May 10, 2019

Recro Pharma Reports First Quarter 2019 Financial Results

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

MALVERN, Philadelphia, May 10, 2019 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (NASDAQ:REPH), a pharma 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 months ended March 31, 2019.

“Our CDMO business is off to a strong start this year, generating $25.1 million in first quarter revenues, a 28% increase from the prior year first quarter,” said Gerri Henwood, President and Chief Executive Officer of Recro Pharma. “Growth of the Gainesville CDMO continues to accelerate as a result of strong demand from the existing commercial portfolio and growth in new business development activity. Operating income, Adjusted EBITDA* and operating income, as adjusted*, for the first quarter of 2019 was $9.1 million, $11.6 million and $9.2 million, respectively, which is an increase of 38%, 68% and 90%, respectively, compared to the same quarter of 2018.”

“In the Acute Care segment, we continue to believe that IV meloxicam is an important product that can ultimately receive FDA approval and that it is an attractive non-opioid pain management candidate for acute pain. We will continue to pursue FDA approval for IV meloxicam. While we continue to pursue potential approval and partnering of IV meloxicam, the Company and Board are also exploring and evaluating other possible corporate structures, including the possibility of separating the Acute Care and CDMO business segments,” concluded Ms. Henwood.

First Quarter 2019 and Recent Events

Recro Gainesville

- **Strong Gainesville Manufacturing Performance.** Recro’s manufacturing business continued to perform well with revenues of $25.1 million for the first quarter ended March 31, 2019, compared to $19.5 million in the first quarter ended March 31, 2018.

- **Signed Multi-Year Extension Agreements with Teva and Novartis** Under the terms of the extended Teva agreement, effective January 1, 2019, Recro Gainesville, LLC will continue to supply Teva with Verapamil SR® capsules for six years through 2024 and Teva will continue to be Recro Gainesville’s exclusive U.S. distributor of Verapamil SR. Under the terms of the extended Novartis agreement, also effective January 1, 2019, Recro Gainesville will continue to be the exclusive global supplier of Ritalin LA® and Focalin XR® capsules to Novartis for five years through 2023.

IV Meloxicam

- **Received Complete Response Letter (CRL) from FDA for IV Meloxicam New Drug Application (NDA).** Recro received a second CRL from the FDA regarding its NDA seeking approval for IV meloxicam for the management of moderate to severe pain. Recro intends to continue pursuing regulatory approval for IV meloxicam, while also working to secure a strategic partner for the potential commercialization of the asset.

- **Data Presentations and Publications.** During the first quarter of 2019, the Company had several data presentations at medical meetings and manuscripts published in peer-reviewed medical journals, including:
  - Presented New Meta-Analysis for IV Meloxicam at the 44th Annual Regional Anesthesiology and Acute Pain Medicine Meeting;
  - Hosted Educational Symposiums on Pain Management Options in Total Joint Replacements at AAOS;
  - Published a New Pooled Analysis of IV Meloxicam’s Safety and Opioid-Reducing Effects Across Three Phase III and Four Phase II Studies; and
  - Published Phase III Study Evaluating the Safety of IV Meloxicam in Patients Following Major Elective Surgery.

Corporate and Financial

- **Restructured Acute Care Segment.** Following receipt of the second CRL, Recro reduced the operating expenses of its Acute Care Segment, including a reduction in staff of approximately 50 employees. Recro Pharma believes this initiative significantly reduces its 2019 planned cash burn and anticipates becoming cash flow breakeven in the third quarter of 2019 and cash flow positive in the second half of 2019 (excluding the impact from any potential partnering or strategic transactions).

- **Obtained Non-Dilutive Capital Through Expanded Athyrium Credit Facility.** The Company closed on an amended and expanded $125 million credit facility with investment funds managed by Athyrium Capital Management, LP. The prior $100 million credit facility, under which Recro had drawn $70 million, required various conditions to draw the remaining $30 million of available capital. This amendment substantially increased and fully funded the capital under the expanded $125 million credit facility, providing immediately available net proceeds of $40.5 million upon closing.

- **Board Appointment.** Recro appointed Arnaud Ajdler to the Company's Board of Directors. Mr. Ajdler is the managing partner of Engine Capital, L.P. and brings over 15 years of finance and corporate governance experience to Recro's Board.

Financial Results

As of March 31, 2019, Recro had cash, cash equivalents and short-term investments of $58.0 million.

Revenues and cost of sales were $25.1 million and $14.4 million, respectively for the three months ended March 31, 2019, compared to $19.5 million and $10.5 million for the three months ended March 31, 2018. The increase of $5.6 million in revenue was due to increased royalties recognized from one of our commercial partners and an increase in product sales to various commercial partners. Cost of sales increased due to expansion of our service and development capabilities as well as growth in manufacturing demand.

Research and development expenses for the three months ended March 31, 2019 were $9.6 million, compared to $8.4 million for the three-month ended March 31, 2018. The increase of $1.2 million was primarily due to an increase in pre-commercialization manufacturing costs for IV meloxicam and a net increase in development costs for other pipeline products.

General and administrative expenses for the three months ended March 31, 2019 were $14.2 million, compared to $9.5 million for the same period in 2018. The increase of $4.7 million was due to commercial team personnel and pre-commercial consulting costs in preparation of the anticipated launch of IV meloxicam, costs associated with the debt financing, public company costs including legal and audit fees, business development costs in our CDMO segment as well as increased professional fees associated with addressing the original and second CRLs issued by the FDA regarding our NDA for IV meloxicam. We believe these increased first quarter 2019 expenses will not recur in 2019, although the majority of the recent restructuring and associated costs following the second CRL will be incurred in the second quarter of 2019.

Change in contingent consideration valuation for the three months ended March 31, 2019 was ($15.1) million for the three months ended March 31, 2019, compared to $2.5 million for the three months ended March 31, 2018. This non-cash expense was related to the change in the 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 of intangibles for the three months ended March 31, 2019 was $0.6 million for each of the three months ended March 31, 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 $3.6 million for the three months ended March 31, 2019, compared to $2.0 million for the three months ended March 31, 2018. The increase of $1.6 million was primarily due to the higher principal balance on our Athyrium senior secured term loan and amortization of the related financing costs.

The Company recorded a full valuation allowance against its deferred tax assets therefore, there was no income tax benefit for the three months ended March 31, 2019. For the three months ended March 31, 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 March 31, 2019, Recro reported a net loss of $2.0 million, or $0.09 per share, compared to a net loss of $12.5 million, or $0.65 per share, for the comparable period in 2018.

Financial Guidance

As of May 10, 2019, Recro Pharma is reiterating that its revenue guidance for 2019 is expected to be in the range of $85-87 million. The Company is also reiterating that its operating income is expected to be in the range of $28-30 million and EBITDA (as Adjusted*) is expected to be in the range of $38-40 million. All of these projections are based on current CDMO business 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.

**Operating income, as adjusted, and EBITDA, as Adjusted are non-GAAP financial measures.*

Conference Call and Webcast

Recro Pharma management will be hosting a conference call and webcast today beginning at 8:00 a.m. 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 8294704. 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 specialty pharma company that operates through two business divisions, a revenue-generating contract development and manufacturing, or CDMO, division, located in Gainesville, GA and an Acute Care division primarily focused on products for the hospital and other acute care settings. The Company's CDMO division 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 division.

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 attract a strategic partner for the development and commercialization of IV meloxicam, the Company's ability to adequately resolve the deficiencies identified by the FDA in the second CRL for IV meloxicam, and the time frame associated with any such resolution, including whether the FDA will require additional clinical studies and the time and cost of such studies; whether the Company will prepare an amended NDA for IV meloxicam and, whether the FDA will accept and approve any such resubmitted NDA and the labeling under any such approval; 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	**March 31, 2019**	**December 31, 2018**
Current assets:		
Cash and cash equivalents	$ 45,981	$ 38,514
Short-term investments	12,034	—
Accounts receivable	16,218	12,866
Contract Asset	5,108	5,201
Inventory	10,168	10,699
Prepaid expenses and other current assets	5,128	3,861
Total current assets	$ 94,637	$ 71,141
Property, plant and equipment, net	46,622	45,640
Right of Use asset	1,693	—
Intangible assets, net	31,620	32,266
Goodwill	6,446	6,446
Total assets	$ 181,018	$ 155,493
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	10,540	4,510
Accrued expenses & other current liabilities	10,137	14,165
Current operating lease liability	636	
Current portion of contingent consideration	5,235	10,354
Total current liabilities	26,548	29,029
Long-term debt, net	105,939	64,243
Warrants & other long-term liabilities	838	1,163
Long-term operating lease liability	1,136	—
Long-term portion of contingent consideration	65,585	80,558
Total liabilities	200,046	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, 22,133,388 shares at March 31, 2019 and 21,799,961 shares at December 31, 2018	221	218
Additional paid in-capital	170,982	168,535

Accumulated deficit	(190,230)	(188,253)
Accumulated other comprehensive loss	(1)	—
Total shareholders' equity	(19,028)	(19,500)
Total liabilities and shareholders' equity	$ 181,018	$ 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 March 31,	
	2019	**2018**
Revenue	$ 25,065	$ 19,542
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	14,391	10,490
Research and development	9,554	8,442
General and administrative	14,179	9,518
Amortization of intangible assets	646	646
Change in warrant valuation	(263)	773
Change in contingent consideration valuation	(15,092)	2,520
Total operating expenses	23,415	32,389
Operating loss	1,650	(12,847)
Other income (expense):		
Interest income	138	142
Interest expense	(3,765)	(2,103)
Net loss before income taxes	$ (1,977)	$ (14,808)
Income tax benefit	—	2,353
Net loss	$ (1,977)	$ (12,455)
Per share information:		
Net loss per share of common stock, basic	$ (0.09)	$ (0.65)
Net loss per share of common stock, diluted	$ (0.10)	$ (0.65)
Weighted average common shares outstanding, basic	21,918,175	19,053,636
Weighted average common shares outstanding, diluted	21,978,606	19,219,257
Other comprehensive loss:		
Unrealized gain/(loss) on available-for-sale securities	(1)	—
Comprehensive loss	$ (1,978)	$ (12,455)

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 March 31, 2019 and 2018

CDMO Business (amounts in millions)	Three Months Ended March 31, 2019	Three Months Ended March 31, 2018	Year over Year % change
As reported operating income	$ 9.1	$ 6.6	38%
less: Revenue recognition (a)	$ (0.1)	$ 1.8	
Operating income, as adjusted	$ 9.2	$ 4.8	90%
Depreciation	$ 1.3	$ 1.2	
Amortizaiton of intangible assets	$ 0.6	$ 0.6	
Non-Cash stock-based compensation	$ 0.5	$ 0.3	
EBITDA, as adjusted	$ 11.6	$ 6.9	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	$28.0 - $30.0
less: Revenue recognition (a)	n/a	1.4	-
Operating income, as adjusted	$ 25.4	$ 23.5	$28.0 - $30.0
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	$38.0 - $40.0

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

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Source: Recro Pharma, Inc.