012, Novartis' Sandoz generics unit announced that it had begun two Phase III trials on its own biosimilar versions of Neupogen and Neulasta. These trials are aimed at gaining U.S. approval; the Neupogen biosimilar is already marketed as Zarzio in more than 30 ex-U.S. countries, while the Neulasta biosimilar is a new product candidate. Zarzio was launched in Europe in 2009, and in July 2013, Sandoz reported that Zarzio had become the first biosimilar to overtake its reference product (Neupogen) in market share within Europe, becoming the most prescribed daily G-CSF in Europe. In July 2014, the FDA accepted Sandoz's BLA, making Sandoz's biosimilar of Neupogen the first biologic on the FDA biosimilar pathway.

## ***Biosimilar Background***

### **Legislation Has Moved Forward, But It Is Still Vague**

In February 2012, the FDA released its initial draft guidance for biosimilar development under the 351(k) pathway for public comment. As we expected the FDA will use a "totality of the evidence approach" on a case by case basis in evaluating differences between the test and reference products. The FDA recommends a stepwise approach in the development of biosimilar products beginning with: (1) extensive structural and functional characterization of both the proposed product and the reference product which will serve as the foundation of any biosimilar development program. Further requirements will be determined by the extent to which the biosimilar is structurally different from the reference listed biologic "if rigorous structural and functional comparisons show minimal or no difference between the proposed product and the reference product, the stronger the scientific justification for a selective and targeted approach to animal and/or clinical testing to support a demonstration of

Our regulatory consultants indicate that the E.U. pathway is a reasonable proxy for the FDA, but that class-specific (antibodies, proteins, vaccines) or product-specific guidance is years away. In the interim, policy is likely to be established by a few trailblazing products as they encounter FDA feedback, advisory panels, and Citizen's Petitions.

Details on what exactly "fingerprint-like similarity" entails are lacking and companies are still seeking clarity on this issue. Notably, the FDA admits that it does not as yet see a scientifically defensible pathway to granting pharmacy-level interchangeability to biosimilars.

In July 2014, the FDA accepted Sandoz's BLA, making Sandoz's biosimilar of Neupogen the first biologic on the FDA biosimilar pathway. EMA approved its first application for a biosimilar monoclonal antibody in September 2013, Inflectra/Remsima (infliximab), which is a biosimilar for Remicade produced by Celltrion and partner Hospira.

biosimilarity."; (2) sponsors will consider the role of animal data in assessing toxicity and, in some cases, in providing additional support for demonstrating biosimilarity and in contributing to the immunogenicity assessment; and (3) the sponsor will then conduct comparative human PK studies, and PD studies if there is a clinically relevant PD measure, in an appropriate study population.

Products for which there are clear assays or a known mechanism of action may require less clinical testing, "the available information about assays, including sensitivity, specificity, and extent of validation, can affect the amount and type of additional animal or clinical data that may be needed to establish biosimilarity," and further "A sufficient understanding of the mechanism of action (MOA) of the drug substance and clinical relevance of any observed structural differences, clinical knowledge of the reference product and its class indicating that the overall safety risks are low, and the availability of a clinically relevant PD measure may provide further scientific justification for a selective and targeted approach to animal and/or clinical studies." Our regulatory consultants indicate that the E.U. pathway is a reasonable proxy for the FDA, but that class-specific (antibodies, proteins, vaccines) or product-specific guidance is years away. In the interim, policy is likely to be established by a few trailblazing products as they encounter FDA feedback, advisory panels, and Citizen's Petitions.

For filing, the first step in this process is the patent exchange that is triggered by the FDA acceptance of the biosimilar application. This may take up to 250 days. This is followed by the actual litigation of these patents (2-3 years). In cases where an appeal is initiated, another 1-1.5 years could be added to the timeline. Thus, the IP and legal side of biosimilars is a convoluted and time-consuming process that may trap challengers into drawn out litigations or forcing biosimilar developers to "launch at risk". The FDA plans to review each application on a case-by-case basis, and expects to require significant preclinical and clinical data generation by the sponsor. In May 2014, the FDA released a new draft guidance for biosimilars that requires companies to submit data in support of a fingerprint-like similarity between the proposed biosimilar and the original product. Details on what exactly "fingerprint-like similarity" entails are lacking and companies are still seeking clarity on this issue. Notably, the FDA admits that it does not as yet see a scientifically defensible pathway to granting pharmacy-level interchangeability to biosimilars. In August 2014, the FDA issued additional draft guidance entitled, "Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act". Under the additional guidance, a reference biologic sponsor can provide information at the time of application or as an amendment to make a case that their product differs enough from other structurally related product to merit its own reference product exclusivity.

In July 2014, the FDA accepted Sandoz's BLA, making Sandoz's biosimilar of Neupogen the first biologic on the FDA biosimilar pathway. EMA approved its first application for a biosimilar monoclonal antibody in September 2013, Inflectra/Remsima (infliximab), which is a biosimilar for Remicade produced by Celltrion and partner Hospira. Inflectra was approved for RA, ankylosing spondylitis, IBD, psoriatic arthritis, and psoriasis by the European Commission for these indications in September 2013 following the CHMP's positive opinion in June 2013 and launch efforts are ongoing, however, details are lacking.

In past Cowen conferences, Dr. Janet Woodcock, the FDA's deputy commissioner, has noted that the agency finds it difficult to predict immunogenicity based on animal data. Therefore – as noted above – it is clear that clinical trials will be required.

## Approval Likely To Be Established On A Product-Specific Basis

The generics industry is hoping that via the rule-writing process the scientific decisions on the requirements for biosimilar approvals are left to the FDA. They believe the Agency is best positioned to make regulatory decisions on a product-by-product basis. Meanwhile, branded companies are seeking a bit more uniformity via the rule writing that mandates certain types of clinical testing (for example immunogenicity) for all biosimilars. While FDA leaders indicate they are scientifically prepared to begin dealing with biosimilar applications, formal requirements on what types of studies are required for specific products are lacking and FDA leaders admit much uncertainty in addressing certain classes such as antibodies. In past Cowen conferences, Dr. Janet Woodcock, the FDA's deputy commissioner, has noted that the agency finds it difficult to predict immunogenicity based on animal data. Therefore – as noted above – it is clear that clinical trials will be required.

## Initial Biosimilar Launches Likely In Next Five Years

The Patient Protection and Affordable Care Act in March 2010 created the very basic regulatory framework for a biosimilar pathway, establishing essentially two levels of “biosimilar” and “interchangeable,” but ceded nearly all of the details to the FDA. Our regulatory consultants indicate that the E.U. pathway is a reasonable proxy for the FDA, but that class-specific (antibodies, proteins, vaccines) or product-specific guidance is years away. In the interim, policy is likely to be established by a few trailblazing products as they encounter FDA feedback, advisory panels, and Citizen's Petitions. We would note that the FDA has the authority to approve interchangeable biologics today. However, interchangeability is clearly a more controversial issue and it appears the FDA is not equipped with the pharmaco-vigilance systems required to assure safety.

As for the opportunity itself, before discussing the actual likely regulatory scheme, we wanted to introduce a thought about which manufacturers will be the ultimate participants. Although there has been growing enthusiasm about the potential of the biosimilars opportunity for generic drug manufacturers, we believe that investors are overlooking what could be potentially broad ramifications of other competitors entering once a proper regulatory pathway is established in the U.S. In our discussions with consultants and industry experts, it appears that the scientific, manufacturing and marketing investments required for successful introduction of biosimilars are likely to limit all but a handful of generic drug companies from participating in this market. Alternatively, our thesis is that this opportunity could include a variety of other players, such as some large-cap pharmaceutical and biotech companies as well as select mid- and small-cap biotech companies – all of which may look at each specific biologic opportunity and decide whether to make targeted or broader investments. The bottom line, in our view, is that generic drug manufacturers may not be as well positioned as generally believed. Or, to state it differently, other players with vastly superior capabilities and resources may be at least equally – if not better – suited to participate.

## Europe Appears More Amenable To Biosimilars

Biosimilar regulatory guidelines have been in place in Europe since 2004 and were first published in Japan in 2008. Close to 20 biosimilars have been approved in Europe, but several of these would not be considered biosimilars in the U.S. due to differences

in definitions. Our regulatory consultants indicate that the FDA will continue to establish statutory guidelines for biosimilar development and approvals, but ultimately will likely set specific requirements on a drug-by-drug basis.

The EMEA has outlined specific clinical and non-clinical guidelines for four major biosimilar categories: recombinant insulin, human growth factor, erythropoietin, and colony stimulating factors. The most important guidelines include: (1) the molecular property conformance of biosimilars need to be rigorously confirmed via physicochemical and biological characterization; (2) prior to initiating clinical trials, *in vitro* studies must be performed to detect any significant differences between the biosimilar being evaluated and its reference (cell-based functional assay comparisons; toxicity and toxicokinetics studies in animal models such as primates); (3) clinical trials must include comparative pharmacokinetic profiles for reference, and the biosimilar must be evaluated in the appropriate patient population; (4) comparative efficacy must be assessed in clinical trials; and (5) biosimilar safety and immunogenicity must be assessed in a post-approval setting. These appear to be similar to the FDA guidelines.

Figure 25 Comparison Of Regional Biosimilar Guidelines

	Europe	United States	Japan
<b>Product Characterization</b>	Establish comparability in reactivity through relevant physicochemical characterization studies; receptor-binding, structural characterization.	Analytical studies required. Complexities of protein therapeutics require sophisticated evaluation of amino acid sequence, amino acid modifications (glycosylation, side chain analysis), and higher-order structure (protein folding and protein-protein interactions).	Stability testing required; comparison to reference product.
<b>Non-Clinical Studies</b>	Animal studies to assess PD effect relative to clinical application. Non-clinical toxicity as determined in at least one repeat dose toxicity study, including toxicokinetic measurements (antibody titer, cross reactivity, and neutralizing capacity).	In-vitro functional characterization. Animal studies; PK/PD, immunogenicity. Human PK/PD studies. Clinically relevant PD markers should be evaluated to provide scientific justification for type/duration of clinical studies.	Comparative studies with reference product; animal models, in-vitro/in-vivo bioactivity, immunologic response, PK/PD.
<b>Clinical Trials</b>	Comparative clinical trials usually required. Requirements dependent upon existing knowledge of reference product and claimed therapeutic indications. In certain cases, PK/PD studies may be appropriate for demonstrating clinical comparability.	Comparative PD studies required unless sponsor provides adequate scientific justification. Where surrogate PD markers of efficacy are not well established, clinical safety and efficacy must be established through clinical trials; non-inferiority designs appropriate. Sufficient immunogenicity data required.	Required, but flexible; results of animal work and human PK/PD will determine type, length, and number of trials required. Surrogate markers of efficacy may substitute for true endpoints where appropriate.
<b>Post-Marketing</b>	Required	Required	Required

Source: FDA, CHMP, PMDA, Cowen and Company

In August, the EMA approved the first biosimilar to infliximab/Remicade, which is a monoclonal antibody. This approval bears watching for its implications for other significant biologics. Typically, for monoclonal antibodies, the endpoint is efficacy, which is difficult to assess. And there is the issue of whether we can extrapolate the data from one trial across indications. Nevertheless, the EMA appeared to feel comfortable with these issues to allow for the approval of Remicade biosimilars.

#### Biosimilar Capabilities Are More Readily Found In Large Cap Pharma And In The Biotech Industry Itself...

The capabilities necessary to participate in the biosimilar opportunity are inherently different than small molecule generics. These include: (1) biologic formulation capabilities; (2) biologic manufacturing capabilities; (3) clinical trial capabilities; (4) sales forces capable of marketing these products, since biosimilars are unlikely to be



We would argue that from a generic manufacturer perspective, participating may be much less lucrative and/or more difficult especially if these other better resourced pharmaceutical/biotechnology companies enter.

deemed substitutable; and (5) sufficient capital to invest in 1-4 as well as the scale in the respective P&Ls to withstand the necessary incremental annual costs.

These capabilities are mostly domiciled within large-capitalization pharmaceutical manufacturers as well as large-cap biotechnology companies. And we would place Teva in that field given its size and internal biologics division, acquired with the Sicor transaction. Teva has also improved its ability to participate in this arena significantly with the Barr acquisition, which will contribute Pliva's capabilities – as well as its joint venture with Lonza, one of the global leading biologic outsourcing manufacturing firms. Mid- and small-cap biotech companies that have capabilities 1-3, but have failed in their original targets and/or strategies, may also seek to participate. However, the generic industry – which may have the least of the necessary capabilities – is typically given the largest amount of investor attention when discussing the opportunity. We would argue that from a generic manufacturer perspective, participating may be much less lucrative and/or more difficult especially if these other better resourced pharmaceutical/biotechnology companies enter.

#### ...Novartis, And To A Lesser Extent, Shire, Are Early Examples

The prime example most investors highlight as being best positioned to capitalize on biosimilars is Novartis/Sandoz. We would argue this is the case not because of the generic skill set realized in the Sandoz division – but rather from what the Novartis brand division brings via its biologics formulation and manufacturing capabilities. Novartis's recent experience in marketing biosimilars in Europe should also provide the company with valuable expertise. In fact, Novartis/Sandoz is currently developing a competitor biosimilar for each product that Coherus has in development. While Coherus has the technical capabilities and experience personnel to compete with the likes of Novartis/Sandoz, it is important to remember that the primary objective for the Coherus is to simply capture a meaningful portion of the biosimilar market, which could provide significant top- and bottom-line contributions for a company of its size.

Figure 26 Competitive Landscape For Coherus

	Originator	Selected Potential Biosimilar Competitors
CHS-0214 (etanercept biosimilar)	Pfizer	Samsung Bioepis Sandoz Hanwha
CHS-1420 (adalimumab biosimilar)	AbbVie	Samsung Bioepis Actavis / Amgen Sandoz Boehringer Pfizer Ingelheim
CHS-1701 (pegfilgrastim biosimilar)	Amgen	Apotex Teva Sandoz Hospira

Source: Company Reports; Cowen and Company

Another company that has been operating as a stealth biosimilar producer for a few of its development products is Shire Pharmaceuticals. Via its acquisition of Transkaryotic Therapies, Shire launched its branded formulation of erythropoietin (Dyneo) into the European markets in 2006. Shire has since withdrawn the product due to a lack of

profitability. In fact, Shire's withdrawal of Dynepo shows that even a company of its size faces challenges in the biosimilars space: Shire took the product through a full development program and was offering Dynepo at a 30% discount to the other branded EPOs on the market – which is a generic strategy. Dynepo was not substitutable; however, there is no other meaningful clinical or label differentiation. Dynepo was one of the first test cases to gauge how willing clinicians and government payers are to utilize a lower-cost biosimilar.

In addition, Shire has successfully developed its own version of gene-activated glucocerebrosidase (GA-GCB), which was approved in February 2010 under the trade name Vpriv. Vpriv is competing against Genzyme's Cerezyme (GA-GCB) for Gaucher disease. Shire performed a full clinical program, filed a BLA, and is marketing the product at a 15% discount to Cerezyme. Both of these strategies are essentially pure-play branded/generic in nature – and obviously Shire is not a generic manufacturer. We believe these examples illustrate that the opportunities may be captured by a variety of players depending on their own unique capabilities.

We believe that in addition to Merck, that Pfizer/Wyeth, Eli Lilly, Roche, Bristol-Myers Squibb, GlaxoSmithKline, AstraZeneca, and others are analyzing the various opportunities. In fact, a recent SEC filing reported that Lilly has taken a 9.1% passive stake in Coherus. Our consultants note that big pharma's intentions in biosimilars were hinted at Merck's decision in May 2006 to acquire GlycoFi, which specializes in yeast glycoengineering and optimization of biologic drug molecules. As for the possibility that the biotechnology industry will "turn on its own" and pursue other's key products within their industry, we have seen this before. Recall that the generic industry has participated in "authorized" generics even though overall industry profits have declined with their use. Given the capabilities available, we believe that certain biotech companies will weigh the benefits and participate, at least for some opportunities. In January 2012, Amgen signed a development agreement with Actavis to co-develop multiple biologic candidates and Biogen is collaborating with Samsung in a similar agreement.

### Capabilities 1-3: Formulation, Manufacturing, Clinical Trials

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#### For Generic Drug Manufacturers, Biosimilars Opportunity Hinges On Cost Advantages

Given that the generic drug industry thrives on being able to operate in a low-cost environment, we believe that two issues will be key if it is to be successful in the biosimilars opportunity: (1) a cost-of-goods advantage; and (2) a significantly abbreviated (and hence, less costly) development pathway to market. Much of the initial entry by companies into the biosimilars arena will depend on whether there is a cost arbitrage available, i.e., if generic companies can limit the cost of goods and still be competitive.

#### Biosimilar Manufacturing Costs

The production of a biologic drug begins with the development of a genetically engineered cell line, which is replicated and eventually transferred to large-scale production tanks. Manufacturing costs vary according to whether the method of manufacture is from bacterial (microbial manufacturing) or mammalian cells (mammalian cell manufacturing).

Our consultants estimate that microbial manufacturing, which is an older method, costs about 75% compared to mammalian cell manufacturing. This is the simplest method of producing recombinant protein by inserting a human gene encoding for a specific protein, into the DNA of a simple host like yeast. Bacterial systems are,

however, limited to the production of simple molecules, as they do not allow for modification processes that are required for complex proteins such as glycosylation. Mammalian cell manufacturing typically costs more. Therefore, a critical component in evaluating the biosimilars opportunity hinges on the cost of manufacturing.

Additionally, there appear to be few available production facilities with the capability to manufacture at a large scale. Most existing facilities belong to big pharma/biotech or to contract manufacturing organizations. Small- to mid-sized biotech companies tend to contract most of their manufacturing. Therefore, companies seeking to be participants in biosimilars in the near future may need to partner with large pharma/biotech companies or contract out manufacturing. Additionally, our consultants indicate that companies will need to make an initial investment of \$15-20MM in manufacturing validation and other CMC requirements prior to transferring production to a CMO. These costs include 3-5 initial pilot scale runs showing that the manufacturing process is validated.

#### **Low-Cost Sites Could Cut Manufacturing Expenditure By 50%**

Our consultants indicate that outside the U.S. and Europe, the cost of manufacturing is approximately halved. There are several companies in India and China that manufacture biologicals such as EPO or insulin. A few companies in Asia such as Biocon, Dr. Reddy's Laboratories and The Hong Kong Institute of Biotechnology perform contract manufacturing. A host of smaller companies make similar claims.

Several manufacturers have already started to look at alternative low cost sites. In recent years, Singapore has attracted four major biologics investments totaling close to \$1B. Genentech invested in a \$140MM commercial-scale microbial-based manufacturing facility to produce Lucentis. GlaxoSmithKline is constructing a \$200MM E-coli-based manufacturing facility to produce pediatric vaccines against meningitis and typhoid. Lonza is building two commercial-scale mammalian cell-based contract manufacturing facilities. Lonza's first \$250MM contract manufacturing facility has been outsourced to produce Genentech's Avastin. The second \$350MM facility will support the needs of additional customers and/or Teva.

#### **Lower-Cost Pathway Would Still Require \$30-50MM Per Opportunity**

Even if a generic drug company already has and/or is able to internally develop or partner with an outside contractor and therefore obtain the necessary manufacturing capabilities, much of the cost advantage will be predicated on whether there is an abbreviated regulatory pathway. For the time being, a significantly abbreviated pathway is unlikely, meaning that some clinical studies will need to be performed to demonstrate therapeutic equivalence to the innovator product. These most likely will be structured as Phase III trials, although Phase II studies for certain products may also be required. Our consultants continue to estimate that a full scale Phase III program would likely carry significant costs.

**The reason for the likely more comprehensive studies is due to the fact that our consultants believe that any regulatory pathway will specifically require immunogenicity studies.**

The reason for the likely more comprehensive studies is due to the fact that our consultants believe that any regulatory pathway will specifically require immunogenicity studies. The FDA's recent guidelines suggest that specific requirements for the FDA, such as switching studies, are likely to increase the trial costs. In addition, the agency has indicated that the scope of immunogenicity tests could vary greatly and in some cases may be the same for innovators as for follow on biologics.

With these issues in mind, our consultants indicate that for any biologic, the cost of regulatory development including chemistry, manufacturing, and controls and

abbreviated Phase III studies would likely cost about \$30-50MM. Our consultants believe that an abbreviated pathway at the FDA is unlikely to eliminate the Phase II level expense, which they regard as a necessary and initial cost. Beyond this amount, we would include additional tests such as immunogenicity requirements discussed above, specific to the targeted molecule, as well as post-marketing studies. Indeed, BioGenerix (a subsidiary of Teva/Ratiopharm) indicates in its presentations that the cost of developing a biosimilar could be \$20-80MM, which mirrors our consultants' targets. We would note that this \$30-50MM cost per opportunity would likely be spread over multiple years, so the annual spend for a single opportunity may be smaller. Nonetheless, if this analysis is correct, the burden of this expense will vary according to each company's P&L. We believe that this cost issue is often overlooked by investors. Assuming that a manufacturer is pursuing a few products (3-5 to be conservative for this analysis), the annual cost could reach \$30-50MM. Note, for large-cap pharma and biotech companies, this level of expense would be trivial within their P&Ls (roughly 1%) versus an average of 15% for the generic drug industry.

#### **Capability 4: Sales Force Support: Marketing Of "Follow-On" Biologics Will Likely Be Necessary**

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As we have indicated, because it appears unlikely that biogenerics will be deemed bioequivalent to the reference drug, pharmacy level substitution is unlikely to be allowed, and therefore, we expect clinicians will continue to play a major role in the drug utilization decision process. Thus, we believe that cost is not the only factor: sales and marketing support that provides perspective on the safety and efficacy of the product may prove critical in driving uptake.

As a result, it is unlikely that all biosimilars will be used equally. With standard oral solid dose generics we often see 90%+ generic substitution nearly immediately following launch. This will unlikely be the case with biosimilars. We believe the type of treatment market and/or reference product will have significant influence on whether clinicians will use a biosimilar. Indeed, lower costs may prove a secondary concern given: (1) the complex process required to formulate consistent product; (2) the way the product is used (critical care or chronic); and/or (3) the way the drug is dosed or the device in which it is approved may also have an impact.

We believe the Human Growth Hormone market is illustrative of some of these issues, particularly dosing challenges. In the U.S. there are currently five branded products with total sales of roughly \$1.0B annually. Meanwhile, the two generic biosimilars from Teva and Novartis/Sandoz have made almost no impact (less than 5% share), in spite of their significant price discounting. The brand products are marketed with a variety of pen needle systems that make the injection simple and relatively painless for children, while the generics have standard delivery devices.

Figure 27 CHS-1420 Rheumatoid Arthritis Market Model

ESTIMATED U.S. RHEUMATOID ARTHRITIS MARKET											
	2013	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	CAGR Comments
Total U.S. Population ('000)	332,000	335,500	338,855	342,240	345,665	349,120	352,610	356,135	359,695	363,295	
Prevalence of Rheumatoid Arthritis (RA)	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	
Total U.S. Patients with RA ('000)	2,490	2,516	2,541	2,567	2,592	2,618	2,645	2,671	2,698	2,725	
% Not Entering Remission	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	- Only 15% of patients enter remission without treatment
% Requiring Add-On Therapy	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	- Including 20% patients failing all treatment & 15-25% failing MTX
Total RA Add-On Therapy Population ('000)	847	858	864	873	881	890	899	908	917	928	- Total number of patients that are candidates for anti-TNF therapy
% Growth		+1%	+1%	+1%	+1%	+1%	+1%	+1%	+1%	+1%	
Remicade Penetration of U.S. RA Add-On Market (JNJ)	10%	8%	9%	5%	4%	3%	3%	3%	2%	2%	
Average Annual Patients ('000)	36	32	29	25	23	20	18	16	14	12	-11%
Annual Cost of Therapy (\$'000)	\$21.8	\$21.8	\$21.8	\$21.8	\$21.8	\$21.8	\$21.8	\$21.8	\$21.8	\$21.8	
Estimated Remicade U.S. RA Sales (\$MM)	\$785	\$700	\$620	\$545	\$480	\$435	\$390	\$360	\$305	\$280	-12%
% Growth		-11%	-11%	-12%	-10%	-11%	-10%	-10%	-13%	-15%	- Simponi cannibalizing sales in RA
Enbrel Penetration of U.S. RA Add-On Market (AMGN/PFE)	31%	30%	29%	27%	26%	24%	23%	23%	23%	23%	
Average Annual Patients ('000)	116	116	117	117	117	117	116	115	114	113	-0.2%
Annual Cost of Therapy (\$'000)	\$22.2	\$22.9	\$23.5	\$24.2	\$25.0	\$25.7	\$26.5	\$27.3	\$28.1	\$29.0	
Estimated Enbrel U.S. RA Sales (\$MM)	\$2,085	\$2,050	\$2,145	\$2,085	\$2,020	\$1,910	\$1,875	\$1,840	\$1,805	\$1,770	+3%
% Growth		+3%	+4%	+3%	+3%	+3%	+2%	+2%	+2%	+2%	
Humira Penetration of U.S. RA Add-On Market (ABBV)	30%	30%	29%	28%	27%	25%	25%	24%	24%	24%	
Average Annual Patients ('000)	120	124	127	130	133	133	132	130	128	126	1%
Annual Cost of Therapy (\$'000)	\$20.7	\$21.4	\$22.0	\$22.7	\$23.4	\$24.1	\$24.8	\$25.5	\$26.3	\$27.1	
Estimated Humira U.S. RA Sales (\$MM)	\$2,490	\$2,650	\$2,795	\$2,945	\$3,105	\$3,200	\$3,270	\$3,315	\$3,385	\$3,410	+4%
% Growth		+6%	+5%	+5%	+5%	+3%	+2%	+1%	+2%	+1%	
Orencia Penetration of U.S. RA Add-On Market (BMY)	10%	10%	11%	11%	11%	10%	10%	11%	11%	11%	
Average Annual Patients ('000)	40	43	47	50	51	51	52	51	50	49	+2%
Annual Cost of Therapy (\$'000)	\$19.9	\$20.9	\$22.0	\$23.1	\$24.2	\$25.4	\$26.7	\$28.1	\$29.5	\$30.9	
Estimated Orencia U.S. RA Sales (\$MM)	\$800	\$900	\$1,020	\$1,155	\$1,235	\$1,300	\$1,375	\$1,430	\$1,475	\$1,515	+7%
% Growth		+13%	+13%	+13%	+7%	+5%	+6%	+4%	+3%	+3%	
Rituxan Penetration of U.S. RA Add-On Market (RHHBY)	0%	0%	5%	5%	4%	4%	4%	4%	4%	4%	
Average Annual Patients ('000)	27	29	28	28	27	26	26	25	25	24	-1%
Annual Cost of Therapy (\$'000)	\$17.1	\$17.6	\$18.1	\$18.6	\$19.2	\$19.8	\$20.4	\$21.0	\$21.6	\$22.3	
Estimated Rituxan U.S. RA Sales (\$MM)	\$460	\$500	\$505	\$510	\$515	\$520	\$525	\$530	\$535	\$540	+2%
% Growth		+9%	+1%	+1%	+1%	+1%	+1%	+1%	+1%	+1%	
Cimzia Penetration of U.S. RA Add-On Market (UCB)	4%	5%	5%	5%	5%	5%	5%	5%	5%	5%	
Average Annual Patients ('000)	17	20	23	25	27	30	30	31	31	31	+7%
Annual Cost of Therapy (\$'000)	\$21.5	\$21.5	\$21.5	\$21.5	\$21.5	\$21.5	\$21.5	\$21.5	\$21.5	\$21.5	
Estimated Cimzia U.S. RA Sales (\$MM)	\$365	\$430	\$485	\$535	\$585	\$635	\$685	\$735	\$785	\$835	+7%
% Growth		+18%	+13%	+10%	+9%	+9%	+2%	+1%	+0%	+0%	
Simponi Penetration of U.S. RA Add-On Market (JNJ)	4%	4%	5%	5%	5%	6%	6%	6%	6%	6%	
Average Annual Patients ('000)	13	15	17	19	22	24	25	25	25	24	+7%
Annual Cost of Therapy (\$'000)	\$26.2	\$27.0	\$27.8	\$28.6	\$29.5	\$30.3	\$31.2	\$32.2	\$33.2	\$34.1	
Estimated Simponi U.S. RA Sales (\$MM)	\$340	\$385	\$400	\$450	\$485	\$530	\$575	\$620	\$665	\$710	+10%
% Growth		+16%	+16%	+20%	+15%	+15%	+9%	+3%	+3%	+1%	
Actemra Penetration of U.S. RA Add-On Market (RHHBY)	4%	5%	5%	5%	5%	5%	5%	5%	5%	5%	
Average Annual Patients ('000)	17	21	23	25	27	29	30	30	30	30	+7%
Annual Cost of Therapy (\$'000)	\$19.7	\$20.1	\$20.5	\$20.9	\$21.3	\$21.7	\$22.2	\$22.6	\$23.1	\$23.5	- Price of 8mg is \$25,500/year and price of 4mg is \$12,700/year
Estimated Actemra U.S. RA Sales (\$MM)	\$325	\$410	\$475	\$525	\$575	\$625	\$685	\$740	\$795	\$850	+9%
% Growth		+26%	+16%	+11%	+10%	+9%	+6%	+2%	+1%	+1%	
Xeljanz Penetration of U.S. RA Add-On Market (PFE)	1%	3%	5%	9%	13%	14%	15%	15%	15%	15%	
Average Annual Patients ('000)	4	10	19	38	56	65	71	71	71	71	+37%
Annual Cost of Therapy (\$'000)	\$25.0	\$25.5	\$26.0	\$26.5	\$27.1	\$27.6	\$28.2	\$28.7	\$29.3	\$29.9	
Estimated Xeljanz U.S. RA Sales (\$MM)	\$105	\$260	\$500	\$1,000	\$1,500	\$1,800	\$2,000	\$2,040	\$2,080	\$2,120	+40%
% Growth		+148%	+92%	+100%	+50%	+20%	+11%	+2%	+2%	+2%	
Baricitinib Penetration of U.S. RA Add-On Market (BMY/INCY)				0%	1%	2%	2%	3%	4%	5%	
Average Annual Patients ('000)				1	4	7	11	16	20	23	+84%
Annual Cost of Therapy (\$'000)				\$27.0	\$27.5	\$28.1	\$28.7	\$29.2	\$29.8	\$30.4	
Estimated Baricitinib U.S. RA Sales (\$MM)				\$15	\$100	\$200	\$325	\$470	\$595	\$700	+90%
% Growth					+567%	+100%	+63%	+45%	+27%	+18%	
CHS-1420 Penetration of U.S. RA Add-On Market (Coherus)				0.5%	1.0%	1.5%	2.0%	2.5%	3.0%		
CHS-1420 Penetration of U.S. Humira RA Sales				1.4%	3.0%	4.5%	6.0%	7.5%	9.0%		
Average Annual Patients ('000)				2	5	8	10	13	16	+45%	- Price Discount of 20% from Humira
Annual Cost of Therapy (\$'000)				\$18.7	\$19.2	\$19.8	\$20.4	\$21.0	\$21.7		
Estimated CHS-1420 U.S. RA Sales (\$MM)				\$45	\$100	\$155	\$210	\$275	\$355	\$440	
% Growth					+122%	+55%	+55%	+31%	+22%		
Total U.S. RA Market Sales (\$MM)	\$8,235	\$8,895	\$9,805	\$10,615	\$11,705	\$12,555	\$13,195	\$13,610	\$13,990	\$14,325	+6%
% Growth		+8.0%	+8.0%	+10.5%	+10.3%	+7.3%	+5.1%	+3.1%	+2.8%	+2.4%	
Total U.S. RA Patients Treated with Biologics ('000)	389	409	428	457	487	507	518	519	520	518	

ESTIMATED CHS-1420 EX-US RHEUMATOID ARTHRITIS SALES											
	2013	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	CAGR Comments
Total Humira Ex-US RA Market Sales (\$MM)	\$2,710	\$3,025	\$3,305	\$3,500	\$3,600	\$3,400	\$3,200	\$3,000	\$2,800	\$2,600	-0% - RA Sales Compose ~40% of Total Ex-US Sales
% Growth		+12%	+9%	+6%	+3%	-6%	-6%	-6%	-7%	-7%	
CHS-1420 Penetration of Ex-US Humira RA Sales						4.0%	8.0%	12.0%	16.0%	20.0%	
Estimated CHS-1420 Assumed Partner Ex-US RA Sales (\$MM)						\$100.0	\$190.0	\$270.0	\$335.0	\$390.0	- Price Discount of 25% from Humira
% Growth							+90%	+42%	+24%	+16%	
Royalty Revenue to Coherus						\$20.0	\$40.0	\$55.0	\$65.0	\$80.0	+41% - Royalty Rate of 20% including COGS

Source: Cowen and Company; Company Reports

Figure 28 CHS-1420 Psoriasis Market Model

ESTIMATED U.S. PSORIASIS MARKET											
	2013	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	CAGR Comments
Total U.S. Population ('000)	332,000	335,500	338,855	342,240	345,665	349,120	352,610	356,135	359,695	363,295	
Prevalence of Psoriasis	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	
Total U.S. Patients with Psoriasis ('000)	4,980	5,033	5,083	5,134	5,185	5,237	5,289	5,342	5,395	5,449	
Prevalence of Moderate-to-Severe Psoriasis	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	
% Requiring Add-On Therapy	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	
<b>Total Psoriasis Add-On Therapy Population ('000)</b>	<b>365</b>	<b>368</b>	<b>371</b>	<b>375</b>	<b>379</b>	<b>383</b>	<b>387</b>	<b>391</b>	<b>395</b>	<b>399</b>	
% Growth		+1%	+1%	+1%	+1%	+1%	+1%	+1%	+1%	+1%	
<b>Romidec Penetration of U.S. Psoriasis Add-On Market (JNJ)</b>	<b>3%</b>	<b>2%</b>	<b>2%</b>	<b>1%</b>	<b>1%</b>	<b>1%</b>	<b>1%</b>	<b>1%</b>	<b>1%</b>	<b>1%</b>	
Average Annual Patients ('000)	4.5	4.5	3.9	3.4	3.1	2.8	2.5	2.3	2.1	1.9	-9%
Annual Cost of Therapy (\$'000)	\$17.7	\$17.7	\$17.7	\$17.7	\$17.7	\$17.7	\$17.7	\$17.7	\$17.7	\$17.7	
<b>Estimated Romidec U.S. Psoriasis Sales (\$MM)</b>	<b>\$80</b>	<b>\$80</b>	<b>\$70</b>	<b>\$60</b>	<b>\$55</b>	<b>\$50</b>	<b>\$45</b>	<b>\$40</b>	<b>\$35</b>	<b>\$30</b>	<b>-9%</b>
% Growth		+0%	-13%	-14%	-9%	-9%	-10%	-11%	-13%	+0%	
<b>Enbrel Penetration of U.S. Psoriasis Add-On Market (AMGN/PFE)</b>	<b>30%</b>	<b>37%</b>	<b>37%</b>	<b>30%</b>	<b>35%</b>	<b>35%</b>	<b>34%</b>	<b>34%</b>	<b>34%</b>	<b>35%</b>	
Average Annual Patients ('000)	46	49	52	54	55	56	55	55	55	55	+2%
Annual Cost of Therapy (\$'000)	\$25.9	\$26.7	\$27.5	\$28.3	\$29.2	\$30.1	\$31.0	\$31.9	\$32.8	\$33.8	
<b>Estimated Enbrel U.S. Psoriasis Sales (\$MM)</b>	<b>\$1,185</b>	<b>\$1,285</b>	<b>\$1,415</b>	<b>\$1,815</b>	<b>\$1,805</b>	<b>\$1,870</b>	<b>\$1,705</b>	<b>\$1,785</b>	<b>\$1,855</b>	<b>\$1,930</b>	<b>+8%</b>
% Growth		+8%	+9%	+2%	+0%	+4%	+2%	+3%	+3%	+3%	
<b>Humira Penetration of U.S. Psoriasis Add-On Market (ABBV)</b>	<b>34%</b>	<b>34%</b>	<b>35%</b>	<b>39%</b>	<b>39%</b>	<b>39%</b>	<b>39%</b>	<b>39%</b>	<b>39%</b>	<b>32%</b>	
Average Annual Patients ('000)	42	45	47	50	52	54	55	54	53	52	+2%
Annual Cost of Therapy (\$'000)	\$25.8	\$26.5	\$27.3	\$28.1	\$29.0	\$29.9	\$30.7	\$31.7	\$32.6	\$33.6	
<b>Estimated Humira U.S. Psoriasis Sales (\$MM)</b>	<b>\$1,080</b>	<b>\$1,180</b>	<b>\$1,285</b>	<b>\$1,385</b>	<b>\$1,505</b>	<b>\$1,610</b>	<b>\$1,675</b>	<b>\$1,710</b>	<b>\$1,730</b>	<b>\$1,745</b>	<b>+5%</b>
% Growth		+9%	+9%	+8%	+8%	+7%	+4%	+2%	+1%	+1%	
<b>Stelara Penetration of U.S. Psoriasis Add-On Market (JNJ)</b>	<b>20%</b>	<b>27%</b>	<b>28%</b>	<b>29%</b>	<b>31%</b>	<b>31%</b>	<b>32%</b>	<b>32%</b>	<b>32%</b>	<b>32%</b>	
Average Annual Patients ('000)	36	39	44	48	54	56	58	58	58	58	+5%
Annual Cost of Therapy (\$'000)	\$23	\$24	\$24	\$25	\$26	\$27	\$28	\$28	\$29	\$30	
<b>Estimated Stelara U.S. Psoriasis Sales (\$MM)</b>	<b>\$800</b>	<b>\$925</b>	<b>\$1,075</b>	<b>\$1,210</b>	<b>\$1,400</b>	<b>\$1,495</b>	<b>\$1,605</b>	<b>\$1,645</b>	<b>\$1,685</b>	<b>\$1,745</b>	<b>+9%</b>
% Growth		+11%	+16%	+13%	+16%	+7%	+7%	+3%	+3%	+3%	
<b>CHS-1420 Penetration of U.S. Psoriasis Add-On Market (Coherus)</b>					<b>0.5%</b>	<b>1.0%</b>	<b>1.5%</b>	<b>2.0%</b>	<b>2.5%</b>	<b>3.0%</b>	
<b>CHS-1420 Penetration of U.S. Humira Psoriasis Sales</b>					<b>1.5%</b>	<b>2.4%</b>	<b>3.7%</b>	<b>4.7%</b>	<b>6.0%</b>	<b>7.2%</b>	
Average Annual Patients ('000)					1	2	3	4	5		+44%
Annual Cost of Therapy (\$'000)					\$23.2	\$23.9	\$24.6	\$25.3	\$26.1	\$26.9	- Price Discount of 20% from Humira
<b>Estimated CHS-1420 U.S. Psoriasis Sales (\$MM)</b>					<b>\$20</b>	<b>\$40</b>	<b>\$85</b>	<b>\$95</b>	<b>\$110</b>	<b>\$135</b>	<b>+47%</b>
% Growth					+100%	+100%	+63%	+31%	+29%	+23%	
<b>Total U.S. Psoriasis Market Sales (\$MM)</b>	<b>\$3,185</b>	<b>\$3,480</b>	<b>\$3,845</b>	<b>\$4,180</b>	<b>\$4,685</b>	<b>\$4,825</b>	<b>\$5,020</b>	<b>\$5,100</b>	<b>\$5,265</b>	<b>\$5,385</b>	<b>+8%</b>
% Growth		+9.3%	+10.5%	+8.7%	+9.2%	+5.7%	+4.0%	+2.6%	+2.2%	+2.3%	
Total U.S. Psoriasis Patients Treated with Biologics ('000)	129	137	146	154	164	168	170	169	168	167	

ESTIMATED CHS-1420 EX-US PSORIASIS SALES											
	2013	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	CAGR Comments
Total Humira Ex-U.S. Psoriasis Market Sales (\$MM)	\$1,350	\$1,510	\$1,650	\$1,750	\$1,800	\$1,700	\$1,600	\$1,500	\$1,400	\$1,300	-0% - Psoriasis Sales Compose ~25% of Total Ex-U.S. Sales
% Growth		+12%	+9%	+6%	+3%	-6%	-6%	-6%	-7%	-7%	
CHS-1420 Penetration of Ex-U.S. Humira Psoriasis Sales						4.0%	8.0%	12.0%	16.0%	20.0%	
<b>Estimated CHS-1420 Assumed Partner Ex-U.S. Psoriasis Sales (\$MM)</b>						\$50.0	\$95.0	\$135.0	\$170.0	\$195.0	- Price Discount of 25% from Humira
% Growth							+90%	+42%	+26%	+15%	
<b>Royalty Revenue to Coherus</b>						<b>\$10.0</b>	<b>\$20.0</b>	<b>\$28.0</b>	<b>\$36.0</b>	<b>\$40.0</b>	<b>+41%</b> - Royalty Rate of 20% including COGS

Source: Cowen and Company; Company Reports



Figure 29 CHS-0214 Market Model

ESTIMATED CHS-0214 EX-US INTERNATIONAL SALES											
	2013	2014E	2016E	2016E	2017E	2018E	2018E	2020E	2021E	2022E	CAGR Comments
Total Enbrel Ex-U.S. RA Market Sales (\$MM)	\$1,880	\$1,950	\$2,020	\$2,090	\$2,150	\$2,190	\$2,220	\$2,250	\$2,275	\$2,300	+2% - RA Sales Compose ~40% of Total Ex-U.S. Sales
% Growth		+4%	+4%	+3%	+3%	+2%	+1%	+1%	+1%	+1%	
CHS-0214 Penetration of Ex-U.S. Enbrel RA Sales					3.5%	8.0%	12.0%	17.0%	21.0%	24.0%	
Estimated CHS-0214 Ex-U.S. RA Sales (\$MM)					\$55.0	\$130.0	\$200.0	\$285.0	\$360.0	\$415.0	- Price Discount of 25% from Enbrel
% Growth					+136%	+54%	+43%	+26%	+15%		
Royalty Revenue to Coherus					\$10.0	\$25.0	\$40.0	\$55.0	\$70.0	\$85.0	+83% - Royalty Rate of 20% including COGS
Total Enbrel Ex-U.S. Psoriasis Market Sales (\$MM)	\$940	\$975	\$1,010	\$1,045	\$1,075	\$1,095	\$1,110	\$1,125	\$1,140	\$1,150	+2% - Psoriasis Sales Compose ~25% of Total Ex-U.S. Sales
% Growth		+4%	+4%	+3%	+3%	+2%	+1%	+1%	+1%	+1%	
CHS-0214 Penetration of Ex-U.S. Enbrel Psoriasis Sales					3.5%	8.0%	12.0%	17.0%	21.0%	24.0%	
Estimated CHS-0214 Ex-U.S. Psoriasis Sales (\$MM)					\$30.0	\$65.0	\$100.0	\$145.0	\$180.0	\$205.0	- Price Discount of 25% from Enbrel
% Growth					+117%	+54%	+45%	+24%	+14%		
Royalty Revenue to Coherus					\$5.0	\$15.0	\$20.0	\$30.0	\$35.0	\$40.0	+82% - Royalty Rate of 20% including COGS
Total CHS-0214 Ex-U.S. Coherus Royalties (\$MM)					\$15	\$40	\$60	\$85	\$105	\$125	+83%
% Growth						+167%	+50%	+42%	+24%	+19%	

Source: Cowen and Company; Company Reports

Figure 30 CHS-1701 Market Model

ESTIMATED NEULASTA WW SALES											
	2019	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	CAGR Comments
Neulasta WW Sales (AMGN)											
Estimated U.S. Neulasta Sales (\$MM)	\$3,477	\$3,637	\$3,660	\$3,595	\$3,505	\$3,420	\$3,335	\$3,170	\$3,010	\$2,850	-2%
% Growth		+5%	+1%	-2%	-3%	-2%	-2%	-5%	-5%	-5%	
% of Total Neulasta Sales	79.2%	78.8%	79.1%	79.9%	79.7%	79.5%	79.4%	79.3%	79.2%	79.2%	
Estimated Ex-U.S. Neulasta Sales (\$MM)	\$915	\$980	\$965	\$905	\$895	\$880	\$865	\$830	\$790	\$750	-2%
% Growth		+7%	-2%	-6%	-1%	-2%	-2%	-4%	-5%	-5%	
% of Total Neulasta Sales	20.8%	21.2%	20.9%	20.1%	20.3%	20.5%	20.6%	20.8%	20.8%	20.8%	
Total Neulasta WW Sales (\$MM)	\$4,392	\$4,617	\$4,625	\$4,500	\$4,400	\$4,300	\$4,200	\$4,000	\$3,800	\$3,600	-2%
% Growth		+5%	+0%	-3%	-2%	-2%	-2%	-5%	-5%	-5%	
ESTIMATED CHS-1701 WW SALES											
	2019	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	CAGR Comments
CHS-1701 Penetration of U.S. Neulasta Sales											
					1.0%	2.0%	3.0%	4.0%	5.0%	6.0%	
Estimated CHS-1701 U.S. Market Sales (\$MM)					\$80.0	\$60.0	\$85.0	\$110.0	\$180.0	\$145.0	+87% - Price Discount of 15% from Neulasta
% Growth					+100%	+42%	+23%	+18%	+12%		
CHS-1701 Penetration of Ex-U.S. Neulasta Sales											
					2.5%	4.0%	6.0%	8.0%	10.0%		
Estimated CHS-1701 Assumed Partner Ex-U.S. Market Sales (\$MM)					\$20.0	\$30.0	\$40.0	\$55.0	\$65.0	\$65.0	+84% - Price Discount of 15% from Neulasta
% Growth					+50%	+33%	+33%	+18%	+14%		
Royalty Revenue to Coherus					\$5.0	\$5.0	\$10.0	\$10.0	\$15.0	\$15.0	+82% - Royalty Rate of 20% including COGS
Total CHS-1701 Market Sales (\$MM)											
% Growth					+117%	+38%	+33%	+17%	+14%		

Source: Cowen and Company; Company Reports

Figure 31 Coherus Annual P&L

COHERUS - 2014-2023 ESTIMATED ANNUAL EPS BUILDUP (\$MM)												
	2013	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	CGR Comments
CHS-1420 (Humira) U.S. Direct Revenue					\$65.0	\$140.0	\$220.0	\$295.0	\$385.0	\$470.0	\$575.0	+16% - CHS-1420 completed Phase I studies; U.S. launch in mid-2017
Growth Rate						+115%	+57%	+34%	+31%	+22%	+22%	
CHS-1420 (Humira) Ex-U.S. Royalty Revenue						\$30.0	\$60.0	\$80.0	\$100.0	\$120.0	\$145.0	+9% - Ex-U.S. launch in mid-2018
Growth Rate							+100%	+33%	+25%	+20%	+20%	
CHS-0214 (Enbrel) Ex-U.S. Royalty Revenue					\$15.0	\$40.0	\$60.0	\$85.0	\$105.0	\$125.0	\$150.0	+14% - CHS-0214 conducting Phase III studies; Ex-U.S. launch in early 2017
Growth Rate						+167%	+50%	+42%	+24%	+19%	+20%	
CHS-1701 (Neulasta) U.S. Direct Revenue					\$30.0	\$60.0	\$85.0	\$110.0	\$130.0	\$145.0	\$175.0	+11% - CHS-1420 completed Phase I studies; U.S. launch in mid-2017
Growth Rate						+100%	+42%	+29%	+18%	+12%	+20%	
CHS-1701 (Neulasta) Ex-U.S. Royalty Revenue						\$5.0	\$5.0	\$10.0	\$10.0	\$15.0	\$20.0	+11% - Ex-U.S. launch in mid-2018
Growth Rate							+0%	+100%	+0%	+50%	+20%	
Licensing Revenues	\$2.8	\$10.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	- Daiichi Sankyo, Baxter
Growth Rate												
Total Coherus Revenues	\$2.8	\$10.0	\$0.0	\$0.0	\$110.0	\$275.0	\$430.0	\$580.0	\$730.0	\$875.0	\$1,085.0	+16%
% Change						+150%	+56%	+35%	+26%	+20%	+22%	
Cost of Goods	\$0.0	\$0.0	\$0.0	\$0.0	\$15.0	\$40.0	\$65.0	\$85.0	\$110.0	\$130.0	\$160.0	
Gross Profit	\$2.8	\$10.0	\$0.0	\$0.0	\$95.0	\$235.0	\$365.0	\$495.0	\$620.0	\$745.0	\$905.0	
Gross Margin	100.0%	100.0%			85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	- Solid margins; factors in royalty licensing/partnering revenues
SG&A	\$7.5	\$15.0	\$30.0	\$45.0	\$75.0	\$90.0	\$105.0	\$120.0	\$135.0	\$150.0	\$165.0	+10% - Salesforce expansion beginning in 2017, in preparation for CHS-1420
% of Revs	NM	NM	NM	NM	68%	33%	24%	21%	18%	17%	15%	- Approximately 50 sales reps, 5 NAMs
R&D	\$31.3	\$65.0	\$80.0	\$100.0	\$110.0	\$120.0	\$130.0	\$120.0	\$110.0	\$100.0	\$90.0	-9% - Substantial clinical trial and regulatory costs
% of Revs	NM	NM	NM	NM	100.0%	43.6%	30.2%	20.7%	15.1%	11.4%	8.5%	- CHS-0214, CHS-1420, CHS-1701
Operating Expenses	\$38.7	\$80.0	\$110.0	\$145.0	\$185.0	\$210.0	\$235.0	\$240.0	\$245.0	\$250.0	\$255.0	+2%
% of Revenues	NM	NM	NM	NM	NM	76.4%	54.7%	41.4%	33.6%	28.6%	23.9%	
Operating Income	(\$36.0)	(\$70.0)	(\$110.0)	(\$145.0)	(\$90.0)	\$25.0	\$130.0	\$255.0	\$375.0	\$495.0	\$650.0	- Operating profit expected in 2018
% Operating Margin	NM	NM	NM	NM	NM	NM	30.2%	44.0%	51.4%	56.6%	61.0%	
Non-Operating Income												
Interest Income	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	
Interest Expense	(5.3)	(7.8)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Other Income	(12.3)	(14.6)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Non-Operating Income	(\$17.6)	(\$22.4)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	
Pretax Income	(\$53.6)	(\$92.4)	(\$110.0)	(\$145.0)	(\$90.0)	\$25.0	\$130.0	\$255.0	\$375.0	\$495.0	\$650.0	NM
% of Revs	NM	NM	NM	NM	NM	NM	30.2%	44.0%	51.4%	56.6%	61.0%	
Income Taxes							\$45.5	\$89.3	\$131.3	\$173.3	\$227.5	NM
Income Tax Rate							35.0%	35.0%	35.0%	35.0%	35.0%	
Net Income - Operations	(\$53.6)	(\$92.4)	(\$110.0)	(\$145.0)	(\$90.0)	\$25.0	\$84.5	\$165.8	\$243.8	\$321.8	\$422.5	NM
% Net Margin	NM	NM	NM	NM	NM	NM	19.7%	28.6%	33.4%	36.8%	39.7%	
Extraordinary Items	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	
Reported Net Income	(\$53.6)	(\$92.4)	(\$110.0)	(\$145.0)	(\$90.0)	\$25.0	\$84.5	\$165.8	\$243.8	\$321.8	\$422.5	NM
Interest Add-Back	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	
EPS (Non-GAAP) - Before Ex. Item:	(\$2.19)	(\$2.50)	(\$2.90)	(\$3.65)	(\$2.15)	\$0.55	\$1.85	\$3.45	\$4.90	\$6.20	\$7.80	NM - Profitable in 2018 following Ex-US launches of CHS-1420/1710
Growth	NM	NM	NM	NM	NM	NM	NM	NM	+42%	+27%	+26%	
EPS - Extraordinary Items	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	
EPS - Reported	(\$2.19)	(\$2.50)	(\$2.90)	(\$3.65)	(\$2.15)	\$0.55	\$1.85	\$3.45	\$4.90	\$6.20	\$7.80	NM
Shares - Fully Diluted (MM)	24.5	37.3	38.0	40.0	42.0	44.0	46.0	48.0	50.0	52.0	54.0	- Diluted shares; assuming some onward dilution from options

Source: Company Reports; Cowen and Company

Figure 32 Coherus Base Case Scenario DCF Indicates \$45 Per Share

Assumptions:		Output:																					
Increase in WC	5.0%	Equity Value	\$1,696.1																				
Discount Rate	11.0%	Estimated Share Price	\$45.00																				
Shares Outstanding	37.3	Net Cash	\$108.9																				
		Enterprise Value	\$1,805.0																				
COHERUS DCF																							
	2011P	2012P	2013P	2014P	2015P	2016P	2017P	2018P	2019P	2020P	2021P	2022P	2023P	2024P	2025P	2026P	2027P	2028P	2029P	2030P	2031P	2032P	2033P
Total Revenues			\$2.8	\$10.0	\$0.0	\$0.0	\$110.0	\$275.0	\$430.0	\$580.0	\$730.0	\$875.0	\$1,065.0	\$1,260.0	\$1,430.0	\$1,550.0	\$1,605.0	\$1,630.0	\$1,510.0	\$1,410.0	\$1,315.0	\$1,225.0	\$1,145.0
% Change								+150%	+56%	+35%	+26%	+20%	+22%	+18%	+13%	+8%	+4%	+2%	-7%	-7%	-7%	-7%	-7%
Cost of Goods			\$0.0	\$0.0	\$0.0	\$0.0	\$15.0	\$40.0	\$65.0	\$85.0	\$110.0	\$130.0	\$160.0	\$190.0	\$215.0	\$230.0	\$240.0	\$245.0	\$225.0	\$210.0	\$195.0	\$185.0	\$170.0
Gross Profit			\$2.8	\$10.0	\$0.0	\$0.0	\$95.0	\$235.0	\$365.0	\$495.0	\$620.0	\$745.0	\$905.0	\$1,070.0	\$1,215.0	\$1,320.0	\$1,365.0	\$1,385.0	\$1,285.0	\$1,200.0	\$1,120.0	\$1,040.0	\$975.0
Gross Margin - Total			100.0%	100.0%			85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
SG&A			\$7.5	\$15.0	\$30.0	\$45.0	\$75.0	\$90.0	\$105.0	\$120.0	\$135.0	\$150.0	\$165.0	\$180.0	\$195.0	\$210.0	\$225.0	\$200.0	\$185.0	\$170.0	\$150.0	\$120.0	\$90.0
% of Revs			NM	NM	NM	NM	68.2%	32.7%	24.4%	20.7%	18.5%	17.1%	15.5%	14.3%	13.6%	13.5%	14.0%	12.3%	12.3%	12.1%	9.1%	6.5%	4.4%
R&D			\$31.3	\$65.0	\$80.0	\$100.0	\$110.0	\$120.0	\$130.0	\$140.0	\$150.0	\$160.0	\$170.0	\$180.0	\$190.0	\$200.0	\$210.0	\$225.0	\$200.0	\$185.0	\$170.0	\$150.0	\$120.0
% of Revs			NM	NM	NM	NM	100.0%	43.6%	30.2%	20.7%	15.1%	11.4%	8.5%	6.3%	4.9%	3.9%	3.1%	2.5%	2.0%	1.4%	0.8%	0.4%	0.4%
Operating Expenses			\$38.7	\$80.0	\$110.0	\$145.0	\$185.0	\$210.0	\$235.0	\$240.0	\$245.0	\$250.0	\$255.0	\$260.0	\$265.0	\$270.0	\$275.0	\$240.0	\$215.0	\$190.0	\$130.0	\$85.0	\$55.0
% of Revenues			NM	NM	NM	NM	76.4%	54.7%	41.4%	33.6%	28.6%	23.9%	20.6%	18.5%	17.4%	17.1%	14.7%	14.2%	13.5%	9.9%	6.9%	4.8%	
Operating Income			(\$36.0)	(\$70.0)	(\$110.0)	(\$145.0)	(\$90.0)	\$25.0	\$130.0	\$255.0	\$375.0	\$495.0	\$650.0	\$810.0	\$950.0	\$1,050.0	\$1,090.0	\$1,145.0	\$1,070.0	\$1,010.0	\$990.0	\$955.0	\$920.0
% Operating Margin			NM	NM	NM	NM	NM	9.1%	30.2%	44.0%	51.4%	56.6%	61.0%	64.3%	66.4%	67.7%	67.9%	70.2%	70.9%	71.6%	75.3%	78.0%	80.3%
Other Income			(\$12.3)	(\$16.6)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Adjusted EBIT			(\$48.3)	(\$84.6)	(\$110.0)	(\$145.0)	(\$90.0)	\$25.0	\$130.0	\$255.0	\$375.0	\$495.0	\$650.0	\$810.0	\$950.0	\$1,050.0	\$1,090.0	\$1,145.0	\$1,070.0	\$1,010.0	\$990.0	\$955.0	\$920.0
% of Revs			NM	NM	NM	NM	NM	9.1%	30.2%	44.0%	51.4%	56.6%	61.0%	64.3%	66.4%	67.7%	67.9%	70.2%	70.9%	71.6%	75.3%	78.0%	80.3%
Taxes							\$0.0	\$45.5	\$89.3	\$131.3	\$173.3	\$227.5	\$283.5	\$332.5	\$387.5	\$431.5	\$460.8	\$374.5	\$353.5	\$346.5	\$334.3	\$322.0	
Income Tax Rate							0.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%
NOPAT			(\$48.3)	(\$84.6)	(\$110.0)	(\$145.0)	(\$90.0)	\$25.0	\$84.5	\$165.8	\$243.8	\$321.8	\$422.5	\$526.5	\$617.5	\$682.5	\$708.5	\$744.3	\$695.5	\$656.5	\$643.5	\$620.8	\$598.0
Adjustments:																							Terminal
Capex			(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$5.0)	(\$5.0)	(\$5.0)	(\$5.0)
Depreciation & Amortization			\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$6.0	\$6.0	\$6.0
Change In Working Capital			(\$3.0)	(\$3.2)	(\$3.3)	(\$3.5)	(\$3.6)	(\$3.8)	(\$4.0)	(\$4.2)	(\$4.4)	(\$4.7)	(\$4.9)	(\$5.1)	(\$5.4)	(\$5.7)	(\$5.9)	(\$6.2)	(\$6.5)	(\$6.9)	(\$7.2)	(\$7.6)	(\$8.0)
Free Cash Flow			(\$56.3)	(\$92.8)	(\$118.3)	(\$153.5)	(\$98.6)	\$16.2	\$75.5	\$156.5	\$234.3	\$312.1	\$412.6	\$516.4	\$607.1	\$671.8	\$697.6	\$733.0	\$684.0	\$649.6	\$637.3	\$614.2	\$591.0

Source: Company Reports; Cowen and Company

Figure 33 Coherus Acquisition Scenario DCF Indicates \$60 Per Share

Assumptions:		Output:																					
Increase in WC	5.0%	Equity Value	\$2,231.1																				
Discount Rate	11.0%	Estimated Share Price	\$60.00																				
Shares Outstanding	37.3	Net Cash	\$108.9																				
		Enterprise Value	\$2,340.0																				
COHERUS DCF																							
	2011P	2012P	2013P	2014P	2015P	2016P	2017P	2018P	2019P	2020P	2021P	2022P	2023P	2024P	2025P	2026P	2027P	2028P	2029P	2030P	2031P	2032P	2033P
Total Revenues			\$2.8	\$10.0	\$0.0	\$0.0	\$110.0	\$275.0	\$430.0	\$580.0	\$730.0	\$875.0	\$1,065.0	\$1,260.0	\$1,430.0	\$1,550.0	\$1,605.0	\$1,630.0	\$1,510.0	\$1,410.0	\$1,315.0	\$1,225.0	\$1,145.0
% Change								+150%	+56%	+35%	+26%	+20%	+22%	+18%	+13%	+8%	+4%	+2%	-7%	-7%	-7%	-7%	-7%
Cost of Goods			\$0.0	\$0.0	\$0.0	\$0.0	\$15.0	\$40.0	\$65.0	\$85.0	\$110.0	\$130.0	\$160.0	\$190.0	\$215.0	\$230.0	\$240.0	\$245.0	\$225.0	\$210.0	\$195.0	\$185.0	\$170.0
Gross Profit			\$2.8	\$10.0	\$0.0	\$0.0	\$95.0	\$235.0	\$365.0	\$495.0	\$620.0	\$745.0	\$905.0	\$1,070.0	\$1,215.0	\$1,320.0	\$1,365.0	\$1,385.0	\$1,285.0	\$1,200.0	\$1,120.0	\$1,040.0	\$975.0
Gross Margin - Total			100.0%	100.0%			85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
SG&A			\$7.5	\$15.0	\$30.0	\$45.0	\$75.0	\$90.0	\$105.0	\$120.0	\$135.0	\$150.0	\$165.0	\$180.0	\$195.0	\$210.0	\$225.0	\$200.0	\$185.0	\$170.0	\$150.0	\$120.0	\$90.0
% of Revs			NM	NM	NM	NM	68.2%	32.7%	24.4%	20.7%	18.5%	17.1%	15.5%	14.3%	13.6%	13.5%	14.0%	12.3%	12.3%	12.1%	9.1%	6.5%	4.4%
R&D			\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
% of Revs			NM	NM	NM	NM	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Operating Expenses			\$7.5	\$15.0	\$30.0	\$45.0	\$75.0	\$90.0	\$105.0	\$120.0	\$135.0	\$150.0	\$165.0	\$180.0	\$195.0	\$210.0	\$225.0	\$200.0	\$185.0	\$170.0	\$150.0	\$120.0	\$90.0
% of Revenues			NM	NM	NM	NM	32.7%	24.4%	20.7%	18.5%	17.1%	15.5%	14.3%	13.6%	13.5%	14.0%	12.3%	12.3%	12.1%	9.1%	6.5%	4.4%	
Operating Income			(\$4.7)	(\$5.0)	(\$30.0)	(\$45.0)	\$20.0	\$145.0	\$260.0	\$375.0	\$485.0	\$595.0	\$740.0	\$890.0	\$1,020.0	\$1,110.0	\$1,140.0	\$1,185.0	\$1,100.0	\$1,030.0	\$1,000.0	\$960.0	\$925.0
% Operating Margin			NM	NM	NM	NM	NM	52.7%	60.5%	64.7%	66.4%	68.0%	69.5%	70.6%	71.3%	71.6%	71.0%	72.7%	72.8%	73.0%	76.0%	78.4%	80.8%
Other Income			(\$12.3)	(\$16.6)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Adjusted EBIT			(\$17.1)	(\$19.6)	(\$30.0)	(\$45.0)	\$20.0	\$145.0	\$260.0	\$375.0	\$485.0	\$595.0	\$740.0	\$890.0	\$1,020.0	\$1,110.0	\$1,140.0	\$1,185.0	\$1,100.0	\$1,030.0	\$1,000.0	\$960.0	\$925.0
% of Revs			NM	NM	NM	NM	NM	52.7%	60.5%	64.7%	66.4%	68.0%	69.5%	70.6%	71.3%	71.6%	71.0%	72.7%	72.8%	73.0%	76.0%	78.4%	80.8%
Taxes							\$0.0	\$91.0	\$131.3	\$169.8	\$208.3	\$259.0	\$311.5	\$357.0	\$398.5	\$399.0	\$414.8	\$385.0	\$360.5	\$335.0	\$336.0	\$323.8	
Income Tax Rate							0.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%
NOPAT			(\$17.1)	(\$19.6)	(\$30.0)	(\$45.0)	\$20.0	\$145.0	\$169.8	\$243.8	\$315.3	\$386.8	\$481.0	\$578.5	\$663.0	\$721.5	\$741.0	\$770.3	\$715.0	\$669.5	\$650.0	\$624.0	\$601.3
Adjustments:																							Terminal
Capex			(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$10.0)	(\$5.0)	(\$5.0)	(\$5.0)	(\$5.0)
Depreciation & Amortization			\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$5.0	\$6.0	\$6.0	\$6.0
Change in Working Capital			(\$3.0)	(\$3.2)	(\$3.3)	(\$3.5)	(\$3.6)	(\$3.8)	(\$4.0)	(\$4.2)	(\$4.4)	(\$4.7)	(\$4.9)	(\$5.1)	(\$5.4)	(\$5.7)	(\$5.9)	(\$6.2)	(\$6.5)	(\$6.9)	(\$7.2)	(\$7.6)	(\$8.0)
Free Cash Flow			(\$25.1)	(\$27.8)	(\$38.3)	(\$53.5)	\$11.4	\$136.2	\$160.0	\$234.5	\$305.8	\$377.1	\$471.1	\$568.4	\$652.6	\$710.8	\$730.1	\$759.0	\$703.5	\$662.6	\$643.8	\$617.4	\$594.3

Source: Company Reports; Cowen and Company

## *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
ABBV	AbbVie
ACT	Actavis
AMGN	Amgen
CHRS	Coherus BioSciences
JAZZ	Jazz Pharmaceuticals
TEVA	Teva Pharmaceutical

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### COWEN AND COMPANY RATING DEFINITIONS

**Cowen and Company Rating System effective May 25, 2013**

**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

**Cowen Securities, formerly known as Dahlman Rose & Company, Rating System until May 25, 2013**

**Buy** – The fundamentals/valuations of the subject company are improving and the investment return is expected to be 5 to 15 percentage points higher than the general market return

**Sell** – The fundamentals/valuations of the subject company are deteriorating and the investment return is expected to be 5 to 15 percentage points lower than the general market return

**Hold** – The fundamentals/valuations of the subject company are neither improving nor deteriorating and the investment return is expected to be in line with the general market return

## Cowen And Company Rating Definitions

### Distribution of Ratings/Investment Banking Services (IB) as of 09/30/14

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	440	59.95%	105	23.86%
Hold (b)	278	37.87%	10	3.60%
Sell (c)	16	2.18%	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.

Note: "Buy", "Hold" and "Sell" are not terms that Cowen and Company, LLC uses in its ratings system and should not be construed as investment options. Rather, these ratings terms are used illustratively to comply with FINRA and NYSE regulations.

### AbbVie Rating History as of 11/28/2014

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### Actavis Rating History as of 11/28/2014

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### Amgen Rating History as of 11/28/2014

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### Coherus BioSciences Rating History as of 11/28/2014

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### Jazz Pharmaceuticals Rating History as of 11/28/2014

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