November 8, 2019

Recro Pharma Reports Third Quarter 2019 Financial Results

CDMO Business Achieves 37% Growth in 2019 Year to Date Revenues; Consolidated Company Achieves Profitability from Operations, Turns Cash Flow Positive and Raises 2019 Revenue Guidance to $98-100 Million

FDA Grants Appeal for IV Meloxicam New Drug Application

Company Remains on Track to Execute Spin Out of Acute Care Business Segment During the Fourth Quarter of 2019

Company to Host Conference Call Today at 8:00 AM ET

MALVERN, Pa., Nov. 08, 2019 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (NASDAQ:REPH), a pharmaceutical company with a high-performing, revenue generating contract development and manufacturing (CDMO) segment and an Acute Care segment, today reported financial results for the three and nine months ended September 30, 2019.

“The CDMO business has continued to deliver record results, generating $81.6 million in year to date revenues, a 37% increase over the comparable nine-month period in 2018, and surpassing our full year 2018 revenues in just nine months,” said Gerri Henwood, President and Chief Executive Officer of Recro Pharma. “We achieved consolidated operating profitability earlier than expected and generated $4.8 million in cash from operations during the third quarter. We are proud of this performance and of the strong year over year growth and are raising our full year CDMO revenue guidance to $98-100 million.”

“As we look ahead to the remainder of 2019 and into 2020, we look forward to several important milestones in both business segments. In the CDMO segment, we look forward to growing our revenues and customer base in 2020. In the Acute Care segment, where we were recently granted an appeal for the intravenous (IV) meloxicam New Drug Application (NDA), we are preparing a comprehensive response to the U.S. Food and Drug Administration (FDA), with the goal of advancing the IV meloxicam opportunity. We also remain on track to complete the spin out of this business segment into a new entity named Baudax Bio during the fourth quarter,” concluded Ms. Henwood.

Third Quarter 2019 and Recent Highlights

- **Strong Gainesville Manufacturing Performance.** Recro’s contract manufacturing business continued to perform well with revenues of $25.3 million for the third quarter of 2019, a 38% increase over the $18.3 million generated in the third quarter of 2018. CDMO operating income, CDMO Adjusted EBITDA* and CDMO operating income, as adjusted*, for the nine months ended September 30, 2019 were $37.3 million, $39.4 million and $31.9 million, respectively, which reflect increases of 80%, 68% and 87%, respectively, compared to the same nine-month period in 2018.

- **Company Achieved Operating Profitability.** During the third quarter of 2019, Recro achieved consolidated operating profitability earlier than expected and generated $4.8 million in cash from operations. The Company expects to remain cash flow positive for the second half of 2019 (excluding the impact from any strategic transactions).
- **FDA Granted Appeal for IV Meloxicam New Drug Application.** In late October, Recro announced that it had received a written decision from the FDA granting its appeal of the Complete Response Letter relating to the NDA seeking approval for IV meloxicam. The Company is now in the process of preparing a comprehensive response to the FDA that includes proposed labeling and certain other information.
- **Board of Directors Approves Separation of Acute Care Segment.** In early November, Recro's Board of Directors approved the planned spin out of the Acute Care business segment, which will be known as Baudax Bio, Inc. and declared a special dividend distribution of all outstanding shares of Baudax Bio common stock. For every two and one half (2.5) shares of Recro common stock held of record as of the close of business on November 15, 2019, Recro shareholders will receive one (1) share of Baudax Bio common stock. The special dividend distribution is expected to be paid on November 21, 2019.

Financial Results for the Third Quarter 2019

As of September 30, 2019, Recro had cash and cash equivalents of $37.9 million.

Revenues and cost of sales were $25.3 million and $11.0 million, respectively, for the three months ended September 30, 2019, compared to $18.3 million and $8.5 million for the three months ended September 30, 2018. The increase of $7.0 million in revenue was due to increased royalties recognized from one of our commercial partners and an increase in product sales to various of our commercial partners. Cost of sales increased primarily due to expansion of our service and development capabilities as well as growth in manufacturing demand, which was partially offset by operating efficiencies gained as a result of higher production volumes.

Research and development expenses for the three months ended September 30, 2019 were $1.8 million, compared to $11.3 million for the three months ended September 30, 2018. The decrease of $9.5 million was primarily due to a decrease in pre-commercialization manufacturing and clinical costs for IV meloxicam, shift of focus of our CDMO formulation and development capabilities to cost of sales activities, a decrease in development costs for other pipeline products and a decrease in personnel costs.

General and administrative expenses for the three months ended September 30, 2019 decreased $0.1 million to $6.9 million, compared to $7.0 million for the same period in 2018.

Change in contingent consideration valuation for the three months ended September 30, 2019 was $3.9 million, compared to $4.1 million for the three months ended September 30, 2018. This non-cash expense was related to the change in the probability adjusted fair value of the contingent consideration that would be due to Alkermes upon passage of time or the achievement of certain milestones.

Amortization expense was $0.6 million for each of the three months ended September 30, 2019 and 2018. This expense was solely related to the amortization of Recro's royalties and contract manufacturing relationships intangible asset over its estimated useful life.

Interest expense, net, was $5.1 million and $2.1 million for the three months ended September 30, 2019 and 2018, respectively. The increase was primarily due to the higher principal balance on our Athyrium senior secured term loan and amortization of the related financing costs.

The Company records a full valuation allowance against its deferred tax assets therefore, there was no income tax benefit for the three months ended September 30, 2019. For the three months ended September 30, 2018, the income tax benefit was $2.4 million, which was recorded prior to the recording of the full valuation allowance for United States operations in the fourth quarter of 2018.

For the three months ended September 30, 2019, Recro reported a net loss of $4.3 million, or $0.19 per share, compared to a net loss of $13.3 million, or $0.64 per share, for the comparable period in 2018.

Financial Results for the Nine Months Ended September 30, 2019

Revenues and cost of sales were $81.6 million and $39.5 million, respectively for the nine months ended September 30, 2019, compared to $59.6 million and $31.0 million for the nine months ended September 30, 2018. The increase of $22.0 million in revenue was due to increased royalties recognized from one of our commercial partners and an increase in product sales to various of our commercial partners. Cost of sales increased primarily due to expansion of our service and development capabilities as well as growth in manufacturing demand, which was partially offset by operating efficiencies gained as a result of higher production volumes.

Research and development expenses for the nine months ended September 30, 2019 were $18.6 million, compared to $29.9 million for the nine months ended September 30, 2018. Excluding $2.8 million of costs associated with the strategic restructuring initiative recorded in the nine months ended September 30, 2019, the decrease of $14.1 million was primarily due to a decrease in pre-commercialization manufacturing and clinical costs for IV meloxicam, a decrease in personnel costs, the shift of focus of our CDMO formulation and development capabilities to cost of sales activities, and a decrease in development costs for other pipeline products.

General and administrative expenses for the nine months ended September 30, 2019 were $31.1 million, compared to $29.4 million for the same period in 2018. Excluding $4.4 million of costs associated with the strategic restructuring initiative recorded in the nine months ended September 30, 2019, the decrease of $2.7 million was due to decreases in commercial team personnel and pre-commercial consulting costs incurred for the anticipated launch of IV meloxicam following the receipt of the second CRL. These decreases in costs were offset by increases in costs associated with the debt financing early in the year, public company costs including legal fees, business development costs in our CDMO segment as well as increased professional fees associated with addressing the first and second CRLs issued by the FDA regarding our NDA for IV meloxicam.

Change in contingent consideration valuation for the nine months ended September 30, 2019 was ($15.2) million, compared to $7.0 million for the nine months ended September 30, 2018. This non-cash expense was related to the change in the probability adjusted fair value of the contingent consideration that would be due to Alkermes upon passage of time

or the achievement of certain milestones. The change in contingent consideration is primarily attributed to the change in estimated timing of potential FDA approval and a potential launch of IV meloxicam.

Amortization expense was $1.9 million for each of the nine months ended September 30, 2019 and 2018. This expense was solely related to the amortization of Recro's royalties and contract manufacturing relationships intangible asset over its estimated useful life.

Interest expense, net, was $13.9 million and $6.1 million for the nine months ended September 30, 2019 and 2018, respectively. The increase was primarily due to the higher principal balance on our Athyrium senior secured term loan and amortization of the related financing costs.

The Company records a full valuation allowance against its deferred tax assets therefore, there was no income tax benefit for the nine months ended September 30, 2019. For the nine months ended September 30, 2018, the income tax benefit was $7.4 million, which was recorded prior to the recording of the full valuation allowance for United States operations in the fourth quarter of 2018.

For the nine months ended September 30, 2019, Recro reported a net loss of $9.1 million, or $0.41 per share, compared to a net loss of $38.4 million, or $1.91 per share, for the comparable period in 2018.

Financial Guidance

For 2019, Recro Pharma is raising its revenue guidance from $91-94 million to an anticipated $98-$100 million. The Company is also raising its CDMO Operating Income guidance from $35-39 million to $40-44 million and CDMO EBITDA, as Adjusted* from $44-46 million to $48-$50 million. These increases are based on current trends, including organic growth from existing customers and new business prospects. This guidance takes into consideration existing contracts and timing of customer order patterns, as well as the Company's experience with customer's product market estimations.

*CDMO Operating Income, as adjusted, and CDMO EBITDA, as adjusted are non-GAAP financial measures (See reconciliation of non-GAAP financial measures in this release).

Conference Call and Webcast

Recro Pharma management will be hosting a conference call and webcast today beginning at 8:00 AM ET. To access the conference call, please dial (844) 243-4691 (local) or (225) 283-0379 (international) at least 10 minutes prior to the start time and refer to conference ID 6880517. A live audio webcast of the call will be available under "Events" in the Investor section of the Company's website, https://ir.recropharma.com/events. An archived webcast will be available on the Company's website approximately two hours after the event and will be available for 30 days.

About Recro Pharma, Inc.

Recro Pharma is a pharma services and pharmaceutical company that operates through two business segments, a revenue-generating contract development and manufacturing, or CDMO, segment, located in Gainesville, GA and an Acute Care segment primarily focused

on products for the hospital and other acute care settings. The Company's CDMO segment leverages its formulation expertise to develop and manufacture pharmaceutical products using its proprietary delivery technologies and other manufacturing services for commercial and development-stage partners who commercialize or plan to commercialize these products. These collaborations can result in revenue streams including royalties, profit sharing, research and development and manufacturing fees, which support continued operations for its CDMO segment.

Cautionary Statement Regarding Forward Looking Statements

This press release contains forward-looking statements that involve risks and uncertainties. Such forward-looking statements reflect Recro's expectations about its future performance and opportunities that involve substantial risks and uncertainties. When used herein, the words "anticipate," "believe," "estimate," "may," "upcoming," "plan," "target," "intend" and "expect" and similar expressions, as they relate to Recro or its management, are intended to identify such forward-looking statements. These forward-looking statements are based on information available to Recro as of the date of this press release and are subject to a number of risks, uncertainties, and other factors that could cause Recro's performance to differ materially from those expressed in, or implied by, these forward-looking statements. Recro assumes no obligation to update any such forward-looking statements. Factors that could cause Recro's actual performance to materially differ from those expressed in the forward-looking statements set forth in this press release include, without limitation: the Company's ability to complete the spin of its Acute Care business segment, uncertainty of whether the anticipated benefits of the spin-off can be achieved, risks of unexpected costs or delays in the Company's ability to complete the spin-off, the Company's ability continue the development and commercialization of IV meloxicam, the Company's ability to execute its strategic initiatives, the Company's ability to adequately resolve the outstanding labeling issues with the FDA for IV meloxicam, and the time frame associated with any such resolution; the Company's ability to raise future financing for continued product development and IV meloxicam commercialization; with regard to the Company's clinical trial results, whether there may be changes in the interpretation by the FDA of the data of the Company's clinical trials and the length, cost and uncertain results and timing of our ongoing clinical trials; with regard to the potential commercial opportunity of IV meloxicam, whether any FDA approval of IV meloxicam will include labeling restrictions and the potential that IV meloxicam does not receive regulatory approval or does not receive reimbursement by third party payors, that IV meloxicam is not accepted by the medical community, including physicians, patients, health care providers and hospital formularies or that a commercial market for IV meloxicam does not develop; the Company's ability to manage costs and execute on its operational and budget plans, the Company's ability to achieve its financial goals, including financial guidance, the Company's ability to pay its debt under its credit agreement; the Company's ability to maintain relationships with CDMO commercial partners; and the Company's ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection. The forward-looking statements in this press release should be considered together with the risks and uncertainties that may affect Recro's business and future results included in Recro's filings with the Securities and Exchange Commission at www.sec.gov.

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RECRO PHARMA, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
(Unaudited)

(amounts in thousands, except share and per share data)

Assets	**September 30, 2019**	**December 31, 2018**
Current assets:		
Cash and cash equivalents	$ 37,944	$ 38,514
Accounts receivable	16,216	12,866
Contract Asset	10,643	5,201
Inventory	12,921	10,699
Prepaid expenses and other current assets	3,784	3,861
Total current assets	$ 81,508	$ 71,141
Property, plant and equipment, net	48,067	45,640
Right of Use asset	1,366	—
Intangible assets, net	30,329	32,266
Goodwill	6,446	6,446
Total assets	$ 167,716	$ 155,493
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	1,017	4,510
Accrued expenses & other current liabilities	8,556	14,165
Current operating lease liability	525	—

Current portion of contingent consideration	—	10,354
Total current liabilities	10,098	29,029
Long-term debt, net	108,859	64,243
Warrants & other long-term liabilities	2,040	1,163
Long-term operating lease liability	915	—
Long-term portion of contingent consideration	65,671	80,558
Total liabilities	187,583	174,993
Shareholders' equity:		
Preferred stock, $0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding.	—	—
Common stock, $0.01 par value. Authorized, 50,000,000 shares; issued and outstanding, 22,614,113 shares at September 30, 2019 and 21,799,961 shares at December 31, 2018	226	218
Additional paid in-capital	177,281	168,535
Accumulated deficit	(197,374)	(188,253)
Accumulated other comprehensive loss	—	—
Total shareholders' equity	(19,867)	(19,500)
Total liabilities and shareholders' equity	$ 167,716	$ 155,493

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(amounts in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenue	$ 25,255	$ 18,283	$ 81,577	$ 59,564
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	11,027	8,472	39,518	31,033
Research and development	1,845	11,348	18,578	29,947
General and administrative	6,879	6,969	31,055	29,442
Amortization of intangible assets	646	646	1,938	1,938
Change in warrant valuation	160	287	939	(78)
Change in contingent consideration valuation	3,909	4,115	(15,241)	7,030
Total operating expenses	24,466	31,837	76,787	99,312
Operating income / (loss)	789	(13,554)	4,790	(39,748)
Other income (expense):				

Interest income	323	126	642	382
Interest expense	(5,417)	(2,198)	(14,553)	(6,490)
Net loss before income taxes	$ (4,305)	$ (15,626)	$ (9,121)	$ (45,856)
Income tax benefit	—	2,370	—	7,430
Net loss	$ (4,305)	$ (13,256)	$ (9,121)	$ (38,426)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.19)	$ (0.64)	$ (0.41)	$ (1.91)
Weighted average common shares outstanding, basic and diluted	22,505,723	20,721,330	22,231,990	20,122,569
Other comprehensive loss:				
Unrealized gain on available-for-sale securities	—	—	(1)	1
Comprehensive loss	$ (4,305)	$ (13,256)	$ (9,122)	$ (38,425)

Reconciliation of Operating Income, as adjusted and EBITDA, as adjusted

To supplement our financial results determined by U.S. generally accepted accounting principles ("GAAP"), we have also disclosed in the tables below the following non-GAAP information for our Contract Development and Manufacturing Organization (CDMO): "Operating Income, as Adjusted" which is Operating Income without the impact of ASU, No. 2014-09 as to remove the variability of timing of revenue recognized and expected cash receipt, and "EBITDA, as Adjusted" which is "Operating Income, as Adjusted" before interest, taxes, depreciation, amortization and non-cash stock-based compensation. We believe these non-GAAP financial measures are helpful in understanding our CDMO Business as it is useful to investors in allowing for greater transparency of supplemental information used by management. "EBITDA, as Adjusted" is used by investors, as well as management in assessing our performance. Non-GAAP financial measures should be considered in addition to, but not as a substitute for, reported GAAP results. Further, Non-GAAP financial measures, even if similarly titled, may not be calculated in the same manner by all companies, and therefore should not be compared.

Three Months Ended September 30, 2019 and 2018

CDMO Business (amounts in millions)	**Three Months Ended**		**Year over Year % change**
	September 30, 2019	**September 30, 2018**	
As reported operating income	$ 12.7	$ 6.9	84%

less: Revenue recognition (a)	$ 2.5	$ 0.6	
Operating income, as adjusted	$ 10.3	$ 6.3	62%
Depreciation	$ 1.5	$ 1.2	
Amortization of intangible assets	$ 0.6	$ 0.6	
Non-Cash stock-based compensation	$ 0.4	$ 0.4	
EBITDA, as adjusted	$ 12.8	$ 8.5	51%

Nine Months Ended September 30, 2019 and 2018

CDMO Business (amounts in millions)	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018	Year over Year % change
As reported operating income	$ 37.3	$ 20.8	80%
less: Revenue recognition (a)	$ 5.4	$ 3.7	
Operating income, as adjusted	$ 31.9	$ 17.1	87%
Depreciation	$ 4.3	$ 3.5	
Amortization of intangible assets	$ 1.9	$ 1.9	
Non-Cash stock-based compensation	$ 1.3	$ 0.9	
EBITDA, as adjusted	$ 39.4	$ 23.5	68%

Full Year Guidance

CDMO Business (amounts in millions)	Full Year 2017	Full Year 2018	Full Year 2019 Estimate
As reported operating income	$ 25.4	$ 24.9	$40.0 - $44.0
less: Revenue recognition (a)	n/a	1.4	$2.0 - $4.0
Operating income, as adjusted	$ 25.4	$ 23.5	$38.0 - $40.0
Depreciation	4.8	4.8	5.6

Amortizaiton of intangible assets	2.6	2.6	2.6
Non-Cash stock-based compensation	1.0	1.3	1.8
EBITDA, as adjusted	$ 33.8	$ 32.2	$48.0 - $50.0

(a) Impact of adoption of ASU, No. 2014-09 starting January 2018.

Source: Recro Pharma, Inc.