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

Aug 8, 2024

– Net revenue of $65.0 million in Q2 2024 –

– CHS-114 Phase 1 Study Recruitment Continues into Expansion Cohorts in Head and Neck Cancer in Combination with LOQTORZI *–*

– Bryan McMichael Appointed as Chief Financial Officer –

– Conference call today at 5:00 p.m. Eastern Time –

REDWOOD CITY, Calif., Aug. 08, 2024 (GLOBE NEWSWIRE) -- **Coherus BioSciences, Inc.** (Coherus, Nasdaq: CHRS), today reported financial results for the quarter ended June 30, 2024 and recent business highlights:

RECENT BUSINESS HIGHLIGHTS

UDENYCA® RESULTS
UDENYCA net product sales were $50.9 million in Q2 2024, an increase of 19% compared to $42.7 million in Q1 2024 and a 60% increase compared to $31.7 million in Q2 2023.

- Total unit demand increased 25% in Q2 2024 compared to Q1 2024, and 138% compared to Q2 2023.
- Based on data from IQVIA, UDENYCA franchise market share for Q2 2024 was 29.0%, an increase of 4 market share points from Q1 2024.

LOQTORZI® LAUNCH UPDATE

- LOQTORZI, the first and only FDA-approved treatment for recurrent, locally advanced or metastatic nasopharyngeal carcinoma (NPC), commercially launched on January 2, 2024.
- LOQTORZI net sales in Q2 2024 of $3.8 million, with new patient uptake primarily in relapsed locally advanced and 1L metastatic disease, a potential driver of long-term revenue growth.
- LOQTORZI can now be ordered in all 33 National Comprehensive Cancer Network (NCCN) institutions.
- The Centers for Medicare and Medicaid Services granted LOQTORZI a product-specific, permanent J Code, which was implemented on July 1, 2024.

ADVANCEMENT OF PROMISING IMMUNO-ONCOLOGY PIPELINE

- Clinical data from the dose escalation stage of the Phase 1 study of CHS-114, a highly selective cytolytic anti-CCR8 antibody, was presented at the 2024 ASCO Annual Meeting in June. These data showed selective depletion of peripheral CCR8+ regulatory T cells, establishing proof of mechanism for CHS-114, and an acceptable safety profile with no dose-limiting toxicities, and a disease control rate of 47% in heavily pretreated patients with solid tumors. Expansion cohorts evaluating CHS-114 as monotherapy and in combination with toripalimab are currently enrolling patients with advanced/metastatic head and neck squamous cell carcinoma (HNSCC).
- A Phase 2 study evaluating casdozokitug, an immune regulatory IL-27 antagonizing antibody, in combination with toripalimab and bevacizumab in treatment naïve patients with unresectable locally advanced or metastatic hepatocellular carcinoma is expected to begin enrolling patients in Q4 2024.
- An Investigational New Drug (IND) application for CHS-1000, a novel humanized Fc-modified IgG1 monoclonal antibody specifically targeting ILT4 (LILRB2), was filed with the U.S. Food and Drug Administration (FDA) in Q2 2024 and received clearance. Coherus plans to initiate a Phase 1 study in the coming months.

“The first half of 2024 has been a period of disciplined execution of our strategy, which included improving our capital structure, advancing our innovative oncology pipeline and driving increasing sales of our commercial portfolio. We continue to streamline our operations, solidifying our focus on our oncology business,” said Denny Lanfear, Coherus’ Chairman and Chief Executive Officer. “Bryan McMichael, our newly appointed Chief Financial Officer, will play a key role on our management team as we further translate this oncology focus into shareholder value.”

“I am honored to carry forward my work at Coherus in the role of Chief Financial Officer. The strength of the team, commercial portfolio, and pipeline gives me great confidence in the Company’s future,” said Bryan McMichael, Coherus’ Chief Financial Officer. “I look forward to continuing in my partnership with Denny, the Board, and other members of management to execute our strategy and bring value to shareholders.”

SECOND QUARTER 2024 FINANCIAL RESULTS

Net revenue was $65.0 million during the three months ended June 30, 2024, and included $50.9 million of net sales of UDENYCA, $3.8 million of net sales of LOQTORZI, which was launched on January 2, 2024, $3.8 million of net sales of YUSIMRY, which was divested to Hong Kong King-Friend Industrial Company Ltd. (“HKF”) on June 26, 2024, and other revenue of $6.5 million which included 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. Net revenue was $58.7 million during the three months ended June 30, 2023 and included $26.7 million in revenues for CIMERLI, which was divested on March 1, 2024. Net revenue was $142.0 million and $91.2 million for the six months ended June 30, 2024 and 2023, respectively. Total net revenues attributable to the Company’s divested products, CIMERLI and YUSIMRY, during the first half of 2024 and 2023 were $35.9 million and $32.9 million, respectively.

Cost of goods sold (COGS) was $28.4 million and $24.8 million during the three months ended June 30, 2024 and 2023, respectively, and $63.0 million and $41.7 million during the six months ended June 30, 2024 and 2023, respectively. UDENYCA COGS included a mid-single digit royalty on net sales which expired on July 1, 2024. The increases in COGS in both 2024 periods were primarily driven by increased unit volumes, and in the second quarter of 2024, a $4.5 million fee for a contract change with a CMO, partially offset by a $9.7 million decrease in royalty costs in the second quarter of 2024, due to the CIMERLI divestiture on March 1, 2024.

Research and development (R&D) expenses were $22.0 million and $23.3 million for the three months ended June 30, 2024 and 2023, respectively, and $50.4 million and $57.4 million for the six months ended June 30, 2024 and 2023, respectively. The decreases were primarily due to savings from reduced headcount and lower costs related to biosimilar products, partially offset by increased costs for development of casdozokitug and CHS-114.

Selling, general and administrative (SG&A) expenses were $35.2 million and $45.1 million during the three months ended June 30, 2024 and 2023, respectively, and $91.7 million and $94.3 million during the six months ended June 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 six-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.

Gain on Sale Transactions, Net which included the divestiture of the YUSIMRY franchise, which closed during the three months ended June 30, 2024, was $22.9 million, and reflects total cash proceeds of $40.0 million, net of assets transferred to HKF, liabilities derecognized, and transactions costs of $0.9 million. Gain on Sale Transactions, net for the first half of 2024 was $177.7 million and included a $154.8 million gain on the divestiture of the CIMERLI franchise, which closed during the three months ended March 31, 2024. There was no gain on Sale Transactions in the first half of 2023.

Interest expense was $5.3 million and $9.9 million during the three months ended June 30, 2024 and 2023, respectively, and $16.5 million and $19.7 million during the six months ended June 30, 2024 and 2023, respectively. The declines in both periods were primarily due to prepaying $175.0 million of the principal amount of the senior secured term loan facility that was entered into on January 5, 2022 on April 1, 2024 and prepaying the remaining $75.0 million principal amount on May 8, 2024. This was offset by interest on the $38.7 million principal amount of the new term loan facility and the revenue participation right purchase and sale agreement, both commencing May 8, 2024, as well as an average higher variable rate in the first half of 2024 compared to the first half of 2023.

Net loss for the second quarter of 2024 was $12.9 million, or $(0.11) per share on a diluted basis, compared to a net loss of $42.9 million, or $(0.49) per share on a diluted basis for the same period in 2023. Net income for the first half of 2024 was $90.0 million, or $0.73 per share on a diluted basis, compared to a net loss of $118.6 million, or $(1.42) per share on a diluted basis for the first half of 2023.

Non-GAAP net loss for the second quarter of 2024 was $16.4 million, or $(0.14) per share on a diluted basis, compared to $32.8 million, or $(0.38) per share for the same period in 2023. Non-GAAP net loss for the first half of 2024 was $52.2 million, or $(0.46) per share on a diluted basis, compared to $92.3 million, or $(1.11) per share for the first half of 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 $159.2 million as of June 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 $265 million. This guidance includes approximately $40 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 and HKF 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: Thursday, August 8, 2024, starting at 5:00 p.m. Eastern Daylight 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/BI9dd3f986eeb7428485a66ce1fb34999f
Please dial in 15 minutes early to ensure a timely connection to the call.

Webcast: https://edge.media-server.com/mmc/p/kguryzuk

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. CHS-1000 is a novel humanized Fc-modified IgG1 monoclonal antibody specifically targeting ILT4 (LILRB2). An IND application has been accepted by the FDA and Coherus plans to initiate a Phase 1 study in the coming months.

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 the start of a Phase 1 study for CHS-1000; Coherus’ expected timing for enrolling patients in a Phase 2 study evaluating casdozokitug; Coherus’ future projections for R&D

and SG&A expenses; and Coherus' expectations about long term revenue growth.

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' competitive position; the risks and uncertainties of the regulatory approval process, including the speed of regulatory review and the timing of Coherus' regulatory filings; the risk of FDA review issues; 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 filing on Form 10-Q for the fiscal quarter ended June 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 June 30, 2024 are not necessarily indicative of its operating results for any future periods.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net revenue	$ 64,979	$ 58,716	$ 142,042	$ 91,152
Costs and expenses:				
Cost of goods sold	28,368	24,848	62,954	41,722
Research and development	21,955	23,267	50,425	57,421
Selling, general and administrative	35,165	45,144	91,697	94,297
Total costs and expenses	85,488	93,259	205,076	193,440
Loss from operations	(20,509)	(34,543)	(63,034)	(102,288)
Interest expense	(5,334)	(9,943)	(16,450)	(19,655)
Gain on Sale Transactions, net	24,085	—	177,732	—
Loss on debt extinguishment	(12,630)	—	(12,630)	—
Other income (expense), net	1,467	1,617	4,336	3,345
Income (loss) before income taxes	(12,921)	(42,869)	89,954	(118,598)
Income tax provision	—	—	—	—
Net income (loss)	$ (12,921)	$ (42,869)	$ 89,954	$ (118,598)
Net income (loss) per share:				
Basic	$ (0.11)	$ (0.49)	$ 0.79	$ (1.42)
Diluted	$ (0.11)	$ (0.49)	$ 0.73	$ (1.42)
Weighted-average number of shares used in computing net income (loss) per share:				
Basic	114,819,965	87,269,614	113,784,636	83,469,247
Diluted	114,819,965	87,269,614	126,174,802	83,469,247

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

	June 30, 2024	December 31, 2023

Assets		
Cash and cash equivalents	$ 159,240	$ 102,891
Investments in marketable securities	—	14,857
Trade receivables, net	175,251	260,522
TSA receivables, net	138,317	—
Inventory	112,041	130,100
Intangible assets, net	55,455	71,673
Other assets	34,551	49,561
Total assets	$ 674,855	$ 629,604
Liabilities and Stockholders' Deficit		
Accrued rebates, fees and reserve	$ 177,455	$ 169,645
TSA payables and other accrued liabilities	133,536	—
Term loans	36,541	246,481
Convertible notes	227,555	226,888
Other liabilities	183,876	180,015
Total stockholders' deficit	(84,108)	(193,425)
Total liabilities and stockholders' deficit	$ 674,855	$ 629,604

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Cash, cash equivalents and restricted cash at beginning of the period	$ 260,227	$ 16,585	$ 103,343	$ 63,987
Net cash provided by (used in) operating activities	59,734	(38,915)	12,968	(107,647)
Proceeds from maturities of investments in marketable securities	—	47,250	6,200	64,750
Proceeds from sale of investments in marketable securities	—	13,282	8,688	13,282
Cash received from CIMERLI sale	—	—	187,823	—
Cash received from YUSIMRY sale	40,000	—	40,000	—
Milestone based license fee payment to Junshi Biosciences	(12,500)	—	(12,500)	—
Purchases of investments in marketable securities	—	(19,507)	—	(19,507)
Other investing activities, net	156	340	208	366
Net cash provided by investing activities	27,656	41,365	230,419	58,891
Proceeds from 2029 Term Loan, net of debt discount & issuance costs	37,120	—	37,120	—
Proceeds from Revenue Purchase and Sale Agreement, net of issuance costs	36,495	—	36,495	—
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	(52)	(74)	1,455	6,761
Proceeds from issuance of common stock under Public Offering, net of issuance costs	—	53,625	—	53,625
Proceeds from issuance of common stock upon exercise of stock options	—	14	291	117
Proceeds from purchase under the employee stock purchase plan	685	1,337	685	1,337
Repayment of 2027 Term Loans, premiums and fees	(260,387)	—	(260,387)	—
Taxes paid related to net share settlement	(1,711)	(305)	(2,456)	(3,086)
Other financing activities	(75)	(272)	(241)	(625)
Net cash (used in) provided by financing activities	(187,925)	54,325	(187,038)	58,129
Net increase (decrease) in cash, cash equivalents and restricted cash	(100,535)	56,775	56,349	9,373
Cash, cash equivalents and restricted cash at end of the period	$ 159,692	$ 73,360	$ 159,692	$ 73,360
Reconciliation of cash, cash equivalents, and restricted cash				
Cash and cash equivalents	$ 159,240	$ 72,920	$ 159,240	$ 72,920
Restricted cash balance	452	440	452	440
Cash, cash equivalents and restricted cash	$ 159,692	$ 73,360	$ 159,692	$ 73,360

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 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 June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
GAAP net income (loss)	$ (12,921)	$ (42,869)	$ 89,954	$ (118,598)
Adjustments:				
Stock-based compensation expense[1]	7,231	10,077	14,550	21,410
Gain on Sale Transactions, net	(24,085)	—	(177,732)	—
Loss on debt extinguishment	12,630	—	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
Amortization of intangible assets	704	—	1,634	—
Non-GAAP net loss	$ (16,441)	$ (32,792)	$ (52,192)	$ (92,312)
GAAP				
Net income (loss) per share, basic	$ (0.11)	$ (0.49)	$ 0.79	$ (1.42)
Net income (loss) per share, diluted	$ (0.11)	$ (0.49)	$ 0.73	$ (1.42)
Shares used in computing basic net income (loss) per share	114,819,965	87,269,614	113,784,636	83,469,247
Shares used in computing diluted net income (loss) per share	114,819,965	87,269,614	126,174,802	83,469,247
Non-GAAP				
Net loss per share, basic and diluted	$ (0.14)	$ (0.38)	$ (0.46)	$ (1.11)
Shares used in computing basic and diluted net loss per share	114,819,965	87,269,614	113,784,636	83,469,247

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

Coherus

Source: Coherus BioSciences, Inc.