Coherus BioSciences Reports Fourth Quarter and Full Year 2022 Results

Mar 6, 2023

– Net product sales of $45.4 million in the fourth quarter 2022 and $211.0 million in FY 2022 –
– FDA is planning the toripalimab manufacturing site inspection in Q2 2023 –
– UDENYCA® autoinjector approved by FDA; UDENYCA® on-body injector under review by FDA –
– Planning underway for potential 2023 commercial launches of toripalimab, YUSIMRY™, UDENYCA® AI and UDENYCA® OBI –
– Conference call today at 5 p.m. ET –

REDWOOD CITY, Calif., March 06, 2023 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. ("Coherus" or the "Company", Nasdaq: CHRS), today reported financial results for its fiscal fourth quarter and full year ended December 31, 2022 and recent business highlights:

RECENT BUSINESS HIGHLIGHTS

- The U.S. Food and Drug Administration (FDA) has notified the Company of the planned dates in the second quarter of 2023 for its required inspection of the toripalimab manufacturing facility in China. The inspection, previously hindered by COVID-related travel restrictions, is part of the FDA's review of the biologics license application (BLA) for toripalimab, a PD-1 inhibitor for the treatment of nasopharyngeal carcinoma (NPC). Coherus plans to launch toripalimab in the U.S. directly upon potential approval by the FDA.
- The FDA on March 3, 2023 approved a single-dose, prefilled autoinjector presentation of UDENYCA® (pegfilgrastim-cbqv), which represents the first presentation innovation in the pegfilgrastim space in eight years and highlights Coherus' commitment to developing innovative treatments that expand access and address the needs of patients undergoing cancer treatment. Coherus plans to launch UDENYCA® AI in the second quarter.
- The FDA review of the prior approval supplement for Coherus' third pegfilgrastim presentation, the UDENYCA ® on-body injector (OBI), is ongoing, and Coherus plans to launch UDENYCA® OBI directly upon potential approval later this year.
- In February, the U.S. Centers for Medicare & Medicaid Services (CMS) assigned to CIMERLI® (ranibizumab-eqrn) a permanent, product-specific Q-code, which will become active on April 1, 2023. The Q-code is expected to enable more efficient billing processes and speed time to reimbursement for providers.
- On March 3, 2023, Coherus implemented a reduction in force impacting approximately 60 full-time and part-time employees in order to focus resources on strategic priorities including the commercialization of its diversified product portfolio and development of innovative immuno-oncology product candidates.
- Coherus is introducing a guidance range of combined R&D and SG&A expenses for 2023 of $315 to $335 million. This guidance reflects nearly $100 million in expense reductions compared to prior 2023 guidance provided in April 2022.

"2023 will be a year of continued transformation for Coherus with significant value drivers including four anticipated product launches and multiple upcoming clinical catalysts," said Denny Lanfear, Coherus' Chairman and Chief Executive Officer. "We are strengthening the UDENYCA ® franchise by offering unprecedented choice for patients and physicians with a prefilled syringe, autoinjector, and an on-body injector presentation of pegfilgrastim expected later this year. With onsite manufacturing inspections now being scheduled for toripalimab, we look forward to the approval and launch of toripalimab in NPC. We remain sharply focused on commercial execution as we accelerate near-term revenue growth with CIMERLI®, our Lucentis® biosimilar, further penetrate the pegfilgrastim market with new presentations for UDENYCA®, prepare for the launch of our Humira biosimilar, YUSIMRY™, and gain approval for and launch toripalimab in NPC."

Mr. Lanfear continued: "We expect significant topline revenue growth in 2023 and beyond as we execute commercially on our new product launches. We are also tightly focused on expense management throughout the Company and in coordination with our development and manufacturing partners, and the 2023 operating expense guidance we are providing today is nearly $100 million lower than we projected in April 2022. We expect revenue growth and expense control to enable a return to profitability in 2024."

FOURTH QUARTER and FULL YEAR 2022 FINANCIAL RESULTS

Net revenue was $45.4 million during the three months ended December 31, 2022 and included $38.3 million of net sales of UDENYCA® and $6.9 million of net sales of CIMERLI®, which was launched in October 2022. Net sales of UDENYCA® for the fourth quarter of 2022 were reduced by a $4.7 million charge for a contingent liability related to resolving a dispute regarding certain sales from October 2020 through December 2021. Net revenue was $73.4 million during the three months ended December 31, 2021. For the twelve months ended December 31, 2022 and 2021, net revenue was $211.0 million and $326.6 million, respectively, and consisted primarily of net sales of UDENYCA®. The decline for both the fourth quarter and the full year 2022 was primarily due to a decrease in the number of units of UDENYCA® sold as well as a lower net realized price due to increased competition.

Cost of goods sold (COGS) was $14.2 million and $12.1 million during the three months ended December 31, 2022 and 2021, respectively, and $70.1 million and $57.6 million during the full year ended December 31, 2022 and 2021, respectively. COGS for the full year of 2022 included a $26.0 million write-down taken in the third quarter 2022 for inventory at risk of expiration, and 2021 included the write-down of $5.1 million of inventory that did not meet Coherus' acceptance criteria. UDENYCA ® COGS also 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, 2022 and 2021 was $29.0 million and $50.8 million, respectively, driven by lower development costs. For the full year ended December 31, 2022 and 2021, R&D expense was $199.4 million and $363.1

million, respectively. The decrease was primarily due to the $136.0 million upfront license fee paid to Junshi Biosciences in 2021, less spending in 2022 related to additional presentations of UDENYCA®, and higher YUSIMRY™ development costs in 2021 for pre-approval inspections, all partially offset by the $35.0 million option exercise fee for CHS-006 in the first quarter of 2022.

Selling, general and administrative (SG&A) expense was $53.6 million and $50.1 million during the three months ended December 31, 2022 and 2021, respectively, and $198.5 million and $169.7 million during the full year ended December 31, 2022 and 2021, respectively. The increases were primarily driven by higher commercialization expenses in preparation for the commercial launch of CIMERLI® in 2022 and for multiple new product launches anticipated in 2023, including, of toripalimab, YUSIMRY™, the autoinjector and the on-body injector presentations of UDENYCA®.

Net loss for the fourth quarter of 2022 was $58.9 million, or $(0.76) per share on a basic and diluted basis, compared to a net loss of $45.7 million, or $(0.60) per share on a basic and diluted basis for the same period in 2021. Net loss for the full year of 2022 was $291.8 million, or $(3.76) per share on a basic and diluted basis, compared to a net loss of $287.1 million, or $(3.81) per share on a basic and diluted basis for the full year of 2021.

Non-GAAP net loss for the fourth quarter of 2022 was $47.1 million, or $(0.60) per share on a basic and diluted basis, compared to non-GAAP net loss of $35.1 million, or $(0.46) per share on a basic and diluted basis for the same period in 2021. Non-GAAP net loss for the full year of 2022 was $234.8 million, or $(3.02) per share on a basic and diluted basis, compared to non-GAAP net loss of $224.5 million, or $(2.98) per share on a basic and diluted basis for the full year of 2021. Beginning in the first quarter of 2022, the Company no longer regularly excludes upfront and milestone-based license fee payments from its non-GAAP financial information. To conform to this change, the prior period non-GAAP financial information has been recast to include upfront and milestone-based license fee payments. 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 $191.7 million as of December 31, 2022, compared to $417.2 million at December 31, 2021.

2023 R&D and SG&A Expense Guidance

Coherus is introducing a guidance range of combined 2023 R&D and SG&A expenses from $315 to $335 million. This guidance includes approximately $50 million of stock-based compensation expense and excludes any collaboration upfront payments to Klinge Pharma for the in-license of their Eylea® biosimilar program or milestones payments to Junshi Biosciences due upon U.S. approval of toripalimab. 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, March 6th, 2023, starting at 5 p.m. ET

Please register through the following link for dial-in information and personal PIN:
https://edge.media-server.com/mmc/p/jcpis3ko

Please register 15 minutes early to ensure a timely connection to the call.

A replay of the webcast will be archived at https://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 and the commercialization of our portfolio of FDA-approved therapeutics. Coherus' strategy is to build a leading immuno-oncology franchise funded with cash generated through net sales of its diversified portfolio of FDA-approved therapeutics.

In 2021, Coherus in-licensed toripalimab, an anti-PD-1 antibody, in the United States and Canada. The BLA for toripalimab in combination with chemotherapy as treatment for recurrent or metastatic nasopharyngeal carcinoma is currently under review by the FDA.

Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta®, and CIMERLI® (ranibizumab-eqrn), a biosimilar of Lucentis®, in the U.S., and expects to launch the FDA-approved Humira® biosimilar YUSIMRY™ (adalimumab-aqvh) in the U.S. in 2023.

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 build its immuno-oncology franchise to achieve a leading market position; Coherus' ability to generate cash; Coherus' investment plans; Coherus' future projections for R&D and SG&A expenses and the year in which it will become profitable and whether it can meet those projections; Coherus' launch date for YUSIMRY™; Coherus' ability to launch multiple new products and find catalysts in the future; Coherus' ability to increase revenues and decrease expenses; and the impact of the CIMERLI® Q-code.

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 need to schedule inspections in China 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' drug 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 the year ended December 31, 2022, to be filed with the Securities and Exchange Commission on or about March 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 and full year ended December 31, 2022 are not necessarily indicative of our operating results for any future periods.

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,	
	2022	2021	2022	2021
Net revenue	$ 45,352	$ 73,371	$ 211,042	$ 326,551
Costs and expenses:				
Cost of goods sold	14,202	12,104	70,083	57,591
Research and development	29,022	50,762	199,358	363,105
Selling, general and administrative	53,621	50,052	198,481	169,713
Total costs and expenses	96,845	112,918	467,922	590,409
Loss from operations	(51,493)	(39,547)	(256,880)	(263,858)
Interest expense	(9,385)	(5,793)	(32,474)	(22,959)
Loss on debt extinguishment	—	—	(6,222)	—
Other income (expense), net	2,008	(385)	3,822	(283)
Loss before income taxes	(58,870)	(45,725)	(291,754)	(287,100)
Income tax provision	—	—	—	—
Net loss	$ (58,870)	$ (45,725)	$ (291,754)	$ (287,100)
Basic and diluted net loss per share	$ (0.76)	$ (0.60)	$ (3.76)	$ (3.81)
Weighted-average number of shares used in computing basic and diluted net loss per share	77,955,769	76,828,940	77,630,020	75,449,632

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

	December 31, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 63,547	$ 417,195
Investments in marketable securities	128,134	—
Trade receivables, net	109,964	123,022
Inventory	115,051	93,252
Other assets	64,151	45,865
Total assets	$ 480,847	$ 679,334
Liabilities and Stockholders' Equity (Deficit)		
Accrued rebates, fees and reserve	$ 54,461	$ 79,027
Term loans	245,483	75,513
Convertible notes	225,575	332,767
Other liabilities	92,746	94,301
Total stockholders' equity (deficit)	(137,418)	97,726
Total liabilities and stockholders' equity (deficit)	$ 480,847	$ 679,334

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Cash, cash equivalents and restricted cash at beginning of the period	$ 287,245	$ 360,980	$ 417,635	$ 541,598
Net cash used in operating activities	(99,953)	(52,322)	(241,124)	(37,432)
Purchases of investments in marketable securities	(127,382)	(10,706)	(127,382)	(182,485)
Proceeds from maturities of investments in marketable securities	—	36,992	—	99,692

Proceeds from sale of investments in marketable securities	—	81,672	—	81,672
Upfront and option payments to Junshi Biosciences[1]	—	—	(35,000)	(136,000)
Cash used in other investing activities	(2,516)	(468)	(4,468)	(1,289)
Net cash (used in) provided by investing activities	(129,898)	107,490	(166,850)	(138,410)
Proceeds from 2027 Term Loans, net of debt discount & issuance costs	—	—	240,679	—
Proceeds from issuance of common stock to Junshi Biosciences, net of issuance costs	—	—	—	40,903
Proceeds from issuance of common stock upon exercise of stock options	60	673	691	10,399
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	6,358	—	6,358	—
Proceeds from purchase under the employee stock purchase plan	665	1,017	2,320	3,002
Taxes paid related to net share settlement of RSUs	(123)	(23)	(3,744)	(1,753)
Repayment of 2022 Convertible Notes and premiums	—	—	(109,000)	—
Repayment of 2025 Term Loan, premiums and exit fees	—	—	(81,750)	—
Other financing activities	(367)	(180)	(1,228)	(672)
Net cash provided by financing activities	6,593	1,487	54,326	51,879
Net (decrease) increase in cash, cash equivalents and restricted cash	(223,258)	56,655	(353,648)	(123,963)
Cash, cash equivalents and restricted cash at end of the period	$ 63,987	$ 417,635	$ 63,987	$ 417,635
Reconciliation of cash, cash equivalents, and restricted cash				
Cash and cash equivalents	$ 63,547	$ 417,195	$ 63,547	$ 417,195
Restricted cash balance	440	440	440	440
Cash, cash equivalents and restricted cash	$ 63,987	$ 417,635	$ 63,987	$ 417,635

(1) 2021 payments include license fees of $145.0 million pursuant to the collaboration agreement with Junshi Biosciences paid in the first quarter which was partially offset by a $9.0 million credit related to the fair value of the discount for lack of marketability on the common shares purchased under the stock purchase agreement with Junshi Biosciences in the second quarter.

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, loss on debt extinguishment and costs related to the termination of the CHS-2020 development program that Coherus announced in February 2021. Starting in the first quarter of 2022, Coherus no longer excludes upfront and milestone-based license payments from its non-GAAP financial information. Comparative prior year non-GAAP amounts were recast and now include upfront and milestone-based license fee payments. 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 [1]

(in thousands, except share and per share data)

(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
GAAP net loss	$ (58,870)	$ (45,725)	$ (291,754)	$ (287,100)
Adjustments:				
Stock-based compensation expense	11,726	10,946	50,737	51,364
Loss on debt extinguishment	—	—	6,222	—
Costs related to termination of CHS-2020 development program	—	(292)	—	11,211
Non-GAAP net loss	$ (47,144)	$ (35,071)	$ (234,795)	$ (224,525)
GAAP net loss per share, basic and diluted	$ (0.76)	$ (0.60)	$ (3.76)	$ (3.81)

Non-GAAP net loss per share, basic and diluted	$ (0.60)	$ (0.46)	$ (3.02)	$ (2.98)
Shares used in computing basic and diluted net loss per share	77,955,769	76,828,940	77,630,020	75,449,632

(1) Beginning in the first quarter of 2022, the Company no longer regularly excludes upfront and milestone-based license fee payments from its non-GAAP financial information. To conform to this change, the prior period non-GAAP financial information has been recast to include upfront and milestone-based license fee payments.

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Source: Coherus BioSciences, Inc.