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): November 5, 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:

	Trading	Name of each exchange
Title of each class	Symbol(s)	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 \Box

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. \Box

Item 2.02 Results of Operations and Financial Conditions

On November 5, 2020, the Company issued a press release regarding its financial results for its third quarter ended September 30, 2020. 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) <u>Exhibits</u>.

Exhibit No. Description

- 99.1 Press release dated November 5, 2020.
- 104 Cover page Interactive Data file (embedded within the Inline XBRL document)

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 5, 2020

COHERUS BIOSCIENCES, INC.

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



Coherus BioSciences Reports Third Quarter 2020 Financial Results

Third Quarter UDENYCA® Net Sales of \$113.6 Million – Net Income of \$27.9 Million – Non-GAAP Net Income of \$39.7 Million –

REDWOOD CITY, Calif., November 5, 2020 – Coherus BioSciences, Inc. ("Coherus" or the "Company", Nasdaq: CHRS), today reviewed corporate events and reported financial results for the third quarter and nine months ended September 30, 2020.

"In September, Coherus celebrated its ten year anniversary, and I am thrilled by what we have accomplished at this milestone," said Denny Lanfear, Coherus President and CEO. "Coherus is fully integrated with competencies in research, development, and commercialization, and we are successfully fulfilling our mission to deliver value to patients by providing them access to cost effective drugs that can have a major impact on their lives. Moreover, our Udenyca business is generating significant cash flow, enabling investments in our pipeline of product candidates which, if approved, would expand our addressable market opportunity from \$4 billion to \$30 billion."

Third Quarter 2020 and Recent Corporate Highlights

- Net product revenue for the third quarter of 2020 was \$113.6 million, and net income was \$27.9 million, or \$0.33 per share on a diluted basis.
- Non-GAAP income during the third quarter of 2020 was \$39.7 million, or \$0.47 per share on a diluted basis.
- Cash flow from operating activities was \$47.4 million for the third quarter of 2020.

Third Quarter 2020 Financial Results

Net product revenue for the third quarter of 2020 was \$113.6 million. Cost of goods sold for the third quarter of 2020 was \$9.0 million, resulting in a gross profit margin of 92%.

Research and development (R&D) expense for the third quarter of 2020 was \$38.9 million, as compared to \$21.6 million for the same period in 2019. R&D expense for the nine months ended September 30, 2020 was \$98.1 million, as compared to \$59.2 million for the same period in 2019. The increase in R&D expense in both periods was primarily due to preparations for the biologics license application (BLA) filing of CHS-1420, Coherus' biosimilar to Humira® (adalimumab), as well as other pipeline activities.

Selling, general and administrative (SG&A) expense for the third quarter of 2020 was \$32.0 million, as compared to \$31.8 million for the same period in 2019. SG&A expense for the nine months ended September 30, 2020 was \$101.4 million, as compared to \$101.0 million for the same period in 2019.

Cash, cash equivalents and investments in marketable securities for the third quarter increased to \$503.4 as of September 30, 2020, as compared to \$456.5 million as of June 30, 2020 and \$177.7 million as of December 31, 2019. The increase in the third quarter of 2020 is primarily due to generating \$47.4 million in net cash from operating activities.

Net income for the third quarter of 2020 was a \$27.9 million, or \$0.33 per share on a diluted basis, compared to \$47.0 million, or \$0.63 per share on a diluted basis for the same period in 2019.

Non-GAAP net income for the third quarter of 2020 was \$39.7 million, or \$0.47 per share on a diluted basis, compared to non-GAAP income of \$55.7 million, or \$0.74 per share on a diluted basis for the same period in 2019. See "Non-GAAP Financial Measures" below for a discussion on how the Company calculates non-GAAP net income and a reconciliation to the most directly comparable GAAP measures.

Guidance for the Next Twelve Months from September 30, 2020

Coherus will continue to lay the foundation for long-term growth across its three therapeutic areas:

Oncology

- Deliver continued unit share growth with UDENYCA® against all Neulasta® dosage forms, while
 maintaining average selling price ("ASP") discipline, leveraging the validated branded-biosimilar strategy of
 offering a robust value proposition across all key customer segments.
- Advance the Company's biosimilar candidate to Avastin® (bevacizumab) in-licensed from Innovent toward an expected 351(k) BLA submission with the U.S. FDA in 2021, depending on the outcome of the three-way pharmacokinetic ("PK") study, the timing of required interactions with the FDA, as well as completion of analytical similarity exercises.

Ophthalmology

- Facilitate Bioeq's resubmission of a 351(k) BLA with the FDA for the biosimilar candidate to Lucentis® (ranibizumab) in 2021.
- Advance the Company's internally developed CHS-2020 biosimilar candidate to Eylea® (aflibercept) to a projected Phase 3 clinical trial initiation in 2021, with launch projected in 2025, if approved.

Immunology

 Submit the 351(k) BLA for the Company's internally developed Humira® (adalimumab) biosimilar, CHS-1420, by year end 2020, consistent with prior guidance, and continue other activities to advance toward a projected market entry in the United States on or after July 1, 2023, if approved.

Financial Guidance

 R&D and SG&A expenses combined for the full fiscal year 2020 are expected to come in at the low end of the previously stated range of \$285 million to \$310 million, excluding upfront or milestone payments from any potential new collaborations.

Conference Call Information

When: Thursday, November 5, 2020 starting at 4:30 p.m. ET

Webcast: at https://investors.coherus.com.

The conference call will be broadcast live in listen-only mode on the Company's investor relations website at https://investors.coherus.com/. If you would like to ask a question, the dial in number for the conference call is 844-452-6826 (Toll-Free U.S. and Canada) or 765-507-2587 (International).

Conference ID: 7079429

Please dial-in 15 minutes early to ensure a timely connection to the call.

Third quarter 2020 financial results are posted on the Coherus website at https://investors.coherus.com/. The webcast will be archived on the Coherus website.

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, clinical-regulatory development and commercialization. Coherus is positioned as a leader in the global biosimilar marketplace. Coherus commercializes UDENYCA® (pegfilgrastim-cbqv) in the United States and is advancing additional product candidates including CHS-1420, a Humira® (adalimumab) biosimilar, Bioeq's Lucentis® (ranibizumab) biosimilar, Innovent's Avastin® (bevacizumab) biosimilar towards commercialization, as well as CHS-2020, an Eylea® (aflibercept) biosimilar. 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 forwardlooking 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 generate cash flow from its UDENYCA® business, Coherus' ability to expand its addressable market opportunity and to lay the foundation for long-term growth across its three therapeutic areas; Coherus' ability to deliver continued unit share growth with UDENYCA® against all Neulasta® dosage forms, Coherus' ability to maintain ASP discipline, leveraging the validated branded-biosimilar strategy of offering a robust value proposition across all key customer segments; Coherus' ability to advance the Company's oncology biosimilar candidate to Avastin® (bevacizumab) in-licensed from Innovent toward an expected 351(k) BLA submission with the U.S. FDA in 2021, depending on the outcome of the three-way PK study, the timing of required interactions with the FDA, as well as completing analytical similarity exercises; Coherus' ability to submit a 351(k) BLA with the FDA in 2021 for the Innovent biosimilar candidate to Avastin®; Coherus' ability to launch Innovent's biosimilar candidate to Avastin® in the United States; Coherus' ability to facilitate Bioeq's resubmission of a 351(k) BLA with the FDA for the ophthalmology biosimilar candidate to Lucentis® (ranibizumab) in 2021 and Coherus' ability to launch the product, if approved; Coherus' ability to advance CHS-2020 an Eylea® (aflibercept) ophthalmology biosimilar currently in preclinical development by initiating an projected Phase 3 clinical trial in 2021, with launch projected in 2025, if approved; Coherus' ability to submit the 351(k) BLA for CHS-1420, a Humira® (adalimumab) biosimilar by year end 2020, and continue other activities to advance toward a projected market entry in the United States on or after July 1, 2023; and Coherus' ability to meet its R&D and SG&A expenses guidance for the full fiscal year 2020. 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 forwardlooking 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, 2020, its Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2020, filed with the Securities and Exchange Commission on November 5, 2020 and its future periodic reports to be

filed with the Securities and Exchange Commission. Our results for the quarter ended September 30, 2020 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® 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) (unaudited)

		Three Months Ended September 30,					nths Ended nber 30,		
		2020		2019		2020	2019		
Revenue:									
Net product revenue	\$	113,551	\$	111,684	\$	365,405	\$	232,215	
Operating expenses:									
Cost of goods sold		9,000		6,447		25,994		9,273	
Research and development		38,851		21,568		98,131		59,240	
Selling, general and administrative		31,984		31,828		101,386		100,967	
Total operating expenses		79,835		59,843		225,511		169,480	
Income from operations		33,716		51,841		139,894		62,735	
Interest expense		(5,656)		(4,469)		(15,495)		(13,118)	
Other income, net		56		518		548		1,887	
Net income before income taxes		28,116		47,890		124,947		51,504	
Income tax provision		183		847		2,411		898	
Net income	\$	27,933	\$	47,043	\$	122,536	\$	50,606	
Net income per share:									
Basic	\$	0.39	\$	0.67	\$	1.72	\$	0.73	
Diluted	\$	0.33	\$	0.63	\$	1.52	\$	0.69	
Weighted-average number of shares used in computing net income per share:									
Basic	7	1,649,350	6	9,877,693	7	1,138,973	6	9,501,835	
Diluted	8	7,470,337	7	8,530,227	8	2,043,469	7	2,872,076	

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

	Se	September 30, 2020		cember 31, 2019
Assets				
Cash and cash equivalents	\$	292,465	\$	177,668
Investments in marketable securities		210,966		
Trade receivables, net		160,707		141,992
Inventory		85,964		55,071
Other assets		53,631		34,196
Total assets	\$	803,733	\$	408,927
Liabilities and Stockholders' Equity				
Accrued rebates, fees and reserve	\$	75,961	\$	51,120
Convertible notes due 2022		79,537		78,542
Convertible notes due 2022 - related parties		26,512		26,181
Convertible notes due 2026		222,718		
Term loan		74,267		73,663
Other liabilities		69,007		74,207
Total stockholders' equity		255,731		105,214
Total liabilities and stockholders' equity	\$	803,733	\$	408,927

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

		nths Ended nber 30,	Nine Months Ended September 30,				
	2020	2019	2020	2019			
Cash, cash equivalents and restricted cash at beginning of the period	\$225,057	\$106,762	\$ 177,908	\$ 73,191			
Net cash provided by operating activities	\$ 47,353	\$ 54,951	\$ 121,021	\$ 10,645			
Purchases of investments in marketable securities	(41,981)	(5,371)	(273,845)	(20,235)			
Proceeds from maturities of investments in marketable securities	63.000	6.000	63,000	15,000			
Upfront and milestone based license fee payments to Innovent	(2,500)	-	(7,500)				
Purchases of property and equipment and other investing activities	(2,112)	(918)	(6,112)	(1,435)			
Net cash provided by (used in) investing activities	\$ 16,407	\$ (289)	\$(224,457)	\$ (6,670)			
Proceeds (payments) related to issuance of Convertible Notes due 2026,							
net of issuance costs	(674)	_	222,156	_			
Purchase of capped call options related to convertible notes due 2026	_		(18,170)	_			
Proceeds (payments) related to the term loan, net of issuance costs Proceeds from common stock offering, net of underwriters discounts,	_	(106)		72,955			
commissions and offering costs		_	_	8,153			
Proceeds from issuance of common stock upon exercise of stock options	4,909	3,789	13,014	5,184			
Proceeds from purchase under the employee stock purchase plan			2,557	1,878			
Cash used in other financing activities	(147)		(1,124)				
Net cash provided by financing activities	\$ 4,088	\$ 3,683	\$ 218,433	\$ 88,170			
Effect of exchange rate changes on cash	_	59	—	(170)			
Net increase in cash, cash equivalents and restricted cash	\$ 67,848	\$ 58.404	\$ 114,997	\$ 91,975			
Net increase in cash, cash equivalents and restricted cash	φ 07,040	φ 50,404	Ψ 114,557	Φ 51,575			
Cash, cash equivalents and restricted cash at end of the period	\$292,905	\$165,166	\$ 292,905	\$165,166			
Reconciliation of cash, cash equivalents, and restricted cash							
Cash and cash equivalents	\$292,465	\$165,116	\$ 292,465	\$165,116			
Restricted cash – current		50		50			
Restricted cash – non-current	440		440				
Cash, cash equivalents and restricted cash	\$292,905	\$165,166	\$ 292,905	\$165,166			

Non-GAAP Financial Measures

To supplement the financial results presented in accordance with GAAP, Coherus has also included in this press release non-GAAP net income, and the related per share measures, which exclude from net income, and the related per share measures, stock-based compensation expense, upfront and milestone payments under the license agreements and the related income tax effect of those non-GAAP adjustments. These non-GAAP financial measures are not prepared in accordance with GAAP, do not serve as an alternative to GAAP and may be calculated differently than similar non-GAAP financial information disclosed by other companies. Coherus encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP financial information and the reconciliation between these presentations set forth below, to more fully understand Coherus' business.

Coherus believes that the presentation of these non-GAAP financial measures provides useful supplementary information to, and facilitates additional analysis by, investors. In particular, Coherus believes that these non-GAAP financial measures, when considered together with its financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare Coherus' results from period to period, and to identify operating trends in Coherus' business. Coherus also regularly uses these non-GAAP financial measures internally to understand, manage and evaluate its business and to make operating decisions.

Coherus BioSciences, Inc. Reconciliation of GAAP Net Income to Non-GAAP Net Income (in thousands, per share data) (unaudited)

	Three Months Ended September 30,			Ν	line Mont Septem	hs Ended ber 30,			
		2020		2019		2020		2019	
GAAP net income	\$2	7,933	\$4	7,043	\$12	22,536	\$5	0,606	
Adjustments:									
Stock based compensation expense		9,308 8,790		2	28,287	26,319			
Upfront and milestone based license fee payments to Innovent	2,500		_		7,500		_		
Income tax effect of the above adjustments		(77)		(155)		(691)		(459)	
Non-GAAP net income	\$3	\$39,664		\$55,678		\$157,632		\$76,466	
GAAP net income per share, basic	\$	0.39	\$	0.67	\$	1.72	\$	0.73	
GAAP net income per share, diluted	\$	0.33	\$	0.63	\$	1.52	\$	0.69	
Non-GAAP net income per share, basic	\$	0.55	\$	0.80	\$	2.22	\$	1.10	
Non-GAAP net income per share, diluted	\$	0.47	\$	0.74	\$	1.93	\$	1.05	

Contact

David S. Arrington Investor Relations & Corporate Affairs Coherus BioSciences, Inc. darrington@coherus.com +1 (650) 395-0196