

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): February 27, 2020

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

Check 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 provisions:

- 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	CHRS	The Nasdaq Global Market

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).

Emerging growth company

If 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 revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Conditions

On February 27, 2020, the Company issued a press release regarding its financial results for its fourth quarter and full year ended December 31, 2019. 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.

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Press release dated February 27, 2020.
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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: February 27, 2020

COHERUS BIOSCIENCES, INC.

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

Coherus BioSciences Reports Fourth Quarter and Full Year 2019 Financial Results

– Full Year Udenyca® Sales of \$356.1 Million –

– Full Year Cash Flow from Operating Activities of \$28.4 million –

REDWOOD CITY, Calif., February 27, 2020 – Coherus BioSciences, Inc. (“Coherus” or the “Company”, Nasdaq: CHRS), today reviewed corporate events and reported financial results for the quarter and full year ended December 31, 2019.

Fourth Quarter 2019 and Recent Corporate Highlights

Coherus’ commercial capabilities advanced its core mission to expand choice, improve patient access and lower healthcare costs in the United States:

- **UDENYCA® (pegfilgrastim-cbqv) launch continues to deliver strong results using its validated branded-biosimilar approach across all market segments:**
 - Udenyca® continues to be the U.S. market-leading pegfilgrastim biosimilar and achieved approximately 20.5% unit market share, as measured by IQVIA, at year-end 2019.
 - Udenyca® was the top pharmaceutical launch in 2019 based on IQVIA sales figures.
 - **Strong financial position to support pipeline and potential long-term growth:**
 - Cash flow was positive after just two quarters post-launch in 2019.
 - Cash flow from operating activities was \$28.4 million for the full year and \$17.7 million for the fourth quarter of 2019.
 - Coherus had cash and cash equivalents of \$177.7 million at December 31, 2019.
 - Net product revenue for the fourth quarter of 2019 was \$123.9 million, and net income was \$39.2 million, or \$0.53 per share on a fully diluted basis.
 - Net product revenue for the full-year 2019 was \$356.1 million. Net income attributable to Coherus for the same period was \$89.8 million, or \$1.23 per share on a fully diluted basis.
 - **Coherus completed key licensing transactions to enhance its midterm product pipeline in the United States:**
 - Acquired exclusive rights from Bioeq AG (“Bioeq”), a Swiss biopharmaceutical joint venture, to commercialize Bioeq’s Lucentis® (ranibizumab) biosimilar candidate in the United States.
 - Entered into a license agreement with Innovent Biologics, (Suzhou) Co., Ltd., (“Innovent”), a leading biopharmaceutical company headquartered in China, to commercialize Innovent’s biosimilar candidate to Avastin® (bevacizumab) in the United States and Canada.
 - Under the terms of the agreement with Innovent, Coherus also acquired an option to commercialize Innovent’s biosimilar to Rituxan® (rituximab) in the United States and Canada.
 - **The Company advanced its internal pipeline in ophthalmology and immunology:**
 - Further advanced internally developed ophthalmology product candidate, CHS-2020, a biosimilar candidate to Eylea® (aflibercept), which is in the preclinical stage.
 - Completed certain development and regulatory objectives for its internally developed immunology product, CHS-1420, a biosimilar candidate to Humira® (adalimumab), to support a potential BLA filing with the U.S. FDA in 2020.
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Fourth Quarter and Full Year 2019 Financial Results

Net product revenue for fourth quarter of 2019 was \$123.9 million. Cost of goods sold for the same quarter was \$7.8 million, resulting in a gross profit margin of 94%.

Research and development (R&D) expenses for the fourth quarter of 2019 were \$34.9 million, as compared to \$26.7 million for the same period in 2018. The increase in R&D expenses for the quarter year-over-year was mainly due to the \$11.1 million in upfront and milestone payments to Bioeq for the development of Bioeq's Lucentis biosimilar in the fourth quarter of 2019. R&D expenses for the fiscal year 2019 were \$94.2 million, as compared to \$110.2 million for the same period in 2018. The decrease in R&D expenses for the full year-over-year was due primarily to the capitalization of UDENYCA® manufacturing costs that had a \$33.9 million impact since the approval of UDENYCA® on November 2, 2018. This decrease was offset by an increase of \$15.6 million, which was primarily related to the upfront and milestone payments to Bioeq for \$11.1 million and the development of other biosimilar product candidates.

Selling, general and administrative (SG&A) expenses for the fourth quarter of 2019 were \$36.1 million, as compared to \$33.8 million for the same period in 2018. SG&A expenses for the full year 2019 were \$137.0 million, as compared to \$94.2 million for the same period in 2018. The increases in SG&A expenses for the quarter year-over-year and the full year-over-year were mainly attributable to an increase in sales force personnel and related commercial functions in connection with the commercialization of UDENYCA®.

Cash and cash equivalents: As of December 31, 2019, Coherus had \$177.7 million of cash and cash equivalents compared to \$72.4 million as of December 31, 2018. During 2019, Coherus generated \$28.4 million in operating cash flow, used \$12.7 million in investing activities, including \$11.1 million in upfront and milestone payments to Bioeq, and received net cash proceeds of \$73.0 million, included in cash flow from financing activities, related to the issuance of debt to HealthCare Royalty Partners in January 2019.

Assets and working capital: As of December 31, 2019, Coherus had \$408.9 million in total assets compared to \$99.5 million as of December 31, 2018. Working capital increased from \$51.2 million at the beginning of 2019 to \$228.0 million at the end of 2019. The quadrupling in working capital was mainly due to increases in UDENYCA® trade receivables of \$142.0 million.

Net income attributable to the Company for the fourth quarter of 2019 was \$39.2 million, or \$0.53 per share on a fully diluted basis, compared to a net loss of (\$62.6) million, or (\$0.92) per share on a basic and fully diluted basis for the same period in 2018. Net income attributable to Coherus for the fiscal year 2019 was \$89.8 million, or \$1.23 per share on a fully diluted basis, compared to a net loss of (\$209.3) million, or (\$3.22) per share on a basic and fully diluted basis for 2018.

Guidance for the Next Twelve Months from December 31, 2019

Coherus will continue delivering on the promise of biosimilars and laying the foundation for long-term growth across its three therapeutic areas:

Oncology

- UDENYCA® (pegfilgrastim-cbqv)
 - Maintain market position as the leading pegfilgrastim biosimilar of choice, leveraging the validated branded-biosimilar strategy of offering a robust value proposition across all key customer segments including ample product supply.
 - Increase penetration against all Neulasta® dosage forms, while maintaining average selling price (ASP) discipline.
 - Advance its Avastin (bevacizumab) oncology biosimilar candidate in-licensed from Innovent toward the filing of a BLA with the U.S. FDA in late 2020 or early 2021 depending on FDA interaction timing and development requirements, with an expected launch directly upon approval.
 - Diligence the option to commercialize Innovent's Rituxan (rituximab) oncology biosimilar in the U.S.
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Ophthalmology

- Facilitate Bioeq filing a BLA with the FDA for the biosimilar candidate to Lucentis (ranibizumab) in 2020, with expected product launch in the United States to address a \$6 billion anti-VEGF ophthalmology market, if approved.
- Advance internally developed CHS-2020 Eylea (aflibercept) ophthalmology biosimilar currently in preclinical stage to an expected Phase 3 clinical trial initiation in 2021, with launch projected in 2025, if approved.

Immunology

- Complete certain development and regulatory objectives with CHS-1420, Humira (adalimumab) immunology biosimilar candidate to support the filing of a BLA with the U.S. FDA in 2020 with an expected competitive launch in 2023 in the largest biologics market, if approved.

CHS-131

- The Company has decided to pursue strategic alternatives for its program in CHS-131, a small molecule for nonalcoholic steatohepatitis (NASH) and multiple sclerosis.

Conference Call Information

When: Thursday, February 27, 2020 starting at 4:30 p.m. ET

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

Conference ID: 9658203

Webcast: <https://investors.coherus.com>

Please join the conference call at least 10 minutes early to register. The webcast will be archived on the Coherus website.

Fourth quarter and full year 2019 financial results, are posted on the Coherus website at <https://investors.coherus.com>.

About Coherus BioSciences, Inc.

Coherus is a leading biosimilar company that develops and commercializes its own high-quality therapeutics as well as those of others seeking capable access to the United States market. 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 and marketing and clinical-regulatory development, Coherus is positioned as a leader in the global biosimilar marketplace. Coherus commercializes UDENYCA® (pegfilgrastim-cbqv) in the U.S. and has received regulatory approval for UDENYCA® in the European Union. Coherus is advancing late-stage clinical products CHS-1420, Humira (adalimumab) biosimilar, Bioeq's Lucentis® (ranibizumab) biosimilar and Innovent's Avastin (bevacizumab) biosimilar towards commercialization, and early-stage clinical products, CHS-2020, Eylea (aflibercept) biosimilar, and 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' ability to continue delivering on the promise of biosimilars and laying the foundation for long-term growth across its three therapeutic areas; Coherus' ability to continue to expand choice, improve patient access and lower healthcare costs in the United States; Coherus' ability to maintain UDENYCA®'s market position as the leading pegfilgrastim biosimilar; Coherus' ability to continue to increase penetration in market share from both Neulasta Onpro and Neulasta prefilled syringe; Coherus' ability to maintain ASP discipline for UDENYCA®; Coherus' ability to file a BLA with the FDA for the Innovent biosimilar candidate to Avastin in late 2020 or early 2021 depending on FDA interaction timing and development requirements; Coherus' ability to launch Innovent's biosimilar

candidate to Avastin in the United States; and whether Coherus will exercise its option to commercialize Innovent's Rituxan biosimilar in the U.S.; Coherus' ability to support Bioeq with its BLA filing with the FDA for Bioeq's biosimilar to Lucentis in 2020; Coherus' ability to launch Bioeq's biosimilar to Lucentis, if approved; Coherus' ability to advance its CHS-2020 (Eylea) biosimilar to an expected Phase 3 clinical trial initiation in 2021, with a projected launch in 2025, if approved; and Coherus' plans to complete certain development and regulatory objectives for CHS-1420 Humira biosimilar to support a BLA filing with the FDA in 2020 and a commercial launch in 2023, if approved; Coherus' plans to pursue strategic alternatives for its program in CHS-131. 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' Annual Report on Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission on February 27, 2019 and its future periodic reports to be filed with the Securities and Exchange Commission. Our results for the quarter and year ended December 31, 2019 are not necessarily indicative of our operating results for any future periods.

UDENYCA® is a trademark of Coherus BioSciences, Inc.

Neulasta® and Onpro® are registered trademarks of Amgen Inc.

Avastin®, Rituxan® and Lucentis® are registered trademarks of Genentech, Inc.

Humira® is a registered trademark of AbbVie Inc.

Eylea® is a registered trademark of Regeneron Pharmaceuticals, Inc.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
	<i>(unaudited)</i>			
Revenue:				
Net product revenue	\$ 123,856	\$ —	\$ 356,071	\$ —
Operating expenses:				
Cost of goods sold	7,805	—	17,078	—
Research and development	34,948	26,662	94,188	110,239
Selling, general and administrative	36,070	33,840	137,037	94,177
Total operating expenses	78,823	60,502	248,303	204,416
Income (loss) from operations	45,033	(60,502)	107,768	(204,416)
Interest expense	(4,483)	(2,434)	(17,601)	(9,684)
Other income, net	721	340	2,608	4,691
Net income (loss) before income tax	41,271	(62,596)	92,775	(209,409)
Income tax provision	2,044	—	2,942	—
Net income (loss)	39,227	(62,596)	89,833	(209,409)
Net loss attributable to non-controlling interest	—	—	—	70
Net income (loss) attributable to Coherus	\$ 39,227	\$ (62,596)	\$ 89,833	\$ (209,339)
Net income (loss) per share attributable to Coherus:				
Basic	\$ 0.56	\$ (0.92)	\$ 1.29	\$ (3.22)
Diluted	\$ 0.53	\$ (0.92)	\$ 1.23	\$ (3.22)
Weighted-average number of shares used in computing net income (loss) per share attributable to Coherus:				
Basic	70,208,351	68,089,486	69,679,916	65,034,827
Diluted	78,360,388	68,089,486	73,185,943	65,034,827

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

	<u>December 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Assets		
Cash and cash equivalents	\$ 177,668	\$ 72,356
Trade receivables, net	141,992	—
Inventory	55,071	5,671
Other assets	34,196	21,440
Total assets	<u>\$ 408,927</u>	<u>\$ 99,467</u>
Liabilities and Stockholders' Equity (Deficit)		
Convertible notes	\$ 78,542	\$ 77,319
Convertible notes - related parties	26,181	25,773
Term loan	73,663	—
Other liabilities	125,327	34,966
Total stockholders' equity (deficit)	105,214	(38,591)
Total liabilities and stockholders' equity (deficit)	<u>\$ 408,927</u>	<u>\$ 99,467</u>

Coherus BioSciences, Inc.
Condensed Consolidated Cash Flow
(in thousands)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Cash, cash equivalents and restricted cash at beginning of the period	\$ 165,166	\$ 102,037	\$ 73,191	\$ 127,756
Net cash provided by (used in) operating activities	\$ 17,710	\$ (47,363)	\$ 28,355	\$ (159,266)
Upfront and milestone payments related to license and collaboration arrangements	(11,075)	—	(11,075)	—
Cash used in other investing activities	5,013	15,786	(1,657)	(1,188)
Net cash (used in) provided by investing activities	\$ (6,062)	\$ 15,786	\$ (12,732)	\$ (1,188)
Proceeds from term loan, net of issuance costs	—	—	72,955	—
Proceeds from common stock offering, net of underwriters discounts, commissions and offering costs	—	1,462	8,153	101,748
Cash provided by other financing activities	1,200	1,131	8,262	3,673
Cash provided by (used in) financing activities	\$ 1,200	\$ 2,593	\$ 89,370	\$ 105,421
Effect of exchange rate changes on cash	(106)	138	(276)	468
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 12,742	\$ (28,846)	\$ 104,717	\$ (54,565)
Cash, cash equivalents and restricted cash at end of the period	\$ 177,908	\$ 73,191	\$ 177,908	\$ 73,191
Reconciliation of cash, cash equivalents and restricted cash				
Cash and cash equivalents at end of the period	\$ 177,668	\$ 72,356	\$ 177,668	\$ 72,356
Restricted cash balance	240	835	240	835
Cash, cash equivalents and restricted cash	\$ 177,908	\$ 73,191	\$ 177,908	\$ 73,191

Contact

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