# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K
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CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 6, 2017

# COHERUS BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-36721 (Commission File Number) 27-3615821 (IRS Employer Identification Number)

333 Twin Dolphin Drive, Suite 600 Redwood City, CA 94065 (Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (650) 649-3530

	ck the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following isions:						
	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)						
	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)						
	Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))						
	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))						
Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).							
Eme	rging growth company $\Box$						
	f an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or evised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.						

# **Item 2.02 Results of Operations and Financial Conditions**

On November 6, 2017, Coherus BioSciences, Inc. issued a press release regarding its financial results for its third quarter ended September 30, 2017. The full text of the press release is furnished as Exhibit 99.1 to this Form 8-K.

This information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

# Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	
No.	Description

99.1 Press release dated November 6, 2017.

# EXHIBIT INDEX

Exhibit No.

No. Description

99.1 <u>Press release dated November 6, 2017.</u>

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 6, 2017 COHERUS BIOSCIENCES, INC.

By: /s/ Jean-Frédéric Viret
Name: Jean-Frédéric Viret
Title: Chief Financial Officer

# Coherus BioSciences Reports Third Quarter 2017 Operating and Financial Results

REDWOOD CITY, Calif., November 6, 2017 — 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)
  - o 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
  - o 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)
  - o 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-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.
- 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 Excha

Enbrel<sup>®</sup> and Neulasta<sup>®</sup> are registered trademarks of Amgen Inc. Humira<sup>®</sup> is a registered trademark of AbbVie Inc. Lucentis<sup>®</sup> 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)			(unaudi		udited)	dited)	
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	4,070,872	43	3,469,986	5	51,377,836	2	1,096,783
Diluted	54	4,070,872	5	1,581,298	5	51,377,836	4	1,096,783

# Coherus BioSciences, Inc. Condensed Consolidated Balance Sheets

(in thousands)

	September 30, 2017 (unaudited)	December 31, 2016
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		<del></del>
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