Coherus BioSciences Reports Fourth Quarter, Full Year 2023 Financial Results and Provides Current Business Update

Mar 13, 2024

– Net revenue of $91.5 million in the fourth quarter and $257.2 million in FY 2023 –

– UDENYCA® net sales of $36.2 million in the fourth quarter and $127.1 million in FY 2023 –

– CIMERLI® net sales of $52.4 million in the fourth quarter and $125.4 million in FY 2023 –

– LOQTORZI™ and UDENYCA ONBODY™ successfully launched in Q1 2024

– Reduction of work force of 30% for 2024 initiated on March 7, 2024 –

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

REDWOOD CITY, Calif., March 13, 2024 (GLOBE NEWSWIRE) -- **Coherus BioSciences, Inc.** (Coherus, Nasdaq: CHRS), today reported financial results for its fiscal fourth quarter and full year ended December 31, 2023 and recent business highlights:

RECENT BUSINESS HIGHLIGHTS

CORPORATE RESTRUCTURING SOLIDIFIES FOCUS ON ONCOLOGY

- On March 1, 2024, Coherus closed the divestiture of the ophthalmology franchise to Sandoz for upfront, all-cash consideration of $170 million plus an additional $17.8 million for CIMERLI product inventory and prepaid manufacturing assets.
- On or before April 1, 2024, Coherus plans to prepay $175 million of the $250 million principal balance of its term loan with Pharmakon Advisors LP (“Pharmakon”), leaving a residual balance of $75 million and reducing projected annualized Pharmakon related interest payments by about 70%.
- The sharpened focus in oncology and a subsequent restructuring is expected to result in a reduction in workforce of 30% by the end of 2024, including 35 employees associated with the ophthalmology divestiture, for an estimated annualized cost savings of more than $25 million.
- Expected SG&A and R&D expenses for 2024 reduced from $301.5 million in 2023 to $250-265 million representing at least a 12% decrease year over year.
- The $25 million toripalimab NPC approval milestone due to be paid to Junshi Biosciences in Q1 2024 has been restructured such that $12.5 million will be paid in Q2 2024 and the remainder in Q1 2025, potentially adjusted downward for proceeds from Canadian rights.

UDENYCA® RESULTS and ONBODY LAUNCH UPDATE

- UDENYCA net product sales increased 10% in the fourth quarter 2023 to $36.2 million compared to $33.0 million in the third quarter. Total unit demand grew 7% quarter over quarter. UDENYCA Autoinjector presentation unit demand grew 129% quarter over quarter. Since commercial launch in May 2023, more than 727 accounts have ordered the Autoinjector presentation.
- UDENYCA ONBODY, a novel and proprietary state-of-the-art delivery system for pegfilgrastim-cbqv, was launched in February 2024. High customer demand coupled with confirmed payer coverage, drove robust uptake with 138 accounts ordering ONBODY within the first four weeks of launch.
- Based on data from IQVIA, rolling 4-week UDENYCA market share as of March 1 was 26%.

LOQTORZI™ LAUNCH UPDATE

- LOQTORZI is the first and only FDA-approved treatment for recurrent or metastatic NPC in all lines of therapy with commercial launch commencing on January 2, 2024.
- NCCN Guidelines recommend LOQTORZI as the only immunotherapeutic agent with Preferred Category 1 status in first-line treatment for adults with metastatic or recurrent locally advanced NPC in combination with chemotherapy; LOQTORZI monotherapy is also recommended in NCCN guidelines as the only preferred regimen in subsequent lines of therapy.
- Category 1 represents the highest level of evidence and uniformity among panel members in terms of agreement that translates into ease of reimbursement and the ability to establish a new standard of care for these patients.
- Payer coverage for LOQTORZI has been confirmed across Medicare Fee for Service, as well as national and regional commercial health plans.
- Early demand uptake tracking to expectations, with over 59 NPC targeted accounts ordering the product since launch.

NOVEL IMMUNO-ONCOLOGY PIPELINE ADVANCES

- In January 2024, Coherus entered into a clinical collaboration with INOVIO to evaluate LOQTORZI (toripalimab-tpzi) in combination with INO-3112 in a Phase 3 clinical trial as a potential treatment for patients with locoregionally advanced, high-risk, HPV16/18 positive oropharyngeal squamous cell carcinoma (OPSCC), a type of head and neck cancer commonly known as throat cancer.
- Coherus presented new Phase 1b/2 clinical data for casdozokitug, a first-in-class IL-27 antagonist at the 2023 ESMO IO Congress in December and 2024 ASCO Gastrointestinal Cancers Symposium in January. Results show encouraging signs of antitumor activity and an acceptable safety profile for casdozokitug alone and in combination with PD-(L)1 inhibitors with or without bevacizumab in HCC and NSCLC respectively. Importantly, responses were associated with IL-27 related biomarkers and data support planned clinical trials with casdozokitug/ toripalimab-tpzi in NSCLC and HCC.
- New preclinical data for CHS-1000 has been selected for a poster presentation at the upcoming 2024 AACR Annual Meeting being held April 5-10, 2024, in San Diego.
- Coherus plans to file an Investigational New Drug (IND) application in second quarter of 2024 for CHS-1000, a novel ILT4-targeted antibody.

"Throughout 2023, Coherus demonstrated significant progress in transforming the Company's business model and product portfolio for long-term sustainable growth," said Denny Lanfear, Coherus' Chairman and Chief Executive Officer. "We are clearly focused on driving our revenues, reducing our costs, and advancing our pipeline, with constant attention to long-term shareholder value. The divestiture of CIMERLI and debt paydown improves our capital structure and sharpens our focus on oncology. With a robust portfolio of FDA-approved products and a promising immuno-oncology pipeline, we are now better positioned than ever to execute on our mission of extending the lives of cancer patients."

FOURTH QUARTER and FULL YEAR 2023 FINANCIAL RESULTS

Net revenue was $91.5 million during the three months ended December 31, 2023 and included $36.2 million of net sales of UDENYCA, $52.4 million of net sales of CIMERLI, $2.2 million of net sales of YUSIMRY™ which was launched in July 2023 and $0.6 million of net sales of LOQTORZI which began shipping to distributors in December 2023 in preparation for launch. Net revenue was $45.4 million during the three months ended December 31, 2022. For the twelve months ended December 31, 2023 and 2022, net revenue was $257.2 million and $211.0 million, respectively. The increases in total net revenues were driven by the launches of CIMERLI and YUSIMRY and by the return to growth of UDENYCA throughout 2023.

Cost of goods sold (COGS) was $84.6 million and $14.2 million during the three months ended December 31, 2023 and 2022, respectively, and $159.0 million and $70.1 million during the full year ended December 31, 2023 and 2022, respectively. The increases in COGS for the three month and the annual periods each included a $47.0 million charge for the write-down of slow moving YUSIMRY inventory and the related partial recognition of certain firm purchase commitments. Increases in COGS also included $19.4 million and $47.5 million in royalty costs compared to the quarterly and annual periods in the prior year, respectively and increases in product costs of $11.5 million and $25.0 million, respectively, primarily driven by CIMERLI sales. The increase in the year over year COGS was partially offset by a $26.0 million write-down in the third quarter 2022 of inventory at risk of expiration and due to the sale in the second half 2023 of certain of those UDENYCA units having a total original cost of $9.9 million but no carrying value following the write-down. UDENYCA COGS includes a mid-single digit royalty on net sales payable through the first half of 2024, and CIMERLI® COGS includes a low to mid 50% royalty on gross profits.

Research and development (R&D) expense for the three months ended December 31, 2023 and 2022 was $26.4 million and $29.0 million, respectively. For the full year ended December 31, 2023 and 2022, R&D expense was $109.4 million and $199.4 million, respectively. The decline 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 full year 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 $49.5 million and $53.6 million during the three months ended December 31, 2023 and 2022, respectively, and $192.0 million and $198.5 million during the full year ended December 31, 2023 and 2022, respectively. The decline in SG&A expense in both periods compared to the prior year periods primarily reflects lower headcount, partially offset by transaction costs associated with the Surface acquisition.

Net loss for the fourth quarter of 2023 was $79.7 million, or $(0.71) per share on a basic and diluted basis, compared to a net loss of $58.9 million, or $(0.76) per share on a basic and diluted basis for the same period in 2022. Net loss for the full year of 2023 was $237.9 million, or $(2.53) per share on a basic and diluted basis, compared to a net loss of $291.8 million, or $(3.76) per share on a basic and diluted basis for the full year of 2022.

Non-GAAP net loss for the fourth quarter of 2023 was $68.9 million, or $(0.62) per share on a basic and diluted basis, compared to non-GAAP net loss of $47.1 million, or $(0.60) per share on a basic and diluted basis for the same period in 2022. Non-GAAP net loss for the full year of 2023 was $186.2 million, or $(1.98) per share on a basic and diluted basis, compared to non-GAAP net loss of $234.8 million, or $(3.02) per share on a basic and diluted basis for the full year of 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 $117.7 million as of December 31, 2023, compared to $191.7 million at December 31, 2022.

2024 R&D and SG&A Expense Guidance

Coherus is introducing a guidance range of combined 2024 R&D and SG&A expenses from $250 to $265 million. This guidance includes approximately $40 million of stock-based compensation expense and excludes the effects of 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: Wednesday, March 13, 2024, starting at 5:00 p.m. Eastern Time

To access the conference call, please register through the following link to receive dial-in information and a personal PIN to access the live call: https://register.vevent.com/register/BI41e6b8f8ab024eefafe43493f6fd0cdf

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

Webcast: https://edge.media-server.com/mmc/p/7c7bss7i

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 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 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 1/2 study as a monotherapy in patients with advanced solid tumors. CHS-1000 is a preclinical candidate targeting immune-suppressive mechanisms via the novel pathway ILT4 with an IND filing planned in the first half of 2024.

Coherus markets LOQTORZI™ (toripalimab-tpzi), a novel next generation PD-1 inhibitor, UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta®, and YUSIMRY™ (adalimumab-aqvh), a biosimilar of Humira®.

Neulasta® is a registered trademark of Amgen, 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’ expected timing for filing an IND for CHS-1000; Coherus’ future projections for R&D expense and SG&A expense; Coherus’ expectations for timing, principal paid and interest payment reductions for its term loan with Pharmakon Advisors, LP; the size of the reduction of workforce in 2024; and Coherus’ expectations that it will be able to realize value in the future from its pipeline.

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 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’ Annual Report on Form 10-K for the fiscal year ended December 31, 2023 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 year ended December 31, 2023 are not necessarily indicative of its operating results for any future periods.

Coherus Contact Information:
For Investors:
Jami Taylor
Head of Investor Relations
IR@coherus.com

For Media:
Jodi Sievers
VP, Corporate Communications
media@coherus.com

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Net revenue	$ 91,524	$ 45,352	$ 257,244	$ 211,042
Costs and expenses:				
Cost of goods sold	84,567	14,202	158,992	70,083
Research and development	26,368	29,022	109,436	199,358
Selling, general and administrative	49,494	53,621	192,015	198,481
Total costs and expenses	160,429	96,845	460,443	467,922
Loss from operations	(68,905)	(51,493)	(203,199)	(256,880)
Interest expense	(10,619)	(9,385)	(40,542)	(32,474)
Loss on debt extinguishment	—	—	—	(6,222)

Other income (expense), net	(129)	2,008	5,469	3,822
Loss before income taxes	(79,653)	(58,870)	(238,272)	(291,754)
Income tax provision (benefit)	—	—	(380)	—
Net loss	$ (79,653)	$ (58,870)	$ (237,892)	$ (291,754)
Basic and diluted net loss per share	$ (0.71)	$ (0.76)	$ (2.53)	$ (3.76)
Weighted-average number of shares used in computing basic and diluted net loss per share	111,492,596	77,955,769	94,162,637	77,630,020

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

	December 31, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 102,891	$ 63,547
Investments in marketable securities	14,857	128,134
Trade receivables, net	260,522	109,964
Inventory	130,100	115,051
Intangible assets, net	71,673	5,931
Other assets	49,561	58,220
Total assets	$ 629,604	$ 480,847
Liabilities and Stockholders' Deficit		
Accrued rebates, fees and reserve	$ 169,645	$ 54,461
Term loans	246,481	245,483
Convertible notes	226,888	225,575
Other liabilities	180,015	92,746
Total stockholders' deficit	(193,425)	(137,418)
Total liabilities and stockholders' deficit	$ 629, 604	$ 480,847

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Cash, cash equivalents and restricted cash at beginning of the period	$ 80,711	$ 287,245	$ 63,987	$ 417,635
Net cash used in operating activities	(12,937)	(99,953)	(174,884)	(241,124)
Purchases of investments in marketable securities	—	(127,382)	(19,507)	(127,382)
Proceeds from maturities of investments in marketable securities	36,212	—	144,360	—
Proceeds from sale of investments in marketable securities	—	—	13,282	—
Cash and cash equivalents acquired from Surface Acquisition	—	—	6,997	—
Option payment to Junshi Biosciences	—	—	—	(35,000)
Milestone based license fee payments	(1,051)	(2,429)	(1,051)	(2,429)
Other investing activities, net	42	(87)	559	(2,039)
Net cash provided by (used in) investing activities	35,203	(129,898)	144,640	(166,850)
Proceeds from 2027 Term Loans, net of debt discount & issuance costs	—	—	—	240,679
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	(105)	6,358	18,093	6,358
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	524	60	694	691

Proceeds from purchase under the employee stock purchase plan	472	665	1,809	2,320
Taxes paid related to net share settlement	(326)	(123)	(3,587)	(3,744)
Repayment of 2022 Convertible Notes and premiums	—	—	—	(109,000)
Repayment of 2025 Term Loan, premiums and exit fees	—	—	—	(81,750)
Other financing activities	(199)	(367)	(1,034)	(1,228)
Net cash provided by financing activities	366	6,593	69,600	54,326
Net increase (decrease) in cash, cash equivalents and restricted cash	22,632	(223,258)	39,356	(353,648)
Cash, cash equivalents and restricted cash at end of the period	$ 103,343	$ 63,987	$ 103,343	$ 63,987
Reconciliation of cash, cash equivalents, and restricted cash				
Cash and cash equivalents	$ 102,891	$ 63,547	$ 102,891	$ 63,547
Restricted cash balance	452	440	452	440
Cash, cash equivalents and restricted cash	$ 103,343	$ 63,987	$ 103,343	$ 63,987

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, amortization 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 Loss to Non-GAAP Net Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
GAAP net loss	$ (79,653)	$ (58,870)	$ (237,892)	$ (291,754)
Adjustments:				
Stock-based compensation expense[1]	10,797	11,726	42,161	50,737
Loss on debt extinguishment	—	—	—	6,222
Restructuring charges related to reduction in workforce[1]	—	—	4,876	—
Acquisition-related costs[2]	545	—	5,093	—
Contingent consideration	(920)	—	(920)	—
Amortization of intangible assets	313	—	456	—
Non-GAAP net loss	$ (68,918)	$ (47,144)	$ (186,226)	$ (234,795)
GAAP net loss per share, basic and diluted	$ (0.71)	$ (0.76)	$ (2.53)	$ (3.76)
Non-GAAP net loss per share, basic and diluted	$ (0.62)	$ (0.60)	$ (1.98)	$ (3.02)
Shares used in computing basic and diluted net loss per share	111,492,596	77,955,769	94,162,637	77,630,020

(1) In the year ended December 31, 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 incurred during the quarter ended June 30, 2023 has been excluded from SG&A expense for the year ended December 31, 2023.

Coherus

Source: Coherus BioSciences, Inc.