May 9, 2018

Recro Pharma Reports First Quarter 2018 Financial Results

Upcoming May 26, 2018 PDUFA Date for IV Meloxicam

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

MALVERN, Pa., May 09, 2018 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (NASDAQ:REPH), a revenue generating specialty pharmaceutical company focused on therapeutics for the hospital and other acute care settings, today reported financial results for the three months ended March 31, 2018.

“During the first quarter of 2018, we’ve been actively preparing for commercialization of IV meloxicam, our lead product candidate for the management of moderate to severe pain, as we await the upcoming PDUFA date of May 26, 2018,” said Gerri Henwood, President and Chief Executive Officer of Recro Pharma. “In parallel, we have been presenting at scientific meetings and publishing supportive clinical data so that physicians will have access to the information following our planned product launch. Additionally, the CDMO business is off to a solid start this year generating $19.5 million in first quarter revenues.”

First Quarter 2018 and Recent Highlights

- **Expanded IV Meloxicam Patent Portfolio**. In May 2018, Recro announced the receipt of issue notifications from the U.S. Patent and Trademark Office (USPTO) for three new patents covering IV meloxicam, each of which will issue on May 22, 2018. The three patents relate to the reduced flake-like aggregates of the injectable nanoparticle meloxicam composition and methods of producing such compounds. Recro anticipates one of these patents to be Orange-Book listable. The patents are exclusively licensed from Alkermes Pharma Ireland Limited.

- **Pre-approval Inspections Completed.** During the first quarter of 2018, as previously expected, the U.S. Food and Drug Administration (FDA) completed pre-approval inspections at two sites associated with manufacturing of IV meloxicam drug product and supporting the New Drug Application (NDA) for IV meloxicam.

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

- **Peer-Reviewed Publications**. During the first quarter of 2018, the Company announced the publication of three peer-reviewed journal articles highlighting previously reported IV meloxicam clinical data, including:

- The Company's pivotal Phase III clinical study evaluating IV meloxicam for the treatment of pain following bunionectomy surgery. The article, titled "Efficacy and Safety of Intravenous Meloxicam in Subjects with Moderate-to-Severe Pain Following Bunionectomy," was published online in the Clinical Journal of Pain in March 2018.

- A Phase II clinical study evaluating IV meloxicam for the treatment of pain following unilateral bunionectomy surgery. The article, titled "Evaluation of the safety and efficacy of an intravenous nanocrystal formulation of meloxicam in the management of moderate-to-severe pain after bunionectomy," was published online in the Journal of Pain Research in February 2018.

- A Phase II clinical study evaluating IV meloxicam for the treatment of pain following dental impaction surgery. The article, titled "A Randomized Double-Blind Controlled Trial of Intravenous Meloxicam in the Treatment of Pain Following Dental Impaction Surgery," was published online in the Journal of Clinical Pharmacology in January 2018.

- **Presented IV Meloxicam Data at the 43rd Annual Regional Anesthesiology and Acute Pain Medicine Meeting.** In April 2018, Recro presented eight posters at the 43rd Annual Regional Anesthesiology and Acute Pain Medicine Meeting, co-hosted by the American Society of Regional Anesthesia and Pain Medicine (ASRA). The data describes previously presented results from Recro's Phase II and Phase III clinical development programs for IV meloxicam for the management of moderate to severe pain.

- **Hosted an Investor and Analyst Day.** In February 2018, Recro hosted an investor and analyst day. Featuring Eugene R. Viscusi, M.D., Director, Acute Pain Management, Thomas Jefferson University and Richard Iorio, M.D., Chief of Adult Reconstruction, Recro management discussed the Company's commercialization strategy and launch plans for IV meloxicam, upon approval, as well as a recap of key clinical data and regulatory status.

- **Hosted Educational Symposiums on Challenges in Acute Pain Management and Advances in Evidence-Based Management Approaches at AAOS and ASRA.** In March 2018, Recro hosted an Industry 'Lunch and Learn' Session on the Challenges in Acute Postsurgical Pain and Advances in the Approach to Management at the American Academy of Orthopaedic Surgeons (AAOS) 2018 Annual Meeting. In April 2018, Recro hosted an Industry 'Lunch and Learn' Session on the Challenges in Acute Postsurgical Pain and Advances in the Approach to Management at the 43rd Annual Regional Anesthesiology and Acute Pain Medicine Meeting, co-hosted by ASRA.

- **Presented Pre-Clinical Data on Neuromuscular Blocking and Reversal Agents at AUA.** In April 2018, Recro presented preclinical data for its neuromuscular blocking and reversal agents at the Association of University Anesthesiologists (AUA) 2018 Annual Meeting. The data demonstrates the effective and rapid activity of the ultra-short acting neuromuscular blocking agent in a preclinical primate model, as well as the ability of the rapid-acting reversal agent to antagonize the neuromuscular blocking

molecule and induce recovery.

Financial Results

As of March 31, 2018, Recro had cash, cash equivalents and short-term investments of $51.3 million.

Revenues and cost of sales were $19.5 million and $10.5 million, respectively for the three months ended March 31, 2018, compared to $18.7 million and $10.5 million for the three months ended March 31, 2017. The increase of $0.8 million in revenue was primarily due to the net impact of royalties recognized from one of our commercial partners after the adoption of Accounting Standards Update No. 2014-09, "*Revenue from Contracts with Customers."* Cost of sales remained constant compared to prior year.

Research and development expenses for the three months ended March 31, 2018 were $8.4 million, compared to $7.8 million for the three month period ended March 31, 2017. The increase of $0.6 million was primarily due to an increase in pre-commercialization manufacturing costs for IV meloxicam, an increase in salaries and benefits expense due to increased headcount, and a modest increase in development costs for other pipeline products. These increases in research and development costs were offset by lower IV meloxicam clinical trial expenses.

General and administrative expenses for the three months ended March 31, 2018 were $9.5 million, compared to $4.0 million for the same period in 2017. The increase of $5.5 million was primarily due to building of the commercial team and its related costs.

Amortization of intangibles for each of the three months ended March 31, 2018 and 2017 was $0.6 million, which was exclusively related to the amortization of our CDMO royalties and contract manufacturing relationships intangible asset over its estimated useful life.

Interest expense, net, was $2.0 million for the three months ended March 31, 2018, compared to $1.1 million for the three months ended March 31, 2017. The increase of $0.9 million was primarily due to the higher principal balance on our senior secured term loan with Athyrium Opportunities III Acquisition LP (Athyrium) and the amortization of the related financing costs, which was partially offset by a lower interest rate on our Athyrium senior secured term loan versus our previous loan with OrbiMed Royalties, II, LP.

Income tax benefit was $2.4 million and $0.3 million for the three months ended March 31, 2018 and 2017, respectively, related exclusively to our U.S. operations. The increase of $2.1 million was primarily due to increased losses in the United States.

For the three months ended March 31, 2018, Recro reported a net loss of $12.5 million, or $0.65 per share, compared to net loss of $8.1 million, or $0.42 per share, for the comparable period in 2017.

Financial Guidance

The Company reaffirms its 2018 CDMO guidance and believes it will generate approximately $70 million in revenue despite the anticipated unfavorable impact of the adoption of the new revenue recognition standard, and taking into consideration existing contracts and timing of customer order patterns, as well as our experience with customer's product market

estimations.

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 1133709. A webcast will be available in the investor relations section of the Company's website, www.recropharma.com. 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 60 days.

About IV/IM Meloxicam

Meloxicam is a long-acting, preferential COX-2 inhibitor that possesses analgesic, anti-inflammatory and antipyretic activities, which are believed to be related to the inhibition of cyclooxygenase type 2 pathway (COX-2) and subsequent reduction in prostaglandin biosynthesis. IV meloxicam was designed using the NanoCrystal® platform, a technology that enables enhanced bioavailability of poorly water-soluble drug compounds. NanoCrystal® is a registered trademark of Alkermes Pharma Ireland Limited (APIL).

About Recro Pharma, Inc.

Recro Pharma is a specialty pharmaceutical company that operates through two business divisions, an Acute Care, hospital product division and a revenue-generating contract development and manufacturing, or CDMO division, located in Gainesville, GA. The Acute Care division is primarily focused on developing innovative products for hospital and other acute care settings. The Company’s lead product candidate is a proprietary injectable form of meloxicam, a long-acting preferential COX-2 inhibitor. IV meloxicam has successfully completed two pivotal Phase III clinical efficacy trials, a large double-blind placebo-controlled Phase III safety trial, four Phase II clinical efficacy trials, as well as other safety studies. In 2017, Recro submitted the NDA for IV meloxicam to the FDA for review, it was accepted by the FDA and there is a late May 2018 PDUFA date. As injectable meloxicam is in the non-opioid class of drugs, the Company believes it will overcome many of the issues associated with commonly prescribed opioid therapeutics, including respiratory depression, constipation, excessive nausea and vomiting, as well as having no addictive potential while maintaining meaningful analgesic effects for relief of pain. 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 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 and it contributes non-dilutive funding for the development and pre-commercialization activities of its Acute Care 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," "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 obtain and maintain regulatory approval of its product candidates, including IV meloxicam and the neuromuscular blocking agents, and the labeling under any such approval; the Company's ability to successfully launch and commercialize its product candidates, including IV meloxicam and the neuromuscular blocking agents, in each case if approved; results and timing of the phase IIIb clinical trials of IV meloxicam; the extent to which the Company's product candidates, including IV meloxicam and the neuromuscular blocking agents, in each case if approved, is accepted by the medical community, including physicians, patients, health care providers and hospital formularies; the availability of coverage and adequate and timely reimbursement for such product candidates, if approved; the Company's ability to raise future financing for continued product development, IV meloxicam commercialization and the payment of milestones; the Company's ability to achieve its financial goals, including financial guidance; the Company's ability to pay its debt; regulatory developments in the United States and foreign countries; customer product performance and ordering patterns, the performance of third-party suppliers and manufacturers; the Company's ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection; the results and timing of the preclinical studies and clinical trials of the Company's product candidates, including its neuromuscular blocking agents RP1000 and RP2000; unfavorable new preclinical and clinical data and additional analyses of existing preclinical and clinical data for the Company's product candidates, including RP1000 and RP2000; whether results of early preclinical studies and clinical trials will be indicative of the results of future preclinical studies and clinical trials and whether interim results from a preclinical study or clinical trial will be predictive of the final results of the study or trial; the Company's ability to resolve any clinical holds or other regulatory actions imposed on its neuromuscular blocking agents. 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.

CONTACT:

Investor Relations Contact:
Argot Partners
Susan Kim/Natalie Wildenradt
(212) 600-1902
susan@argotpartners.com
natalie@argotpartners.com

Recro Pharma, Inc.

Ryan D. Lake
(484) 395-2436
rlake@recropharma.com

Media Contact:
Argot Partners
David Rosen
(212) 600-1902
david.rosen@argotpartners.com

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

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

Assets	**March 31, 2018**	**December 31, 2017**
Current assets:		
Cash and cash equivalents	$ 46,284	$ 60,984
Short-term investments	4,989	3,498
Accounts receivable	9,833	9,686
Contract asset	5,508	—
Inventory	10,028	9,839
Prepaid expenses and other current assets	2,686	3,276
Total current assets	$ 79,328	$ 87,283
Property, plant and equipment, net	38,486	39,074
Deferred income taxes	19,989	18,573
Intangible assets, net	34,204	34,850
Goodwill	6,446	6,446
Total assets	$ 178,453	$ 186,226
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	4,336	7,954
Accrued expenses & other liabilities	6,361	9,897
Current portion of contingent consideration	33,957	32,053
Total current liabilities	44,654	49,904
Long-term debt, net	53,957	53,598
Warrants & other long-term liabilities	4,290	3,516
Long-term portion of contingent consideration	50,976	50,360
Total liabilities	153,877	157,378
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, 19,550,414 shares at March 31, 2018 and 19,127,435 shares at December 31, 2017	195	191
Additional paid in-capital	145,367	140,006
Accumulated deficit	(120,985)	(111,348)
Accumulated other comprehensive loss	(1)	(1)
Total shareholders' equity	24,576	28,848
Total liabilities and shareholders' equity	$ 178,453	$ 186,226

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,	
	2018	**2017**
Revenue	$ 19,542	$ 18,742
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	10,490	10,498
Research and development	8,442	7,763
General and administrative	9,518	4,032
Amortization of intangible assets	646	646
Change in warrant valuation	773	291
Change in contingent consideration valuation	2,520	2,814
Total operating expenses	32,389	26,044
Operating loss	(12,847)	(7,302)
Other income (expense):		
Interest income	142	105
Interest expense	(2,103)	(1,183)
Net loss before income taxes	$ (14,808)	$ (8,380)
Income tax benefit	2,353	293
Net loss	$ (12,455)	$ (8,087)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.65)	$ (0.42)
Weighted average common shares outstanding, basic and diluted	19,219,257	19,049,416
Other comprehensive loss:		
Net loss	$ (12,455)	$ (8,087)
Unrealized loss on available-for-sale securities	—	(57)
Comprehensive loss	$ (12,455)	$ (8,144)

Source: Recro Pharma, Inc.