



Coherus BioSciences Reports Third Quarter 2023 Financial Results and Business Highlights

Nov 6, 2023

- Net revenue rose 27% from prior quarter to \$74.6 million –
- CIMERLI[®] net sales increased 50% to \$40 million compared to prior quarter –
- LOQTORZI[™] now approved with launch planned for the first quarter of 2024 –
- Conference call today at 5:00 p.m. Eastern Time –

REDWOOD CITY, Calif., Nov. 06, 2023 (GLOBE NEWSWIRE) -- **Coherus BioSciences, Inc.** (Coherus, Nasdaq: CHRS), today reported financial results for the quarter ended September 30, 2023, and recent business highlights:

RECENT BUSINESS HIGHLIGHTS

CIMERLI[®]

- CIMERLI[®] (ranibizumab-eqrn) net product sales increased in the third quarter 2023 to \$40.0 million compared to \$26.7 million in the second quarter. CIMERLI[®] sales have exceeded 100,000 doses since commercial launch on October 3, 2022, and CIMERLI[®] held a 29% share of the overall ranibizumab market in the third quarter 2023.

UDENYCA[®]

- UDENYCA[®] (pegfilgrastim-cbqv) net product sales increased in the third quarter 2023 to \$33.0 million compared to \$31.7 million in the second quarter. Market share grew to 16.5% in the third quarter 2023, an increase of 4.3 market share percentage points compared to the prior quarter.
- As of late September, more than 250 accounts had ordered the autoinjector (AI) presentation of UDENYCA[®], which was launched commercially on May 22, 2023. Coherus anticipates demand will continue to rise with significantly improved commercial and Medicare Advantage formulary coverage in the fourth quarter of 2023 and in 2024.
- Coherus resubmitted the Biologics License Application (BLA) Supplement for UDENYCA[®] ONBODY[™], the company's on-body injector presentation of UDENYCA[®] (pegfilgrastim-cbqv), to the U.S. Food and Drug Administration (FDA) for review on October 4, 2023. This followed the completion and satisfactory resolution of the FDA's review of inspection findings at a third-party filler, which was the only issue identified in the FDA's September 21, 2023 Complete Response Letter (CRL). Coherus anticipates potential approval for the UDENYCA[®] ONBODY[™] in late 2023 or by early 2024.

LOQTORZI[™] (toripalimab-tpzi)

- On October 27, 2023, the FDA approved LOQTORZI[™] (toripalimab-tpzi) in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent locally advanced nasopharyngeal carcinoma (NPC), and as monotherapy for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after platinum-containing chemotherapy. Commercial launch is expected in the first quarter of 2024.
- Coherus presented new mechanism of action data for LOQTORZI[™] at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics and at the 38th Annual Meeting of Society for Immunotherapy of Cancer (SITC).

YUSIMRY[™]

- Coherus launched YUSIMRY[™], a Humira biosimilar, with a citrate-free and sting-free formulation delivered via a state-of-the-art autoinjector July 3, 2023. YUSIMRY[™] is now available for sale nationwide through retail, mail order and specialty pharmacy channels.

Surface Oncology Acquisition and Novel Immuno-oncology Pipeline

- On September 8, 2023, Coherus announced the closing of its acquisition of Surface Oncology, Inc. The acquisition significantly advanced Coherus' next-generation immuno-oncology pipeline focused on the tumor micro-environment with clinical stage anti-IL-27 and anti-CCR8 monoclonal antibody development programs.
- Coherus presented new preclinical data for casdozokitug, a first-in-class IL-27 antibody and CHS-114, a highly selective cytolytic CCR8 antibody at the 38th Annual SITC meeting.
- Coherus plans to file an Investigational New Drug (IND) application in first quarter of 2024 for CHS-1000, a novel ILT4-targeted antibody.

"With the approval of LOQTORZI[™] and the closing of the Surface Oncology acquisition, Coherus has all the elements in place to realize its vision of building an innovative immuno-oncology company with a commercial-stage PD-1 inhibitor and a highly competitive, next-generation clinical I-O pipeline focused on the tumor microenvironment," said Denny Lanfear, Coherus' Chairman and Chief Executive Officer. "Our net revenues of \$74.6 million in the third quarter represent an increase of 27% compared to Q2, and our SG&A plus R&D costs year to date have declined 28% compared to

the same period last year. Looking forward, we expect further revenue growth driven by CIMERLI[®], the UDENYCA[®] franchise, YUSIMRY[™], and LOQTORZI[™], while holding the line on expenses and focusing on returning to profitability.”

THIRD QUARTER 2023 FINANCIAL RESULTS

Net revenue was \$74.6 million during the three months ended September 30, 2023 and included \$33.0 million of net sales of UDENYCA[®], \$40.0 million of net sales of CIMERLI[®], and \$1.4 million of net sales of YUSIMRY[™], which was launched July 3, 2023. Net revenue for the three months ended September 30, 2022, consisting primarily of UDENYCA[®] net sales, was \$45.4 million. Net revenue was \$165.7 million and \$165.7 million for the nine months ended September 30, 2023 and 2022, respectively. Year to date revenues remained flat compared to the prior period primarily due to a reduction in the number of units of UDENYCA[®] sold as well as a lower net realized price due to increased competition offset by increasing revenue from CIMERLI[®] and YUSIMRY[™] sales during the nine months ended September 30, 2023.

Cost of goods sold (COGS) for the three months ended September 30, 2023 and 2022 was \$32.7 million and \$35.2 million, respectively, and \$74.4 million and \$55.9 million during the nine months ended September 30, 2023 and 2022, respectively. COGS includes a mid-single digit royalty payable on net sales of UDENYCA[®] through the first half of 2024, and 2023 COGS also includes a low to mid 50% royalty payable on gross profits of CIMERLI[®].

The decrease in COGS for the three months ended September 30, 2023 compared to the same period in the prior year was primarily due to the \$26.0 million write-down in the third quarter 2022 of inventory at risk of expiration and due to the sale in the third quarter 2023 of certain of those UDENYCA units having a total original cost of \$2.4 million but no carrying value following the write-off, partially offset by a \$17.0 million increase in royalty costs and \$8.4 million increase in product costs primarily driven by CIMERLI sales and the mix of products sold.

The increase in COGS for the nine months ended September 30, 2023 compared to the same period in the prior year was due to a \$28.1 million increase in royalty costs primarily driven by CIMERLI sales, \$3.0 million in contract modification fees with one of our manufacturers for reducing the number of UDENYCA batches to be produced, and \$2.3 million in write-offs, net of recoveries for inventory that was damaged during processing. These unfavorable factors were partially offset by the factors associated with the write-down in the third quarter of 2022 noted above.

Research and development (R&D) expense for the three months ended September 30, 2023 and 2022 was \$25.6 million and \$45.8 million, respectively. For the nine months ended September 30, 2023 and 2022, R&D expense was \$83.1 million and \$170.3 million, respectively. The decline in R&D expense compared to the prior year periods primarily resulted from the reduction in scope of the toripalimab collaboration and from the recognition in the first quarter of 2022 of the \$35.0 million option exercise fee paid to Junshi Biosciences to license CHS-006. R&D expense for the first nine months of 2022 also included development costs for additional presentations of UDENYCA[®] and certain manufacturing expenses for YUSIMRY[™] which began to be capitalized in mid 2022.

Selling, general and administrative (SG&A) expense was \$48.2 million and \$44.8 million during the three months ended September 30, 2023 and 2022, respectively, and \$142.5 million and \$144.9 million during the nine months ended September 30, 2023 and 2022, respectively. The increase in SG&A expense in the three months ended September 30, 2023 was primarily due to an increase in professional services fees associated with the acquisition of Surface Oncology that was completed in September 2023. The decline in SG&A expense in the nine months ended September 30, 2023 compared to the prior year period primarily reflects lower headcount.

Net loss for the third quarter of 2023 was \$39.6 million, or \$(0.41) per share on a diluted basis, compared to a net loss of \$86.7 million, or \$(1.11) per share on a diluted basis for the same period in 2022. Net loss for the nine months ended September 30, 2023 was \$158.2 million, or \$(1.79) per share on a diluted basis, compared to a net loss of \$232.9 million, or \$(3.00) per share on a diluted basis for the same period in 2022.

Non-GAAP net loss for the third quarter of 2023 was \$26.9 million, or \$(0.27) per share on a diluted basis, compared to non-GAAP net loss of \$74.4 million, or \$(0.96) per share on a diluted basis for the same period in 2022. Non-GAAP net loss for the nine months ended September 30, 2023 was \$117.3 million, or \$(1.33) per share on a diluted basis, compared to non-GAAP net loss of \$187.7 million, or \$(2.42) per share on a diluted basis for the same period in 2022. See “Non-GAAP Financial Measures” below for a discussion on how Coherus calculates non-GAAP net loss and a reconciliation to the most directly comparable GAAP measures.

Cash, cash equivalents and investments in marketable securities were \$131.1 million as of September 30, 2023, compared to \$191.7 million at December 31, 2022.

2023 Revenue and R&D and SG&A Expense Guidance

Primarily due to the delay in the timing of the planned commercial launches of the UDENYCA[®] On-body Injector and of LOQTORZI[™], Coherus is lowering its guidance for 2023 net product revenue to a range of \$250 to \$260 million.

Coherus is lowering its guidance range for combined R&D and SG&A expenses for 2023 from \$315 to \$335 million to a range of \$300 to \$310 million. This guidance range includes \$40 to \$45 million of stock-based compensation expense and excludes the Surface Oncology acquisition cost as well as any potential collaboration upfront or milestone payments.

This financial guidance also excludes the effects of any potential future strategic acquisitions, collaborations or investments, the exercise of rights or options related to collaboration programs, and any other transactions or circumstances not yet identified or quantified. This guidance is subject to a number of risks and uncertainties. See Forward-Looking Statements described in the section below.

Conference Call Information

When: Monday, November 6, 2023, starting at 5:00 p.m. Eastern Time

To access the conference call, please pre-register through the following link to receive dial-in information and a personal PIN to access the live call: <https://register.vevent.com/register/B10eecedfba52f4f83a7438c9f002fabcd4>

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

Webcast Link: <https://edge.media-server.com/mmc/p/z2fatkzx>

A replay of the webcast will be archived on the “Investors” section of the Coherus website at <http://investors.coherus.com>.

About Coherus BioSciences

Coherus is a commercial-stage biopharmaceutical company focused on the research, development and commercialization of innovative

immunotherapies to treat cancer. Coherus is developing an innovative immuno-oncology pipeline that will be synergistic with its proven commercial capabilities in oncology.

Coherus' immuno-oncology pipeline includes multiple antibody immunotherapy candidates focused on enhancing the innate and adaptive immune responses to enable a robust immunologic response and enhance outcomes for patients with cancer. Casdozokitug is a novel first-in-class anti-IL-27 antibody currently being evaluated in Phase 1/2 clinical trials in lung and liver cancer. CHS-114 is a highly selective, competitively positioned, ADCC-enhanced anti-CCR8 antibody currently in a Phase 1/2 study as a monotherapy in patients with advanced solid tumors.

Coherus' earlier-stage immuno-oncology pipeline targets immune-suppressive mechanisms, including CHS-006, a TIGIT-targeted antibody, being evaluated in a Phase 1/2 clinical trial in combination with LOQTORZI in patients with advanced solid tumors, and CHS-1000, a preclinical program targeting the novel pathway ILT4.

Coherus markets UDENYCA[®] (pegfilgrastim-cbqv), a biosimilar of Neulasta[®], CIMERLI[®] (ranibizumab-eqrn), a biosimilar of Lucentis[®], YUSIMRY[™] (adalimumab-aqvh), a biosimilar of Humira[®] and expects to launch LOQTORZI[™] (toripalimab-tpzi), a novel next generation PD-1 inhibitor, in the U.S. in the first quarter of 2024.

Neulasta[®] is a registered trademark of Amgen, Inc.

Lucentis[®] is a registered trademark of Genentech, Inc.

Humira[®] is a registered trademark of AbbVie Inc.

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, statements regarding Coherus' ability to identify synergies between its I-O pipeline and its commercial operations; Coherus' ability to grow revenues; Coherus' future projections for R&D expense, SG&A expense and net product revenue; Coherus' expectations about gaining new product approvals, formulary coverage and launching new products in a timely manner and Coherus' timing of a return to profitability and its filing of an IND for CHS-1000.

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; risks relating to the COVID-19 pandemic; risks related to our existing and potential collaboration partners; risks of Coherus' competitive position; the risks and uncertainties of the regulatory approval process, including the speed of regulatory review, international aspects of Coherus' business, the timing of Coherus' regulatory filings; the risk of FDA review issues; the risks of competition; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus' products and product candidates; and the risks and uncertainties of possible litigation. All forward-looking statements contained in this press release speak only as of the date of this press release. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the significant 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 fiscal quarter ended September 30, 2023 filed with the Securities and Exchange Commission on November 6, 2023, including the section therein captioned "Risk Factors" and in other documents Coherus files with the Securities and Exchange Commission. Coherus' results for the quarter ended September 30, 2023 are not necessarily indicative of our operating results for any future periods.

UDENYCA[®], UDENYCA[®] ONBODY[™], CIMERLI[®], YUSIMRY[™] and LOQTORZI[™], whether or not appearing in large print or with the trademark symbol, are trademarks of Coherus, its affiliates, related companies or its licensors or joint venture partners unless otherwise noted. Trademarks and trade names of other companies appearing in this press release are, to the knowledge of Coherus, the property of their respective owners.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net revenue	\$ 74,568	\$ 45,424	\$ 165,720	\$ 165,690
Costs and expenses:				
Cost of goods sold	32,703	35,234	74,425	55,881
Research and development	25,647	45,808	83,068	170,336
Selling, general and administrative	48,224	44,831	142,521	144,860
Total costs and expenses	106,574	125,873	300,014	371,077
Loss from operations	(32,006)	(80,449)	(134,294)	(205,387)
Interest expense	(10,268)	(7,540)	(29,923)	(23,089)
Loss on debt extinguishment	—	—	—	(6,222)
Other income (expense), net	2,253	1,339	5,598	1,814

Loss before income taxes	(40,021)	(86,650)	(158,619)	(232,884)
Income tax provision (benefit)	(380)	—	(380)	—
Net loss	\$ (39,641)	\$ (86,650)	\$ (158,239)	\$ (232,884)
Basic and diluted net loss per share	\$ (0.41)	\$ (1.11)	\$ (1.79)	\$ (3.00)
Weighted-average number of shares used in computing basic and diluted net loss per share	97,738,509	77,746,895	88,277,936	77,520,244

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

	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Assets		
Cash and cash equivalents	\$ 80,259	\$ 63,547
Investments in marketable securities	50,818	128,134
Trade receivables, net	216,511	109,964
Inventory	145,785	115,051
Goodwill and intangible assets, net	46,524	5,931
Other assets	43,886	58,220
Total assets	<u>\$ 583,783</u>	<u>\$ 480,847</u>
Liabilities and Stockholders' Deficit		
Accrued rebates, fees and reserve	\$ 117,369	\$ 54,461
Term loans	246,217	245,483
Convertible notes	226,557	225,575
Other liabilities	127,239	92,746
Total stockholders' deficit	<u>(133,599)</u>	<u>(137,418)</u>
Total liabilities and stockholders' deficit	<u>\$ 583,783</u>	<u>\$ 480,847</u>

Coherus BioSciences, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Cash, cash equivalents and restricted cash at beginning of the period	\$ 73,360	\$ 275,924	\$ 63,987	\$ 417,635
Net cash used in operating activities	<u>(54,300)</u>	<u>(37,089)</u>	<u>(161,947)</u>	<u>(141,171)</u>
Purchases of investments in marketable securities	—	—	(19,507)	—
Proceeds from maturities of investments in marketable securities	43,398	—	108,148	—
Proceeds from sale of investments in marketable securities	—	—	13,282	—
Option payment to Junshi Biosciences	—	—	—	(35,000)
Cash and cash equivalents acquired from Surface Acquisition	6,997	—	6,997	—
Other investing activities, net	151	(457)	517	(1,952)
Net cash provided by (used in) investing activities	<u>50,546</u>	<u>(457)</u>	<u>109,437</u>	<u>(36,952)</u>
Proceeds from 2027 Term Loans, net of debt discount & issuance costs	—	49,489	—	240,679
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	11,437	—	18,198	—
Proceeds from issuance of common stock under Public Offering, net of issuance costs	—	—	53,625	—
Proceeds from issuance of common stock upon exercise of stock options	53	79	170	631
Proceeds from purchase under the employee stock purchase plan	—	—	1,337	1,655
Taxes paid related to net share settlement	(175)	(321)	(3,261)	(3,621)
Repayment of 2022 Convertible Notes and premiums	—	—	—	(109,000)
Repayment of 2025 Term Loan, premiums and exit fees	—	—	—	(81,750)

Other financing activities	(210)	(380)	(835)	(861)
Net cash provided by financing activities	11,105	48,867	69,234	47,733
Net increase (decrease) in cash, cash equivalents and restricted cash	7,351	11,321	16,724	(130,390)
Cash, cash equivalents and restricted cash at end of the period	\$ 80,711	\$ 287,245	\$ 80,711	\$ 287,245
Reconciliation of cash, cash equivalents, and restricted cash				
Cash and cash equivalents	\$ 80,259	\$ 286,805	\$ 80,259	\$ 286,805
Restricted cash balance	452	440	452	440
Cash, cash equivalents and restricted cash	\$ 80,711	\$ 287,245	\$ 80,711	\$ 287,245

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 loss, and the related per share measures, which exclude from net loss, and the related per share measures, stock-based compensation expense, certain acquisition-related expenses including amortization of intangible assets, loss on debt extinguishment and restructuring charges related to our reduction in workforce. 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 supplemental 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 Loss to Non-GAAP Net Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
GAAP net loss	\$ (39,641)	\$ (86,650)	\$ (158,239)	\$ (232,884)
Adjustments:				
Stock-based compensation expense ⁽¹⁾	9,954	12,282	31,364	39,011
Loss on debt extinguishment	—	—	—	6,222
Restructuring charges related to reduction in workforce ⁽¹⁾	—	—	4,876	—
Acquisition-related costs, including amortization of intangibles ⁽²⁾	2,830	—	4,691	—
Non-GAAP net loss	\$ (26,857)	\$ (74,368)	\$ (117,308)	\$ (187,651)
GAAP net loss per share, basic and diluted	\$ (0.41)	\$ (1.11)	\$ (1.79)	\$ (3.00)
Non-GAAP net loss per share, basic and diluted	\$ (0.27)	\$ (0.96)	\$ (1.33)	\$ (2.42)
Shares used in computing basic and diluted net loss per share	97,738,509	77,746,895	88,277,936	77,520,244

(1) In the nine months ended September 30, 2023, stock-based compensation of \$1.0 million was classified within Restructuring charges related to reduction in workforce.

(2) Beginning in the third quarter of 2023, the Company began excluding acquisition-related costs in its non-GAAP financial information. To conform to this change, \$1.9 million of acquisition-related costs, including amortization of intangibles incurred during the quarter ended June 30, 2023 has been excluded from SG&A expense for the nine months ended September 30, 2023.



Source: Coherus BioSciences, Inc.