

Coherus

4Q CC Takeaways: Several Positive Updates; Well-Positioned for Emerging Biosimilar Opportunity - ALERT

This afternoon, Coherus reported 4Q earnings and provided an update on the development of its lead biosimilars. The company remains on track for a potential CHS-1701 (biosimilar Neulasta) BLA filing in late 2015/early 2016, a potential CHS-0214 (biosimilar Enbrel) MAA filing in mid-2016, and a potential CHS-1420 (biosimilar Humira) BLA filing in 2H 2016. With biosimilars increasingly in focus and a highly experienced management team, we see the company as well-positioned within this emerging market. Reiterate Overweight.

- **Recent Amgen/Sandoz ruling a “clear positive” for biosimilars.** Last week, a U.S. district court rejected Amgen’s motion for an injunction against Sandoz’s Zarxio (biosimilar Neupogen). Coherus management noted that the ruling was a “clear positive” for biosimilars as it held that the BPCIA “patent dance” is not mandatory, and that 180-day notice of launching can be given at the time of the BLA application. To the extent the ruling holds, biosimilar applicants now have additional optionality whether to disclose the BLA application to the originator.
- **We expect a CHS-1701 BLA in late 2015/early 2016.** Coherus recently initiated a second pivotal PK/PD study of CHS-1701 in healthy subjects, which, along with an immunogenicity study, could represent basis for a BLA filing in late 2015/early 2016. Management noted that based on discussions with regulators, they do not believe a phase III study will be required, particularly because (1) pegfilgrastim is a much less complex molecule than monoclonal antibodies, (2) the drug is used in an acute setting and not a chronic one, and (3) there is a similar effect on neutrophil PK in both healthy and sick patients.
- **Phase III CHS-1420 study in psoriasis (2Q expected start) should support broad label extrapolation.** Coherus remains committed to starting a phase III CHS-1420 psoriasis study in 2Q, which could support a BLA in 2H16. The global study will enroll roughly 500 psoriasis patients, and will include a switch from Humira to CHS-1420. Of note, management expects the psoriasis study to support global submissions with broad labels, though Coherus continues to evaluate conducting smaller studies in additional indications for commercial reasons.
- **Coherus working on early-stage pipeline, expects additional disclosures in 2H 2015.** On the call, management noted that they have started to focus more on their earlier-stage pipeline. While Coherus sees over 30 biosimilar opportunities through 2020, the company employs a very rigorous framework to evaluate these opportunities. Management noted that while they have not yet disclosed the molecules in development for competitive reasons, they expect to discuss the pipeline in more detail later this year.

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Overweight

CHRS, CHRS US

Price: \$25.60

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Pharmaceuticals — Major & Specialty

Chris Schott, CFA^{AC}

(1-212) 622-5676

christopher.t.schott@jpmorgan.com

Bloomberg JPMA SCHOTT <GO>

Wendy L Lin

(1-212) 622-5350

wendy.l.lin@jpmorgan.com

Aditi Singhanian, PhD

(1-212) 622-1267

aditi.singhanian@jpmorgan.com

Dana Flanders, CFA

(1-212) 622-1256

dana.c.flanders@jpmorgan.com

J.P. Morgan Securities LLC

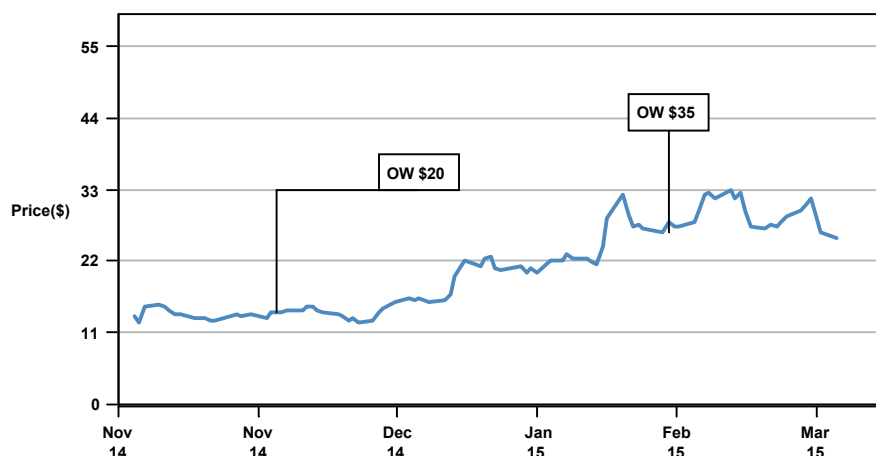
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Coherus (CHRS, CHRS US) Price Chart



Date	Rating	Share Price (\$)	Price Target (\$)
02-Dec-14	OW	14.14	20.00
17-Feb-15	OW	26.58	35.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Dec 02, 2014.

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