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Recro Pharma Reports First Quarter 2016 Financial Results

Enrollment on track in two pivotal Phase III IV meloxicam trials

One trial expected to report top-line results by end of Q3; Other trial to report top-line results by end of Q4

Manufacturing business continues solid performance

MALVERN, Pa., May 12, 2016 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (Nasdaq:REPH), a revenue generating specialty pharmaceutical company focused on products for hospital and ambulatory care settings that is currently developing non-opioid products for the treatment of serious acute pain, today reported financial results for the first quarter ended March 31, 2016.

“During the first quarter of 2016, we advanced our lead program, intravenous (IV) meloxicam into pivotal Phase III clinical development for the treatment of acute postoperative pain – one trial in patients following bunionectomy surgery and one trial in patients following abdominoplasty surgery,” said Gerri Henwood, Recro Pharma’s President and Chief Executive Officer. “We continue to expect top-line data from both Phase III trials by year end 2016, with the first of those trials expected to readout by the end of the third quarter of 2016.

If positive, we anticipate that data from these pivotal trials, along with other planned trials, will lead to a New Drug Application (NDA) submission to the U.S. FDA in 2017.”

First Quarter 2016 and Recent Highlights

- **Strengthened Management Team with the Appointment of Fred Graff as Chief Commercial Officer.** Mr. Graff joined the Company in February 2016 and brings over 20 years of senior commercial leadership and expertise in building high-performance sales organizations and launching new products.
- **Presented Meloxicam Clinical Data at American Pain Society 35th Annual Scientific Meeting.** The Company presented a poster which highlighted data from a clinical trial evaluating the efficacy and safety of IV meloxicam (N1539), in subjects with moderate to severe pain following open abdominal hysterectomy. The study results demonstrated that IV meloxicam was effective at treating moderate to severe pain following open abdominal hysterectomy and the study met both co-primary endpoints at all dose levels producing statistically significant differences in SPID24 and TOTPAR24 compared with placebo. In this study, IV meloxicam was also safe and well tolerated.
- **Initiated Pivotal Phase III Trial of IV Meloxicam in Bunionectomy Surgery:**

February 2016, Recro announced the commencement of dosing in its pivotal Phase III clinical trial evaluating IV meloxicam for acute postoperative pain in patients following bunionectomy surgery, a representative hard tissue surgery. This multicenter, randomized, double-blind, placebo-controlled trial is expected to enroll approximately 200 patients.

- **Initiated Pivotal Phase III Trial of IV Meloxicam in Abdominoplasty Surgery:**In January 2016, Recro announced the commencement of dosing in its pivotal Phase III clinical trial evaluating IV meloxicam for acute postoperative pain in patients following “mini” abdominoplasty surgery, a representative soft tissue surgery. This multicenter, randomized, double-blind, placebo-controlled trial is expected to enroll approximately 200 patients.
- **Reported Positive Phase II Top-Line Results for IV Meloxicam:**In January 2016, Recro reported preliminary results from its Phase II clinical trial evaluating IV meloxicam for the treatment of acute pain following bunionectomy surgery. In this trial, IV meloxicam was well tolerated and both the 30mg and 60mg treatment arms demonstrated statistically significant reductions in pain intensity, as measured by SPID48 ($p=0.0007$ and $p=0.0027$, respectively) compared to placebo.

Financial Results

As of March 31, 2016, Recro Pharma had cash and cash equivalents of \$14.9 million.

Pursuant to the terms of the Company’s credit agreement with OrbiMed, OrbiMed has the option to require the Company to pay down debt with excess free cash flow generated from the Recro Gainesville contract manufacturing facility. In February 2016, the Company paid approximately \$2.6 million to OrbiMed, which was 50% of the free cash flow generated during the fourth quarter of 2015. To date, the Company has paid approximately \$19.0 million, or 38%, of the original \$50.0 million of senior secured term loan from free cash flow generated during the 2015 fiscal year by Recro Gainesville.

For the quarter ended March 31, 2016, Recro Pharma reported a net loss applicable to common shareholders of \$6.5 million, or \$0.71 per share, compared to a net loss applicable to common shareholders of \$4.1 million, or \$0.53 per share, for the comparable period in 2015.

Revenues and COGS for the quarter ended March 31, 2016 were \$17.7 million and \$10.3 million, respectively. There were no revenues and COGS in the comparable period in 2015. The increases in revenues and COGS were the result of the acquired manufacturing business, Recro Gainesville, from Alkermes on April 10, 2015.

Research and development expenses for the quarter ended March 31, 2016 were \$7.8 million, compared to \$1.8 million for the same period in 2015. General and administrative expenses for the quarter ended March 31, 2016, were \$2.7 million, compared to \$2.4 million for the same period in 2015. The increase in research and development expenses were primarily due to the Company’s injectable meloxicam clinical expenses and research and development costs incurred at the Recro Gainesville facility. The increase in general and administrative expenses was primarily due to an increase in management’s salaries, benefits and stock compensation as a result of additional headcount and costs associated with being

a public company.

Amortization of intangibles for the quarter ended March 31, 2016, was \$0.7 million. There was no amortization of intangibles for the comparable period in 2015.

Interest expense for the quarter ended March 31, 2016, was \$1.5 million and consists of interest incurred on our OrbiMed senior secured term loan and amortization of related financing costs. There was no interest expense for the same period in 2015.

About Recro Pharma, Inc.

Recro Pharma is a revenue generating specialty pharmaceutical company focused on products for hospital and ambulatory care settings that is currently developing non-opioid products for the treatment of serious acute pain. Recro Pharma is currently developing IV meloxicam, a proprietary, long-acting preferential COX-2 inhibitor for treatment of acute postoperative pain, and Dex-IN, a proprietary intranasal formulation of dexmedetomidine, for the treatment of peri-procedural pain. Both compounds have successfully completed Phase II clinical trials. As Recro Pharma's product candidates are not in the opioid class of drugs, the Company believes its candidates would avoid many of the side effects associated with commonly prescribed opioid therapeutics, such as addiction, constipation and respiratory distress, while maintaining analgesic effect.

Recro Pharma also owns and operates a 97,000 square foot, DEA-licensed facility that manufactures five commercial products and receives manufacturing revenues and royalties associated with the sales of these products.

Cautionary Statement Regarding Forward Looking Statements

This press release contains forward-looking statements that involve risks and uncertainties. Such forward looking statements reflect Recro Pharma'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 Pharma or its management, are intended to identify such forward-looking statements. These forward looking statements are based on information available to Recro Pharma as of the date of this press release and are subject to a number of risks, uncertainties, and other factors that could cause Recro Pharma's performance to differ materially from those expressed in, or implied by, these forward looking statements. Recro Pharma assumes no obligation to update any such forward-looking statements. Factors that could cause Recro Pharma's actual performance to materially differ from those expressed in the forward-looking statements set forth in this press release include, without limitation: results and timing of the clinical trials of injectable meloxicam and Dex-IN; the ability to obtain and maintain regulatory approval of injectable meloxicam and Dex-IN, and the labeling under any such approval; regulatory developments in the United States and foreign countries; the Company's ability to raise future financing for continued development; the Company's ability to pay its debt; 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; and the successful commercialization of injectable meloxicam and Dex-IN. In addition, the forward looking statements in this press release should be considered together with the risks and uncertainties that may affect Recro Pharma's business and future results included in Recro

Pharma's filings with the Securities and Exchange Commission at www.sec.gov. Recro Pharma assumes no obligation to update any such forward looking statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(unaudited)

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

Assets	March 31, 2016	December 31, 2015
Current assets:		
Cash and cash equivalents	\$ 14,917	\$ 19,779
Accounts receivable	12,182	8,580
Other receivables	23	36
Inventory	7,638	8,982
Prepaid expenses	934	757
Deferred equity costs	512	542
Total current assets	\$ 36,206	\$ 38,676
Property, plant and equipment, net	36,995	37,922
Deferred income taxes	16,043	15,637
Intangible assets, net	39,370	40,016
Goodwill	6,446	6,446
Total assets	\$ 135,060	\$ 138,697
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	1,990	1,553
Accrued expenses	5,606	3,418
Current portion of long-term debt	4,859	4,516
Total current liabilities	12,455	9,487
Long-term debt	22,563	25,244
Warrants	2,176	3,770
Contingent consideration	62,824	59,846
Total liabilities	100,018	98,347
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, 9,318,255 shares at March 31, 2016 and 9,224,315 shares at December 31, 2015	93	92
Additional paid in-capital	72,551	71,321
Accumulated deficit	(37,602)	(31,063)
Total shareholders' equity	35,042	40,350
Total liabilities and shareholders' equity	\$ 135,060	\$ 138,697

RECRO PHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Operations
(unaudited)

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

	Three Months Ended	
	March 31,	
	2016	2015
Revenue:		
Manufacturing, royalty and profit sharing revenue	\$ 17,138	\$ —
Research and development revenue	604	—
Total revenue	17,742	—
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	10,271	—
Research and development	7,808	1,754
General and administrative	2,658	2,386
Amortization of intangible assets	646	—
Change in warrant valuation	(1,594)	—
Change in contingent consideration valuation	2,978	—
Total operating expenses	22,767	4,140
Operating loss	(5,025)	(4,140)
Other income (expense):		
Interest income	9	4
Interest expense	(1,512)	—
Net loss before income taxes	(6,528)	(4,136)
Income tax expense	(11)	
Net loss applicable to common shareholders	(6,539)	(4,136)
Basic and diluted net loss per common share	\$ (0.71)	\$ (0.53)
Weighted average basic and diluted common shares outstanding	9,251,948	7,768,693

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Source: Recro Pharma, Inc.