Coherus BioSciences Reports First Quarter 2022 Results

– CIMERLI ™ BLA review progressing toward August 2022 action date –
– Toripalimab BLA resubmission expected by mid-summer –
– UDENYCA® delivers 1st quarter 2022 net sales of $60.1 million –
– 2022 R&D and SG&A expense guidance reduced by $20 million –
– Conference call today at 4:30 p.m. ET –

REDWOOD CITY, Calif., May 05, 2022 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. ("Coherus" or the "Company", Nasdaq: CHRS), today reported financial results for the quarter ended March 31, 2022 and recent business highlights:

RECENT BUSINESS HIGHLIGHTS

- After receiving a complete response letter ("CRL") for the Biologics License Application ("BLA") for toripalimab, Coherus and partner Shanghai Junshi Biosciences Co., Ltd. ("Junshi Biosciences") plan to resubmit the toripalimab BLA by mid-summer with an expected six month review by the United States Food and Drug Administration ("FDA"). The CRL requests a quality process change that Coherus and Junshi Biosciences believe is readily addressable.
- The FDA review of the BLA for CIMERLI™ (ranibizumab-ranq), a Lucentis® biosimilar, is advancing toward the target action date of August 2, 2022.
- The FDA granted Orphan Drug Designation for toripalimab for the treatment of small cell lung cancer.
- Two proprietary immuno-oncology research programs have advanced to preclinical development: CHS-1000, an ILT4-targeted antibody, and CHS-3318, a CCR8-targeted antibody. Coherus expects to file an investigational new drug application ("IND") for CHS-1000 in 2023.
- Positive toripalimab clinical data were presented and published:
  - Final progression-free survival ("PFS") and interim overall survival ("OS") data from the JUPITER-02 trial evaluating toripalimab plus chemotherapy for advanced nasopharyngeal carcinoma were presented at the annual meeting of the American Association for Cancer Research in April.
  - Final PFS and interim OS data from the CHOICE-01 trial evaluating toripalimab plus chemotherapy for non-small cell lung cancer were presented at the March ASCO Plenary Series.
  - Final PFS and interim OS data from the JUPITER-06 trial evaluating toripalimab plus chemotherapy for first-line treatment of esophageal squamous cell carcinoma were published in the March issue of *Cancer Cell*.
- Coherus has discontinued development of CHS-305 ("IBI-305"), an Avastin® biosimilar candidate, and is returning IBI-305 rights to Innovent Biologics (Suzhou) Co., Ltd.
- Coherus is lowering by $20 million the projected range for combined full year 2022 R&D and SG&A expenses. See "**2022 R&D and SG&A Expense Guidance"** section below.

"As we prepare for as many as four new product launches in 2022 and 2023, we continue to make strong progress transforming Coherus into an innovative immuno-oncology company supported by revenues generated by our diversified commercial portfolio of FDA-approved products," said Denny Lanfear, Coherus' CEO. "Following the recent late-cycle review meeting with the FDA, we are finalizing our preparations to launch CIMERLI™ later this year, if approved, into the $7 billion anti-VEGF ophthalmology market in the United States. We expect to resubmit the toripalimab BLA by mid-summer and are preparing for the commercial launch directly upon approval. We continue to invest significantly in YUSIMRY™ ahead of the planned launch in July 2023, as robust supply availability is a key part of our market strategy. Our UDENYCA® business continues to provide strong funding for our operations, and we look forward to the potential launch next year of our on-body injector presentation which, if approved, would allow us to compete directly with Neulasta® Onpro®, a greater than $1 billion market opportunity."

FIRST QUARTER 2022 FINANCIAL RESULTS

Net revenue, consisting of net sales of UDENYCA®, was $60.1 million and $83.0 million during the three months ended March 31, 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 $9.4 million and $7.5 million during the three months ended March 31, 2022 and 2021, respectively. Until 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 March 31, 2022 was $82.9 million and included a $35 million option exercise fee to Junshi Biosciences to license CHS-006, a clinical stage TIGIT-targeted antibody, as well as development and manufacturing costs for clinical and preclinical pipeline programs. For the same period in 2021, R&D expense was $203.5 million and included a $145 million upfront fee paid to Junshi Biosciences for the license to rights to toripalimab for the United States and Canada, $11.5 million in costs related to the discontinuation of the CHS-2020 (Eylea® biosimilar) program, as well as development costs for clinical and preclinical pipeline programs.

Selling, general and administrative (SG&A) expense for the three months ended March 31, 2022 was $48.8 million compared to $39.4 million for the same period in 2021. The increase was 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 first quarter of 2022 was $96.1 million, or $(1.24) per share on a diluted basis, compared to a net loss of $172.9 million, or $(2.37) per

share on a diluted basis for the same period in 2021.

Non-GAAP net loss for the first quarter of 2022 was $77.0 million, or $(1.00) per share on a diluted basis, compared to non-GAAP net loss of $144.6 million, or $(1.98) per share on a diluted basis for the same period in 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 $325.7 million as of March 31, 2022, compared to $417.2 million at December 31, 2021.

2022 R&D and SG&A Expense Guidance

As a result of the discontinuation of the CHS-305 development program and the delay of the toripalimab commercial launch, Coherus is lowering the projected range for combined full year 2022 R&D and SG&A expenses by $20 million to $395 million to $430 million. This range 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, May 5th, 2022, starting at 4:30 p.m. ET

Dial-in: (844) 452-6826 (Toll-Free U.S. and Canada) or (765) 507-2587 (International)

Conference ID: 4142969

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

Webcast: https://investors.coherus.com/upcoming-events
First 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 an innovative immuno-oncology franchise funded with cash generated by its diversified commercial portfolio of FDA-approved products. In 2021, Coherus in-licensed toripalimab, an anti-PD-1 antibody, in the United States and Canada. Coherus plans to resubmit a BLA for toripalimab for the treatment of advanced nasopharyngeal carcinoma by mid-summer 2022. Toripalimab is also being evaluated in pivotal clinical trials for the treatment of rare and highly prevalent cancers.

Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta® in the United States, and expects to launch the FDA-approved Humira® biosimilar YUSIMRY™ (adalimumab-aqvh) in the United States in 2023. The FDA is currently reviewing the biologics license application for CIMERLI™ (ranibizumab-ranq), a biosimilar of Lucentis®, with a target action date of August 2, 2022.

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' expectations for the launch dates of YUSIMRY™, CIMERLI™, toripalimab and other products; Coherus' plans to resubmit the BLA for toripalimab and obtain FDA approval; expectations for the timing of the submission of an IND for CHS-1000; expectations for the timing of the FDA review of the BLA for CIMERLI™ ; estimates of market opportunities for products and product candidates and Coherus'expectations about R&D and SG&A expense guidance for the full fiscal year 2022 and whether it will be able to meet that guidance.

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 the drug development position of Coherus' competitors; 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 for the quarter ended March 31, 2022, to be filed with the Securities and Exchange Commission on or about May 5, 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

	March 31,	
	2022	2021
Net revenue	$ 60,115	$ 83,034
Costs and expenses:		
Cost of goods sold	9,370	7,511
Research and development	82,917	203,492
Selling, general and administrative	48,753	39,391
Total costs and expenses	141,040	250,394
Loss from operations	(80,925)	(167,360)
Interest expense	(8,969)	(5,648)
Loss on debt extinguishment	(6,222)	—
Other income, net	32	61
Net loss before income taxes	(96,084)	(172,947)
Income tax provision	—	—
Net loss	$ (96,084)	$ (172,947)
Basic and diluted net loss per share	$ (1.24)	$ (2.37)
Weighted-average number of shares used in computing basic and diluted net loss per share	77,253,699	72,832,953

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

	March 31, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 325,680	$ 417,195
Trade receivables, net	117,039	123,022
Inventory	96,372	93,252
Other assets	54,296	45,865
Total assets	$ 593,387	$ 679,334
Liabilities and Stockholders' Equity		
Accrued rebates, fees and reserve	$ 71,894	$ 79,027
Term loans	195,849	75,513
Convertible notes	224,607	332,767
Other liabilities	88,474	94,301
Total stockholders' equity	12,563	97,726
Total liabilities and stockholders' equity	$ 593,387	$ 679,334

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

	Three Months Ended March 31,	
	2022	2021
Cash, cash equivalents and restricted cash at beginning of the period	$ 417,635	$ 541,598
Net cash (used in) provided by operating activities	(54,045)	1,367
Purchases of investments in marketable securities	—	(140,330)
Upfront and option payments to Junshi Biosciences	(35,000)	(145,000)
Cash used in other investing activities	(615)	(145)
Net cash used in investing activities	(35,615)	(285,475)
Proceeds from 2027 Term Loans, net of debt discount & issuance costs	191,190	—
Proceeds from issuance of common stock upon exercise of stock options	544	4,329
Taxes paid related to net share settlement of RSUs	(2,658)	(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	(181)	(160)
Net cash (used in) provided by financing activities	(1,855)	2,439
Net decrease in cash, cash equivalents and restricted cash	(91,515)	(281,669)
Cash, cash equivalents and restricted cash at end of the period	$ 326,120	$ 259,929
Reconciliation of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	$ 325,680	$ 259,489
Restricted cash balance	440	440
Cash, cash equivalents and restricted cash	$ 326,120	$ 259,929

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 supplementary 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 March 31,	
	2022	**2021**
GAAP net loss	$ (96,084)	$ (172,947)
Adjustments:		
Stock-based compensation expense	12,879	16,884
Loss on debt extinguishment	6,222	—
Costs related to termination of CHS-2020 development program	—	11,503
Non-GAAP net loss	$ (76,983)	$ (144,560)
GAAP net loss per share, basic and diluted	$ (1.24)	$ (2.37)
Non-GAAP net loss per share, basic and diluted	$ (1.00)	$ (1.98)
Shares used in computing basic and diluted net loss per share	77,253,699	72,832,953

(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.