Coherus BioSciences Reports Second Quarter 2017 Corporate Highlights and Financial Results

Aug 7, 2017

REDWOOD CITY, Calif., Aug. 07, 2017 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (NASDAQ:CHRS), today reviewed corporate events and reported financial results for the quarter ended June 30, 2017.

Corporate Highlights for the Second Quarter 2017 Include:
Oncology therapeutic franchise:

- CHS-1701 (pegfilgrastim (Neulasta®) biosimilar candidate)
  - Announced completion of initial phases of the Biologic Price Competition and Innovation Act patent exchange with Amgen.
  - Announced receipt of complete response letter from U.S. Food and Drug Administration for CHS-1701's biologic license application ("BLA").

Immunology (anti-TNF) therapeutic franchise:

- CHS-1420 (adalimumab (Humira®) biosimilar candidate)
  - Received decisions from the Patent Trial and Appeal Board of the United States Patent and Trademark Office ("PTAB") in favor of Coherus' petition for Inter Partes Review invalidating all of the claims of AbbVie's U.S. Patents 8,889,135; 9,017,680 and 9,073,987.

Financial Highlights for the Second Quarter and year-to-date 2017

- **Cash used in operations** was $55.6 million in the second quarter and was down 24% from the $73.3 million used in the first quarter of 2017.
- **Total revenue** for the second quarter of 2017 was $1.4 million, as compared to $14.1 million in the second quarter of 2016. Total revenue for the six months ended June 30, 2017 was $1.6 million, as compared to $26.4 million for the same period in 2016. The decrease in revenue from the same period in 2016 was mainly attributable to the termination of an agreement for CHS-0214 (etanercept (Enbrel) biosimilar candidate) with Shire plc (whereupon Coherus regained rights to CHS-0214) in the third quarter of 2016.
- **Research and development (R&D)** expenses for the second quarter of 2017 were $34.5 million, as compared to $65.5 million for the same period in 2016. R&D expenses for the six months ended June 30, 2017 were $88.3 million, as compared to $130.9 million for the same period in 2016. Decreases in R&D expenses were mainly attributable to the completion of Phase 3 and Phase 1 clinical studies for CHS-0214 and CHS-1420 in 2016 and a decrease in other development costs for our pipeline products.
- **General and administrative (G&A)** expenses for the second quarter of 2017 were $23.5 million, as compared to $11.3 million for the same period in 2016. G&A expenses for the six months ended June 30, 2017 were $42.3 million, as compared to $22.7 million for the same period in 2016. Changes in G&A expenses were mainly attributable to legal and other professional fees to support the intellectual property strategy, as well as personnel related costs to support CHS-1701 pre-commercial activities in the first six months of 2017.
- **Net loss** attributable to Coherus for the second quarter of 2017 was ($55.3) million, or ($1.08) per share, as compared to ($70.0) million, or ($1.72) per share, for the same period in 2016.
- **Cash, cash equivalents and investments in marketable securities – short term** totaled $118.3 million as of June 30, 2017, as compared to $174.8 million as of March 31, 2017.

Guidance for the second half of 2017 and first half of 2018:
Oncology therapeutic franchise:

- CHS-1701 (pegfilgrastim biosimilar)
  - Anticipate resubmitting the BLA in the U.S. at the end of the fourth quarter of 2017.
- Anticipate European positive opinion in the first half of 2018, such timing being dependent upon data requests.
  - Commercial partnering discussions are underway for certain ex-U.S. territories.

Immunology (anti-TNF) therapeutic franchise:

- CHS-1420 (adalimumab biosimilar)
  - Anticipate a decision from the PTAB on the petition for Inter Partes Review of AbbVie's U.S. Patent 9,085,619 no later than September 12, 2017.
  - Continue to advance intellectual property strategies, supporting potential 2019 launch.
  - Initiate a pharmacokinetic study with a formulation not impacted by AbbVie's U.S. Patent 9,114,166 in the second half of 2017.

- Anticipate a BLA submission in the U.S. during the first half of 2018.
- CHS-0214 (etanercept biosimilar)
  - Focus on US legal and regulatory issues through the first half of 2018.
  - Provide revised guidance on filing of the marketing authorization application in Europe after CHS-1701 U.S. BLA resubmission.
- Targeting immunology (anti-TNF) partnering therapeutic franchise agreement with discussions ongoing.
- CHS-131 central nervous system anti-inflammatory asset
  - Completing additional animal studies on CHS-131 to further validate its mechanism of action and address drug-derived metabolites. Licensing agreement to follow subject to results.

Cash flow:

- Management anticipates cash usage of approximately $40 - $45 million per quarter in the second half of 2017 and $30 - $35 million per quarter in the first half of 2018.

Conference Call Information
When: August 7, 2017 at 4:30 p.m. ET
Dial-in: (844) 452-6826 (toll free) or (765) 507-2587 (International)
Conference ID: 52510570
Webcast: http://investors.coherus.com
Please join the conference call at least 10 minutes early to register. The webcast will be archived on the Coherus website.

About Coherus BioSciences, Inc.
Coherus is a leading pure-play, global biosimilar company that develops and commercializes high-quality therapeutics for major regulated markets. Biosimilars are intended for use in place of existing, branded biologics to treat a range of chronic and often life-threatening diseases, with the potential to reduce costs and expand patient access. Composed of a team of proven industry veterans with world-class expertise in process science, analytical characterization, protein production, sales & marketing and clinical-regulatory development, Coherus is positioned as a leader in the global biosimilar marketplace. Coherus is advancing three late-stage clinical products towards commercialization, CHS-1701 (pegfilgrastim biosimilar), CHS-1420 (adalimumab biosimilar) and CHS-0214 (etanercept biosimilar), as well as developing a robust pipeline of future products in four therapeutic areas, oncology, immunology (anti-TNF), ophthalmology and multiple sclerosis. For additional information, please visit www.coherus.com.

Forward-Looking Statements
Except for the historical information contained herein, the matters set forth in this press release, including statements regarding Coherus' plans, potential opportunities, expectations, projections, goals, objectives, milestones, strategies, product pipeline, clinical studies, product development, release of data and the potential benefits of its products under development are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including Coherus' ability to resubmit the U.S. BLA with the FDA, obtain European approval and complete a partnering agreement for CHS-1701; initiate a pharmacokinetic study for CHS-1420, file a BLA for and launch CHS-1420; complete a partnering agreement for its immunology (anti-TNF) therapeutic franchise; complete additional studies for and enter into a licensing agreement with respect to CHS-131; and achieve the target ranges for cash use of $40 – 45 million per quarter in second half of 2017 and $30 – 35 million per quarter in the first half of 2018. Such forward-looking statements involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the clinical drug development process, including the regulatory approval process, the timing of our regulatory filings and other matters that could affect the availability or commercial potential of our biosimilar drug candidates, as well as possible patent litigation. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Coherus' business in general, see Coherus' Quarterly Report on Form 10-Q for the period ended June 30, 2017, filed with the Securities and Exchange Commission on August 7, 2017 and its future periodic reports to be filed with the Securities and Exchange Commission.

Neulasta® is a registered trademark of Amgen Inc.
Enbrel® is a registered trademark of Immunex Corporation.
Humira® is a registered trademark of AbbVie Biotechnology Ltd.

Coherus BioSciences, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)		*(unaudited)*	
Revenue:				
Collaboration and license revenue	$ 1,395	$ 14,068	$ 1,556	$ 26,427
Operating expenses:				
Research and development	34,500	65,544	88,275	130,857
General and administrative	23,533	11,260	42,336	22,658
Total operating expenses	58,033	76,804	130,611	153,515
Loss from operations	(56,638)	(62,736)	(129,055)	(127,088)
Interest expense	(2,384)	(2,354)	(4,760)	(3,191)

Other income (expense), net	3,620	(5,060)	3,591	(5,409)
Net loss	(55,402)	(70,150)	(130,224)	(135,688)
Net loss attributable to non-controlling interest	66	183	110	333
Net loss attributable to Coherus	$ (55,336)	$ (69,967)	$ (130,114)	$ (135,355)
Net loss per share attributable to Coherus, basic and diluted	$ (1.08)	$ (1.72)	$ (2.60)	$ (3.39)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	51,291,787	40,698,309	50,008,999	39,897,142

Coherus BioSciences, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2017	December 31, 2016
	(unaudited)	
Assets		
Cash and cash equivalents	$ 73,352	$ 124,947
Investments in marketable securities - short-term	44,980	-
Other assets	53,919	53,538
Total assets	$ 172,251	$ 178,485
Liabilities and Stockholders' Equity		
Deferred revenue	$ -	$ 1,561
Convertible notes	75,687	75,192
Convertible notes-related parties	25,229	25,064
Other liabilities	40,478	57,314
Total stockholders' equity	30,857	19,354
Total liabilities and stockholders' equity	$ 172,251	$ 178,485

CONTACT:
Patrick O'Brien
Senior Vice President, Investor Relations
Coherus BioSciences, Inc.
pobrien@coherus.com
+1 (650) 649-3527

Coherus BioSciences, Inc.