Coherus BioSciences Reports Third Quarter 2017 Operating and Financial Results

REDWOOD CITY, Calif., Nov. 06, 2017 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq:CHRS), today reported financial results and reviewed corporate events for the third quarter ended September 30, 2017.

Corporate Highlights for the Third Quarter 2017 Include:
Immunology (anti-TNF) therapeutic franchise:

- CHS-0214 (etanercept (Enbrel®) biosimilar candidate)
  - Filed petitions for Inter Partes Review ("IPR") in the United States Patent and Trademark Office seeking invalidation of U.S. Patents 8,163,522 (" '522 patent") and 8,063,182,
  - (" '182 patent"). Both are generally directed to the etanercept protein, the pharmaceutically active component of Enbrel
  - We expect the PTAB to enter decisions on whether to institute these two IPRs by March 13, 2018 (for the '522 patent) and by March 26, 2018 (for the '182 patent).
- CHS-1420 (adalimumab (Humira®) biosimilar candidate)
  - Reported topline results from a pharmacokinetic bioequivalence ("PK BE") study comparing CHS-1420 to European marketed Humira. The study met the criteria for clinical PK BE on all prospectively defined endpoints and there were no clinically meaningful differences in the safety profile between the two products.

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

- **Cash used in operations** was $41.5 million in the third quarter, down 25% from the $55.6 million used in the second quarter of 2017 and down 43% from the $73.3 million used in the first quarter of 2017. In August 2017, we announced that Temasek, an investment company headquartered in Singapore, plans to invest up to $150 million over two tranches. We received the first tranche of $75 million in aggregate proceeds on August 24, 2017 and issued 6,556,116 shares of common stock at an offer price of $11.4397 per share. The second tranche is projected to be funded following receipt of the U.S. Food and Drug Administration's marketing approval for the CHS-1701 pegfilgrastim biosimilar product candidate, subject to market pricing and certain closing conditions at that time, including each party's final approval.
- **Research and development (R&D)** expenses for the third quarter of 2017 were $42.6 million, as compared to $64.6 million for the same period in 2016. R&D expenses for the nine months ended September 30, 2017 were $130.9 million, as compared to $195.4 million for the same period in 2016. Decreases in R&D expenses were mainly attributable to the decline and end of clinical activities for CHS-0214, CHS-1420 and CHS-131 during the preceding twelve months.
- **General and administrative (G&A)** expenses for the third quarter of 2017 were $14.0 million, as compared to $13.6 million for the same period in 2016. G&A expenses for the nine months ended September 30, 2017 were $56.3 million, as compared to $36.3 million for the same period in 2016. Changes in G&A expenses were mainly attributable to legal and other professional fees to support intellectual property litigation and IPRs, 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 third quarter of 2017 was ($59.0) million, or ($1.09) per share, as compared to net income attributable to Coherus of $83.9 million, or $1.67 per share, for the same period in 2016.
- **Cash, cash equivalents and investments in marketable securities – short term** totaled $150.1 million as of September 30, 2017, as compared to $118.3 million as of June 30, 2017.

Guidance for the fourth quarter of 2017 and first half of 2018:

CHS-1701 (pegfilgrastim (Neulasta®) biosimilar)

- Anticipate resubmitting the BLA in the U.S. mid-first quarter of 2018 subject to meeting with FDA.
- Anticipate European opinion in the first half of 2018, such timing being dependent upon data requests.
- Commercial partnering discussions continue to be underway for certain ex-U.S. territories.

CHS-3351 (ranibizumab (Lucentis®) biosimilar)

- Prioritizing the development of CHS-3351.

CHS-1420 (adalimumab biosimilar)

- Continue to optimize manufacturing.

CHS-0214 (etanercept biosimilar)

- Focus on 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.
- Continue to optimize manufacturing.

- Targeting immunology (anti-TNF) partnering therapeutic franchise agreement.

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

- Anticipate cash use in operations of approximately $35 - $40 million in the fourth quarter of 2017, down approximately $5 million from previous guidance, and $30 - $35 million per quarter in the first half of 2018.

Conference Call Information

When: November 6, 2017 at 4:30 p.m. ET

Dial-in: (844) 452-6826 (toll free) or (765) 507-2587 (International)

Conference ID: 99333721

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), CHS-0214 (etanercept biosimilar), and CHS-3351 (ranibizumab 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, preclinical and 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 a BLA in the US and receive marketing approval in Europe for CHS-1710; make advances in the development of CHS-3351; continue to advance its intellectual property strategy and complete partnering agreements for CHS-1420 and CHS-0214; file an MAA for CHS-0214; and complete additional studies and a licensing agreement for CHS-131. 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 quarter ended September 30, 2017, filed with the Securities and Exchange Commission on November 6, 2017 and its future periodic reports to be filed with the Securities and Exchange Commission.

Enbrel® and Neulasta® are registered trademarks of Amgen Inc.
Humira® is a registered trademark of AbbVie Inc.
Lucentis® is a registered trademark of Genentech, Inc.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(unaudited)		*(unaudited)*	
Revenue:				
Collaboration and license revenue	$ -	$ 162,835	$ 1,556	$ 189,262
Operating expenses:				
Research and development	42,626	64,573	130,901	195,430
General and administrative	13,989	13,645	56,325	36,303
Total operating expenses	56,615	78,218	187,226	231,733
Income (loss) from operations	(56,615)	84,617	(185,670)	(42,471)
Interest expense	(2,392)	(2,420)	(7,152)	(5,611)

Other income (expense), net	14	1,647	3,605	(3,762)
Net income (loss)	(58,993)	83,844	(189,217)	(51,844)
Net loss attributable to non-controlling interest	4	95	114	428
Net income (loss) attributable to Coherus	$ (58,989)	$ 83,939	$ (189,103)	$ (51,416)
Net income (loss) per share attributable to Coherus				
Basic	$ (1.09)	$ 1.93	$ (3.68)	$ (1.25)
Diluted	$ (1.09)	$ 1.67	$ (3.68)	$ (1.25)
Weighted-average number of shares used in computing net income (loss) per share attributable to Coherus				
Basic	54,070,872	43,469,986	51,377,836	41,096,783
Diluted	54,070,872	51,581,298	51,377,836	41,096,783

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

	September 30, 2017	December 31, 2016
	(unaudited)	
Assets		
Cash and cash equivalents	$ 135,557	$ 124,947
Investments in marketable securities - short-term	14,493	-
Other assets	39,708	53,538
Total assets	$ 189,758	$ 178,485
Liabilities and Stockholders' Equity		
Deferred revenue	$ -	$ 1,561
Convertible notes	75,944	75,192
Convertible notes-related parties	25,314	25,064
Other liabilities	33,593	57,314
Total stockholders' equity	54,907	19,354
Total liabilities and stockholders' equity	$ 189,758	$ 178,485

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