



Coherus BioSciences Reports Third Quarter 2024 Financial Results and Provides Business Update

- Net revenue of \$70.8 million in Q3 2024 driven by 30% increase in UDENYCA[®] net revenue, quarter-over-quarter –
- UDENYCA labeling and packaging production resuming at third-party contract manufacturing organization –
- LOQTORZI[®] launch progressing to plan, revenues increase 50% quarter-over-quarter –
- Innovative immuno-oncology pipeline advancing to proof-of-concept studies in combination with toripalimab –
- Conference call today at 5:00 p.m. Eastern Time –

REDWOOD CITY, Calif., Nov. 06, 2024 (GLOBE NEWSWIRE) -- **Coherus BioSciences, Inc.** (Coherus or the Company, Nasdaq: CHRS), today reported financial results for the quarter ended September 30, 2024 and recent business highlights:

“Revenue growth was strong in the third quarter, with the UDENYCA franchise increasing 30% compared to the second quarter, and 100% over Q3 2023. LOQTORZI sales grew more than 50% compared to the second quarter of 2024,” said Denny Lanfear, Coherus Chairman and Chief Executive Officer. “Our sharpened focus on oncology is delivering results. Third quarter 2024 revenues are now comparable to Q3 2023, despite our divestitures, with higher gross profit, lower operating expenses and lower interest expense.”

“We continue to make progress towards our long-term vision of bringing innovative, next-generation therapies to extend cancer patient survival. Our competitively positioned pipeline, in combination with LOQTORZI, is advancing to plan in tumor types with high unmet medical need and with robust supportive biology,” continued Mr. Lanfear.

RECENT BUSINESS HIGHLIGHTS

UDENYCA[®] RESULTS

- UDENYCA net product sales were \$66.1 million in Q3 2024, an increase of 30% compared to \$50.9 million in Q2 2024 and a 100% increase compared to \$33.0 million in Q3 2023.
- Q3 revenue was driven by a 54% increase in demand for ONBODY[™] and a higher overall net selling price.
- In Q3, UDENYCA maintained its #2 position in the pegfilgrastim class with 28% market share.

UDENYCA SUPPLY UPDATE

- Coherus’ third-party labeling and packaging contract manufacturing organization (CMO) for UDENYCA has informed the Company that production will resume this week, a few weeks later than previously targeted and disclosed. Based on the production schedule, the backlog of UDENYCA lots of approximately 120,000 units will be completed without further interruption or delay by the end of the year.
- The Company has also made significant progress in its previously announced efforts to diversify its labeling and packaging resources. An additional final packaging and labeling CMO has already started production testing and is expected to start manufacturing saleable product by the end of 2024. Commercial supply from that CMO is expected to commence in the first quarter of 2025, subject to U.S. Food and Drug Administration (FDA) authorization. Once the second facility is commercially operational, the Company projects that its labeling and packaging capacity will have doubled to over one million UDENYCA units annually, consistent with the rest of its supply chain.

LOQTORZI[®] LAUNCH UPDATE

- LOQTORZI, the first and only FDA-approved treatment for recurrent, locally advanced or metastatic nasopharyngeal carcinoma (NPC), commercially launched across all lines of therapy on January 2, 2024.
- LOQTORZI net product sales were \$5.8 million in Q3 2024, an increase of 54% compared to \$3.8 million in Q2 2024.
- The number of LOQTORZI treated patients grew by more than 60% in Q3, with new patient uptake primarily in relapsed locally advanced and 1L metastatic disease, the key driver of long-term revenue growth.
- Since launch, nearly 80% of all National Comprehensive Cancer Network (NCCN) institutions have written prescriptions for at least one new patient.

ADVANCEMENT OF PROMISING IMMUNO-ONCOLOGY PIPELINE

- This quarter, the Company expects to open a Phase 2 randomized study evaluating casdozokitug, an immune regulatory IL-27 antagonist in combination with toripalimab and bevacizumab for the treatment of unresectable locally advanced or metastatic hepatocellular carcinoma (HCC) in treatment-naïve patients.
- The Company also anticipates final data from its Phase 2 trial of casdozokitug combined with atezolizumab and bevacizumab in first-line HCC in the first quarter of 2025. Coherus has received FDA orphan drug status and fast track designation for casdozokitug in HCC.
- A Phase 1 study evaluating CHS-114, a highly selective cytolytic anti-CCR8 antibody, is ongoing. In the first half of 2025,

Coherus expects to report Phase 1 data from expansion cohorts evaluating CHS-114 as monotherapy and in combination with toripalimab in patients with advanced/metastatic head and neck squamous cell carcinoma (HNSCC).

- Coherus plans to initiate Phase 1b dose optimization studies of CHS-114 in combination with toripalimab in patients with HNSCC and gastric cancer in the first quarter of 2025, with initial data for both studies expected in the first half of 2026.

THIRD QUARTER 2024 FINANCIAL RESULTS

Net revenue was \$70.8 million during the three months ended September 30, 2024, and included \$66.1 million of net sales of UDENYCA and \$5.8 million of net sales of LOQTORZI. Net revenue was \$74.6 million during the three months ended September 30, 2023 and included \$33.0 million in net sales of UDENYCA and \$41.4 million attributable to the Company's divested products, CIMERLI and YUSIMRY.

Net revenue was \$212.8 million and \$165.7 million for the nine months ended September 30, 2024 and 2023, respectively. Total net revenue attributable to the Company's divested products, CIMERLI and YUSIMRY, during the first nine months of 2024 and 2023 was \$34.5 million and \$74.3 million, respectively. In addition, the first nine months of 2024 included other revenue of \$7.0 million mainly comprising the \$6.3 million up-front cash payment received for the outlicense to Apotex, Inc. of the Canadian rights to LOQTORZI on June 27, 2024.

Cost of goods sold (COGS) was \$20.7 million and \$32.7 million during the three months ended September 30, 2024 and 2023, respectively, and \$83.7 million and \$74.4 million during the nine months ended September 30, 2024 and 2023, respectively. The decrease in COGS for the third quarter of 2024 compared to the same period in the prior year was primarily due to \$24.1 million of COGS in the third quarter of 2023 related to CIMERLI and YUSIMRY, which were divested during the first half of 2024, partially offset by a \$9.7 million increase in product costs driven by increased UDENYCA volume.

The increase in COGS for the nine months ended September 30, 2024 compared to the same period in the prior year was primarily due to a \$27.8 million increase related to volumes driven by UDENYCA and LOQTORZI, \$4.5 million in connection with a CMO contract change, and \$2.5 million in LOQTORZI royalties. These increases were partially offset by non-recurring COGS related to products divested during the first half of 2024 mentioned above.

Research and development (R&D) expenses were \$21.7 million and \$25.6 million for the three months ended September 30, 2024 and 2023, respectively, and \$72.1 million and \$83.1 million for the nine months ended September 30, 2024 and 2023, respectively. The decreases were primarily due to savings from reduced headcount and lower costs related to biosimilar product divestitures, partially offset by costs for development of casdozokitug and CHS-114.

Selling, general and administrative (SG&A) expenses were \$34.7 million and \$48.2 million during the three months ended September 30, 2024 and 2023, respectively, and \$126.4 million and \$142.5 million during the nine months ended September 30, 2024 and 2023, respectively. The declines in SG&A compared to the prior year periods were driven primarily by lower headcount. The decrease for the nine-month period was partially offset by the net \$6.8 million charge in the first quarter of 2024 associated with the full write-off of the outlicense intangible asset and associated release of the CVR liability related to NZV930, obtained in the Surface Oncology, Inc. acquisition.

Interest expense was \$5.4 million and \$10.3 million during the three months ended September 30, 2024 and 2023, respectively, and \$21.8 million and \$29.9 million during the nine months ended September 30, 2024 and 2023, respectively. The declines in both periods were primarily due to prepaying \$175.0 million of the principal amount due under the 2027 Term Loans on April 1, 2024 and the remaining \$75.0 million principal amount on May 8, 2024, partially offset by interest on the senior secured term loan facility of up to \$38.7 million and the revenue participation right purchase and sale agreement, both commencing May 8, 2024.

Gain on sale transactions, net was \$176.6 million for the nine months ended September 30, 2024 and included a \$153.8 million gain on the divestiture of our CIMERLI ophthalmology franchise, which closed during the first quarter of 2024, and a \$22.9 million gain on the divestiture of our YUSIMRY immunology franchise, which closed during the second quarter of 2024. There was no gain on sale transactions in the nine months ended September 30, 2023.

Net loss for the third quarter of 2024 was \$10.8 million, or \$(0.09) per share on a diluted basis, compared to a net loss of \$39.6 million, or \$(0.41) per share on a diluted basis for the same period in 2023. Net income for the nine months ended September 30, 2024 was \$79.2 million, or \$0.65 per share on a diluted basis, compared to a net loss of \$158.2 million, or \$(1.79) per share on a diluted basis for nine months ended September 30, 2023.

Non-GAAP net loss for the third quarter of 2024 was \$1.7 million, or \$(0.01) per share on a diluted basis, compared to \$26.9 million, or \$(0.27) per share for the same period in 2023. Non-GAAP net loss for the nine months ended September 30, 2024 was \$53.8 million, or \$(0.47) per share on a diluted basis, compared to \$117.3 million, or \$(1.33) per share for the same period in 2023. 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 \$97.7 million as of September 30, 2024, compared to \$117.7 million as of December 31, 2023.

2024 R&D and SG&A Expense Guidance

Coherus projects combined R&D and SG&A expenses for 2024 to be in the range of \$250 to \$260 million. This guidance includes approximately \$30 million of stock-based compensation expense and excludes the effects of acquisitions, collaborations, investments, divestitures including expenses incurred on behalf of and reimbursed by Sandoz Inc. and Hong Kong King-Friend Industrial Company Ltd. to satisfy Coherus' obligations under the transition services agreements with those entities, restructuring, 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: Wednesday, November 6, 2024, 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/Bl6dfb4eba6e9a4322a716df863233a53f>
Please dial in 15 minutes early to ensure a timely connection to the call.

Webcast: <https://edge.media-server.com/mmc/p/fgk872yp>

An archived webcast will be available on the "Investors" section of the Coherus website at <https://investors.coherus.com/events-presentations>.

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 is expected to 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 anti-IL-27 antibody currently being evaluated in two ongoing clinical studies: a Phase 1/2 study in advanced solid tumors and a Phase 2 study in hepatocellular carcinoma. CHS-114 is a highly selective, competitively positioned, ADCC-enhanced anti-CCR8 antibody currently in a Phase 1 study as a monotherapy in patients with advanced solid tumors and in combination with toripalimab in patients with head and neck cancer. CHS-1000 is a novel humanized Fc-modified IgG1 monoclonal antibody specifically targeting ILT4 (LILRB2). Our IND for CHS-1000 was allowed to proceed by the FDA in the second quarter of 2024 and proceeding to the first-in-human clinical study is subject to further evaluation in our portfolio prioritization process.

Coherus markets LOQTORZI[®] (toripalimab-tpzi), a novel next-generation PD-1 inhibitor, and UDENYCA[®] (pegfilgrastim-cbqv), a biosimilar of Neulasta[®].

Neulasta[®] is a registered trademark of Amgen 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' expectations about identifying synergies between its I-O pipeline and its commercial operations; Coherus' expected timing for initiating studies and reporting clinical data for its pipeline product candidates; Coherus' future projections for R&D and SG&A expenses; Coherus' expectations about long term revenue growth; Coherus' expected future packaging and labeling capacity for UDENYCA and Coherus' expectations about the timing for the end of its UDENYCA supply interruption, including timing for resumption of UDENYCA production from its labeling and packaging CMO, timing for the backlog of UDENYCA lots to be completed by its labeling and packaging CMO and projections for the number of units to be completed, the expected timing for its additional packaging and labeling CMO to manufacture final saleable product, receive FDA authorization for UDENYCA production and commence commercial supply.

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 related to Coherus' existing and potential collaboration partners; risks of Coherus' reliance on third-parties; the risks and uncertainties related to manufacturing and supply of Coherus' products, the risks and uncertainties of the regulatory approval process, including the speed of regulatory review and the timing of Coherus' regulatory filings; 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, 2024 filed with the Securities and Exchange Commission on or about the date of this press release, including the section therein captioned "Risk Factors" and in other documents Coherus files with the Securities and Exchange Commission. Coherus' results for the fiscal quarter ended September 30, 2024 are not necessarily indicative of its operating results for any future periods.

UDENYCA[®], UDENYCA[®] ONBODY[™], 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,	
	2024	2023	2024	2023
Net revenue	\$ 70,774	\$ 74,568	\$ 212,816	\$ 165,720
Costs and expenses:				
Cost of goods sold	20,741	32,703	83,695	74,425
Research and development	21,676	25,647	72,101	83,068
Selling, general and administrative	34,744	48,224	126,441	142,521
Total costs and expenses	77,161	106,574	282,237	300,014
Loss from operations	(6,387)	(32,006)	(69,421)	(134,294)
Interest expense	(5,362)	(10,268)	(21,812)	(29,923)
Gain (loss) on Sale Transactions, net	(1,086)	—	176,646	—
Loss on debt extinguishment	—	—	(12,630)	—
Other income (expense), net	2,084	2,253	6,420	5,598

Income (loss) before income taxes	(10,751)	(40,021)	79,203	(158,619)
Income tax provision	—	(380)	—	(380)
Net income (loss)	\$ (10,751)	\$ (39,641)	\$ 79,203	\$ (158,239)
Net income (loss) per share:				
Basic	\$ (0.09)	\$ (0.41)	\$ 0.69	\$ (1.79)
Diluted	\$ (0.09)	\$ (0.41)	\$ 0.65	\$ (1.79)
Weighted-average number of shares used in computing net income (loss) per share:				
Basic	115,210,091	97,738,509	114,263,256	88,277,936
Diluted	115,210,091	97,738,509	126,563,551	88,277,936

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

	September 30, 2024	December 31, 2023
Assets		
Cash and cash equivalents	\$ 97,690	\$ 102,891
Investments in marketable securities	—	14,857
Trade receivables, net	167,559	260,522
TSA receivables, net	31,241	—
Inventory	119,015	130,100
Intangible assets, net	54,313	71,673
Other assets	35,182	49,561
Total assets	\$ 505,000	\$ 629,604
Liabilities and Stockholders' Deficit		
Accrued rebates, fees and reserve	\$ 163,315	\$ 169,645
TSA payables and other accrued liabilities	33,637	—
Term loans	36,618	246,481
Convertible notes	227,891	226,888
Other liabilities	131,512	180,015
Total stockholders' deficit	(87,973)	(193,425)
Total liabilities and stockholders' deficit	\$ 505,000	\$ 629,604

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Cash, cash equivalents and restricted cash at beginning of the period	\$ 159,692	\$ 73,360	\$ 103,343	\$ 63,987
Net cash used in operating activities	(62,016)	(54,300)	(49,048)	(161,947)
Proceeds from maturities of investments in marketable securities	—	43,398	6,200	108,148
Proceeds from sale of investments in marketable securities	—	—	8,688	13,282
Cash and cash equivalents acquired from Surface Acquisition	—	6,997	—	6,997
Cash received from CIMERLI sale	—	—	187,823	—
Cash received from YUSIMRY sale	—	—	40,000	—
Milestone based license fee payment to Junshi Biosciences	—	—	(12,500)	—
Purchases of investments in marketable securities	—	—	—	(19,507)
Other investing activities, net	444	151	652	517
Net cash provided by investing activities	444	50,546	230,863	109,437
Proceeds from 2029 Term Loan, net of debt discount & issuance costs	(141)	—	36,979	—

Proceeds from Revenue Purchase and Sale Agreement, net of issuance costs	(9)	—	36,486	—
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	—	11,437	1,455	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	291	170
Proceeds from purchase under the employee stock purchase plan	—	—	685	1,337
Repayment of 2027 Term Loans, premiums and fees	—	—	(260,387)	—
Taxes paid related to net share settlement	(10)	(175)	(2,466)	(3,261)
Other financing activities	(7)	(210)	(248)	(835)
Net cash (used in) provided by financing activities	<u>(167)</u>	<u>11,105</u>	<u>(187,205)</u>	<u>69,234</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>(61,739)</u>	<u>7,351</u>	<u>(5,390)</u>	<u>16,724</u>
Cash, cash equivalents and restricted cash at end of the period	\$ 97,953	\$ 80,711	\$ 97,953	\$ 80,711
Reconciliation of cash, cash equivalents, and restricted cash				
Cash and cash equivalents	\$ 97,690	\$ 80,259	\$ 97,690	\$ 80,259
Restricted cash balance	<u>263</u>	<u>452</u>	<u>263</u>	<u>452</u>
Cash, cash equivalents and restricted cash	\$ 97,953	\$ 80,711	\$ 97,953	\$ 80,711

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 income (loss), and the related per share measures, stock-based compensation expense, certain acquisition-related expenses, amortization of intangible assets, gain (loss) on divestiture, impairments of intangible assets, contingent consideration, 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 Income (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,	
	2024	2023	2024	2023
GAAP net income (loss)	\$ (10,751)	\$ (39,641)	\$ 79,203	\$ (158,239)
Adjustments:				
Stock-based compensation expense ⁽¹⁾	6,868	9,954	21,418	31,364
Loss (gain) on Sale Transactions, net	1,086	—	(176,646)	—
Loss on debt extinguishment	—	—	12,630	—
Impairment of out-license asset and remeasurement of CVR liability, net	—	—	6,772	—
Restructuring charges related to reduction in workforce ⁽¹⁾	—	—	—	4,876
Acquisition-related costs, including amortization of intangibles ⁽²⁾	1,142	2,830	2,776	4,691
Non-GAAP net loss	<u>\$ (1,655)</u>	<u>\$ (26,857)</u>	<u>\$ (53,847)</u>	<u>\$ (117,308)</u>
GAAP				
Net income (loss) per share, basic	\$ (0.09)	\$ (0.41)	\$ 0.69	\$ (1.79)
Net income (loss) per share, diluted	\$ (0.09)	\$ (0.41)	\$ 0.65	\$ (1.79)
Shares used in computing basic net income (loss) per share	115,210,091	97,738,509	114,263,256	88,277,936
Shares used in computing diluted net income (loss) per share	115,210,091	97,738,509	126,563,551	88,277,936
Non-GAAP				
Net loss per share, basic and diluted	\$ (0.01)	\$ (0.27)	\$ (0.47)	\$ (1.33)
Shares used in computing basic and diluted net loss per share	115,210,091	97,738,509	114,263,256	88,277,936

(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.