Coherus BioSciences Reports Second Quarter 2022 Results and Provides Business Update

Aug 4, 2022

– Commercial launch of CIMERLI ™ planned for early October 2022 –
– PDUFA date for toripalimab BLA is December 23, 2022 –
– Commercial preparation underway for planned July 2023 launch of YUSIMRY ™ –
– UDENYCA® delivers 2nd quarter 2022 net sales of $60.1 million –
– Conference call today at 5 p.m. ET –

REDWOOD CITY, Calif., Aug. 04, 2022 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Coherus or the Company, Nasdaq: CHRS), today reported financial results for the quarter ended June 30, 2022 and recent business highlights:

RECENT BUSINESS HIGHLIGHTS

- The U.S. Food and Drug Administration (FDA) has approved CIMERLI™ (ranibizumab-eqrn) as a biosimilar product interchangeable with Lucentis® (ranibizumab injection) for all five indications, with 12 months of interchangeability exclusivity. Commercial launch of CIMERLI™, in both 0.3 mg and 0.5 mg dosage forms, is planned for early October 2022.
- The FDA accepted for review the Biologics License Application (BLA) resubmission for toripalimab in combination with gemcitabine and cisplatin as first-line treatment for patients with advanced recurrent or metastatic nasopharyngeal carcinoma (NPC) and for toripalimab monotherapy for the second-line or later treatment of recurrent or metastatic NPC after platinum-containing chemotherapy. The FDA set a target action date of December 23, 2022 for the toripalimab BLA.

"Coherus is entering a period of rapid product portfolio expansion as well as revenue growth and diversification, due to the outstanding execution by our team on plans we initiated in 2019. With the approval of CIMERLI™, we now have three FDA-approved products - UDENCYA®, CIMERLI™, and YUSIMRY™, with a fourth product candidate, toripalimab, our PD-1 inhibitor, in the final stages of FDA review. We are preparing to launch four new products in 2022 and 2023, leveraging the scale of our commercial organization to generate sales which will return the company to revenue growth and profitability," said Denny Lanfear, Coherus' CEO. "With $275 million in cash and cash equivalents, access to additional capital through existing agreements, and significant projected revenue growth, we believe we have the financial resources to launch and support these new products, while judiciously continuing to invest in the oncology pipeline and opportunities."

SECOND QUARTER 2022 FINANCIAL RESULTS

Net revenue, consisting primarily of net sales of UDENYCA®, was $60.2 million and $87.6 million during the three months ended June 30, 2022 and 2021, respectively, and $120.3 million and $170.7 million during the six months ended June 30, 2022 and 2021, respectively. The decline 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 $11.3 million and $16.7 million during the three months ended June 30, 2022 and 2021, respectively, and $20.6 million and $24.2 million during the six months ended June 30, 2022 and 2021, respectively, reflecting decreases in the number of units of UDENYCA® sold. Through the first quarter of 2021, Coherus sold inventory that was manufactured and expensed prior to the approval of UDENYCA® in late 2018. This inventory was depleted in the first quarter of 2021, and since then, COGS fully reflects per unit acquisition cost. UDENYCA® COGS also includes a mid-single digit royalty on net sales payable through the first half of 2024.

Research and development (R&D) expense for the three months ended June 30, 2022 and 2021 was $41.6 million and $54.8 million, respectively. The decrease was driven by lower development costs as several clinical studies were completed in 2021, partially offset by higher compensation expense. For the six months ended June 30, 2022 and 2021, R&D expense was $124.5 million and $258.3 million, respectively. The decrease was primarily due to the $136.0 million upfront license fee paid to Junshi Biosciences in 2021 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 $51.3 million and $40.3 million during the three months ended June 30, 2022 and 2021, respectively, and $100.0 million and $79.7 million during the six months ended June 30, 2022 and 2021, respectively. The increases were primarily driven by higher commercialization expenses to support current UDENYCA® sales and in preparation for multiple anticipated new product launches in 2022 and 2023, including CIMERLI™, toripalimab, YUSIMRY™, and the on-body injector presentation of UDENYCA®.

Net loss for the second quarter of 2022 was $50.2 million, or $(0.65) per share on a diluted basis, compared to a net loss of $29.9 million, or $(0.40) per share on a diluted basis for the same period in 2021. Net loss for the first half of 2022 was $146.2 million, or $(1.89) per share on a diluted basis, compared to a net loss of $202.8 million, or $(2.73) per share on a diluted basis for the first half of 2021.

Non-GAAP net loss for the second quarter of 2022 was $36.3 million, or $(0.47) per share on a diluted basis, compared to non-GAAP net loss of $18.3 million, or $(0.24) per share on a diluted basis for the same period in 2021. Non-GAAP net loss for the first half of 2022 was $113.3 million, or $(1.46) per share on a diluted basis, compared to non-GAAP net loss of $162.9 million, or $(2.19) per share on a diluted basis for the first half 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 $275.5 million as of June 30, 2022, compared to $417.2 million at December 31, 2021.

2022 R&D and SG&A Expense Guidance

Coherus is reducing the guidance range of combined 2022 R&D and SG&A expenses from $395 million to $430 million to a revised range of $375 million to $395 million. The revised guidance range reflects a reduction in R&D expenses associated with YUSIMRY™ manufacturing scale up and

autoinjector production which will now be capitalized into inventory in accordance with relevant accounting rules. This guidance includes $55 million to $60 million of stock-based compensation expense and excludes the $35 million license fee paid in the first quarter of 2022 for CHS-006 as well as a potential $25 million milestone payable upon FDA approval of the toripalimab BLA for nasopharyngeal carcinoma. 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: Thursday, August 4th, 2022, starting at 5 p.m. ET
Dial-in: (800) 715-9871 (Toll-Free U.S. and Canada) or (646) 307-1963 (International)
Conference ID: 8699439

Webcast: https://investors.coherus.com/upcoming-events

Please dial-in 15 minutes early to ensure a timely connection to the call. A replay of the webcast will be archived on the Coherus website for 30 days.

Second quarter 2022 financial results are posted on the Coherus website at https://investors.coherus.com/

About Coherus BioSciences

Coherus is a commercial stage biopharmaceutical company building a leading immuno-oncology franchise funded with cash generated by its commercial biosimilar business. In 2021, Coherus in-licensed toripalimab, an anti-PD-1 antibody, in the United States and Canada. A biologics license application for toripalimab for the treatment of nasopharyngeal carcinoma is under review by the FDA with a target action date of December 23, 2022. Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta® in the U.S., and expects to launch CIMERLI™ (ranibizumab-eqrn) in the U.S. in early October 2022, as well as 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 whether it can meet those projections; Coherus' ability to rapidly expand its product portfolio and grow and diversify its revenues; Coherus' ability to return to profitability; and Coherus' ability to launch and support new products, while continuing to invest in its oncology pipeline and opportunities.

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 of Coherus' execution of its change in strategy from a focus on biosimilars to a strategy using cash from its portfolio to fund an immuno-oncology franchise; 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' Quarterly Report on Form 10-Q the fiscal period ended June 30, 2022, to be filed with the Securities and Exchange Commission on or about August 4, 2022, including the section therein captioned "Risk Factors" and in other documents Coherus files with the Securities and Exchange Commission.

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,	
	2022	2021	2022	2021
Net revenue	$ 60,151	$ 87,643	$ 120,266	$ 170,677
Costs and expenses:				
Cost of goods sold	11,277	16,696	20,647	24,207
Research and development	41,611	54,766	124,528	258,258
Selling, general and administrative	51,276	40,345	100,029	79,736
Total costs and expenses	104,164	111,807	245,204	362,201
Loss from operations	(44,013)	(24,164)	(124,938)	(191,524)
Interest expense	(6,580)	(5,747)	(15,549)	(11,395)
Loss on debt extinguishment	—	—	(6,222)	—
Other income, net	443	11	475	72
Loss before income taxes	(50,150)	(29,900)	(146,234)	(202,847)
Income tax provision	—	—	—	—
Net loss	$ (50,150)	$ (29,900)	$ (146,234)	$ (202,847)

Basic and diluted net loss per share	$ (0.65)	$ (0.40)	$ (1.89)	$ (2.73)
Weighted-average number of shares used in computing basic and diluted net loss per share	77,554,717	75,559,697	77,405,040	74,203,858

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

	June 30, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 275,484	$ 417,195
Trade receivables, net	115,711	123,022
Inventory	107,698	93,252
Other assets	47,110	45,865
Total assets	$ 546,003	$ 679,334
Liabilities and Stockholders' Equity (Deficit)		
Accrued rebates, fees and reserve	$ 64,547	$ 79,027
Term loans	196,037	75,513
Convertible notes	224,928	332,767
Other liabilities	83,120	94,301
Total stockholders' equity (deficit)	(22,629)	97,726
Total liabilities and stockholders' equity (deficit)	$ 546,003	$ 679,334

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Cash, cash equivalents and restricted cash at beginning of the period	$ 326,120	$ 259,929	$ 417,635	$ 541,598
Net cash (used in) provided by operating activities	(50,037)	(188)	(104,082)	1,179
Purchases of investments in marketable securities	—	—	—	(140,330)
Proceeds from maturities of investments in marketable securities	—	15,000	—	15,000
Upfront and option payments to Junshi Biosciences[(1)]	—	9,000	(35,000)	(136,000)
Cash used in other investing activities	(880)	(415)	(1,495)	(560)
Net cash used in investing activities	(880)	23,585	(36,495)	(261,890)
Proceeds from 2027 Term Loans, net of debt discount & issuance costs	—	—	191,190	—
Proceeds from issuance of common stock to Junshi Biosciences, net of issuance costs	—	40,903	—	40,903
Proceeds from issuance of common stock upon exercise of stock options	8	4,117	552	8,446
Proceeds from purchase under the employee stock purchase plan	1,655	1,985	1,655	1,985
Taxes paid related to net share settlement of RSUs	(642)	—	(3,300)	(1,730)
Repayment of 2022 Convertible Notes and premiums	—	—	(109,000)	—
Repayment of 2025 Term Loan, premiums and exit fees	—	—	(81,750)	—
Other financing activities	(300)	(153)	(481)	(313)
Net cash provided by (used in) financing activities	721	46,852	(1,134)	49,291
Net (decrease) increase in cash, cash equivalents and restricted cash	(50,196)	70,249	(141,711)	(211,420)
Cash, cash equivalents and restricted cash at end of the period	$ 275,924	$ 330,178	$ 275,924	$ 330,178
Reconciliation of cash, cash equivalents, and restricted cash				
Cash and cash equivalents	$ 275,484	$ 329,738	$ 275,484	$ 329,738
Restricted cash balance	440	440	440	440
Cash, cash equivalents and restricted cash	$ 275,924	$ 330,178	$ 275,924	$ 330,178

(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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
GAAP net loss	$ (50,150)	$ (29,900)	$ (146,234)	$ (202,847)
Adjustments:				
Stock-based compensation expense	13,850	11,595	26,729	28,479
Loss on debt extinguishment	—	—	6,222	—
Costs related to termination of CHS-2020 development program	—	—	—	11,503
Non-GAAP net loss	$ (36,300)	$ (18,305)	$ (113,283)	$ (162,865)
GAAP net loss per share, basic and diluted	$ (0.65)	$ (0.40)	$ (1.89)	$ (2.73)
Non-GAAP net loss per share, basic and diluted	$ (0.47)	$ (0.24)	$ (1.46)	$ (2.19)
Shares used in computing basic and diluted net loss per share	77,554,717	75,559,697	77,405,040	74,203,858

(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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