Coherus BioSciences Reports Corporate Highlights and Second Quarter 2018 Financial Results

REDWOOD CITY, Calif., Aug. 08, 2018 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq: CHRS), today reviewed corporate highlights and reported financial results for the quarter ended June 30, 2018.

Second Quarter 2018 Corporate Highlights Include:

- UDENYCA™ (pegfilgrastim-cbqv), biosimilar candidate to Neulasta®

• On May 3, 2018, Coherus announced the re-submission of its biologics license application (BLA) to the U.S. Food and Drug Administration (FDA) under the 351(k) pathway.
• On May 14, 2018, Coherus announced the FDA accepted and acknowledged for review the resubmission of this BLA.
• On May 28, 2018, Coherus submitted its day-181 responses to the European Medicines Agency's day-180 questions regarding its marketing authorization application in Europe.
• On July 26, 2018, Coherus received a positive opinion for marketing authorization from the Committee for Medicinal Products for Human Use of the European Medicines Agency.

- On May 10, 2018, Coherus announced the appointment of Samuel Nussbaum, M.D. to its Board of Directors. From 2000 until 2016, Dr. Nussbaum served as Executive Vice President, Clinical Health Policy, and Chief Medical Officer for Anthem. In that role, he was the key spokesperson and policy advocate and oversaw clinical strategy and corporate medical and pharmacy policy. He currently serves as a Strategic Consultant to EBG Advisors, consulting arm for Epstein Becker and Green, where he advises life science companies, health care systems and provider organizations.
- In May 2018, Coherus completed an underwritten public offering of 5,948,274 shares of its common stock at a price to the public of $14.50 per share, which includes the closing of the full exercise of the underwriters' option to purchase an additional 775,861 shares of common stock. Coherus received net proceeds of $80.8 million from the offering.

Second Quarter 2018 Financial Results:

- **Research and development (R&D)** expenses for the second quarter of 2018 were $26.5 million compared to $34.5 million for the same period in 2017. R&D expenses for the six months ended June 30, 2018 were $52.0 million, as compared to $88.3 million for the same period in 2017. The decreases in R&D expenses were mainly due to the completion of our clinical trials for the immunology biosimilar drug candidates, CHS-1420 (adalimumab (Humira®) biosimilar) and CHS-0214 (etanercept (Enbrel®) biosimilar), and the reprioritization of resources to advance UDENYCA™.
- **General and administrative (G&A)** expenses for the second quarter of 2018 were $18.4 million, compared to $23.5 million for the same period in 2017. G&A expenses for the six months ended June 30, 2018 were $35.0 million, as compared to $42.3 million for the same period in 2017. The decreases in G&A expenses in 2018 were mainly attributable to a decrease in personnel and in certain legal and consulting services as a result of cost control steps taken since June 2017.
- **Net loss** attributable to Coherus for the second quarter of 2018 was ($43.6) million, or ($0.68) per share, compared to a net loss of ($55.3) million, or ($1.08) per share, for the same period in 2017.
- **Cash and cash equivalents and investments in marketable securities –** totaled $159.8 million as of June 30, 2018, compared to $95.2 million as of March 31, 2018.

Guidance for 2018:
UDENYCA™ (pegfilgrastim-cbqv), biosimilar candidate to Neulasta

- FDA action date is set for November 3, 2018.
- Anticipate regulatory approval for UDENYCA™ from the European Commission on or before October 1, 2018.
- Commercial partnering discussions are projected to continue for certain ex-U.S. territories.
- Anticipate U.S. commercial launch directly following the FDA action date, dependent on regulatory review and approval timing.

CHS-1420 (adalimumab (Humira®) biosimilar)

- Pursue manufacturing objectives in support of a BLA.
- Continue to develop partnering options for ex-U.S. territories.

CHS-3351 (ranibizumab (Lucentis®) biosimilar) and CHS-2020 (aflibercept (Eylea®) biosimilar)

- Initiate clinical development of CHS-3351.
- Continue preclinical development of CHS-2020.

Cash flow

- Anticipate cash use in operations of approximately $48 to $53 million for the third quarter of 2018.

Conference Call Information
When: Wednesday, August 8, 2018 at 4:30 p.m. ET
Dial-in: (844) 452-6826 (toll free) or (765) 507-2587 (International)
Conference ID: 4562488
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 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, UDENYCA™ (pegfilgrastim-cbqv), CHS-1420 (adalimumab biosimilar) and CHS-0214 (etanercept biosimilar), as well as developing a robust pipeline of future products in ophthalmology (including CHS-3351, a ranibizumab biosimilar, and CHS-2020, an aflibercept biosimilar), as well as CHS-131, a small molecule for nonalcoholic steatohepatitis (NASH) 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 are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, Coherus' expectations regarding the FDA's action date; Coherus' expectations regarding regulatory approval for UDENYCA™ from the European Commission; Coherus' ability to enter into commercial collaborations in ex-U.S. territories; Coherus' plan to initiate U.S. commercial launch for UDENYCA™; Coherus' plan to initiate the clinical development of CHS-3351; Coherus' expectation to continue the preclinical development of CHS-2020; Coherus' ability to pursue manufacturing objectives of CHS-1420 in support of a BLA; Coherus' plan to continue to develop partnering options of CHS-1420 for ex-US territories; and Coherus' ability to anticipate cash use for the third quarter of 2018. Such forward-looking statements involve substantial risks and uncertainties that could cause Coherus' actual results, performance or achievements to differ significantly from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the risks and uncertainties inherent in the clinical drug development process; the risks and uncertainties of the regulatory approval process, including the timing of Coherus' regulatory filings; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus' biosimilar drug candidates; and the risks and uncertainties of possible patent litigation. All forward-looking statements contained in this press release speak only as of the date on which they were made. 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 three and six months ended June 30, 2018, filed with the Securities and Exchange Commission on August 8, 2018 and its future periodic reports to be filed with the Securities and Exchange Commission. Our results for the quarter ended June 30, 2018 are not necessarily indicative of our operating results for any future periods.

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,	
	2018	2017	2018	2017
	(unaudited)		*(unaudited)*	
Revenue:				
Collaboration and license revenue	$ -	$ 1,395	$ -	$ 1,556
Operating expenses:				
Research and development	26,519	34,500	51,974	88,275
General and administrative	18,391	23,533	34,968	42,336
Total operating expenses	44,910	58,033	86,942	130,611
Loss from operations	(44,910)	(56,638)	(86,942)	(129,055)
Interest expense	(2,417)	(2,384)	(4,825)	(4,760)
Other income, net	3,642	3,620	3,780	3,591
Net loss	(43,685)	(55,402)	(87,987)	(130,224)
Net loss attributable to non-controlling interest	47	66	52	110
Net loss attributable to Coherus	$ (43,638)	$ (55,336)	$ (87,935)	$ (130,114)
Net loss per share attributable to Coherus, basic and diluted	$ (0.68)	$ (1.08)	$ (1.42)	$ (2.60)

Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	63,960,567	51,291,787	62,051,912	50,008,999

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

	June 30, 2018	December 31, 2017
	(unaudited)	
Assets		
Cash and cash equivalents	$ 130,005	$ 126,911
Investments in marketable securities - short-term	29,813	-
Other assets	28,495	35,700
Total assets	$ 188,313	$ 162,611
Liabilities and Stockholders' Equity		
Convertible notes	$ 76,750	$ 76,206
Convertible notes-related parties	25,583	25,402
Other liabilities	24,149	30,468
Total stockholders' equity	61,831	30,535
Total liabilities and stockholders' equity	$ 188,313	$ 162,611

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