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Recro Pharma Reports Year End 2015 Financial Results

Pivotal Phase III IV Meloxicam Program Underway with Top-line Data Expected by Year End 2016

MALVERN, Pa., March 24, 2016 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (Nasdaq:REPH), a revenue generating specialty pharmaceutical company developing multiple non-opioid therapeutics for the treatment of serious acute pain, today reported financial results for the year ended December 31, 2015.

“The favorable tolerability and statistically significant efficacy observed in our completed Phase II clinical trial with IV meloxicam in bunionectomy surgery patients is encouraging and the pivotal Phase III program is now underway,” said Gerri Henwood, Recro Pharma’s President and Chief Executive Officer. “We look forward to top-line data from both Phase III trials by year end 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.”

“We are also pleased with the strong performance by our Recro Gainesville manufacturing business,” said Donna Nichols, Recro Pharma’s Chief Accounting Officer. “The free cash flow generated in just three quarters of 2015 paid down $19.0 million, or 38%, of the original $50 million loan.”

Fourth Quarter 2015 and Recent Highlights

- **Initiated Pivotal Phase III Trial of Intravenous (IV) Meloxicam in Bunionectomy Surgery:** In 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 and the Company expects to report top-line results by year end 2016.

- **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 and the Company expects to report top-line results by year end 2016.

- **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.

- **Strengthened Management Team with the Appointment of Dr. Stewart McCallum as Chief Medical Officer and Fred Graff as Chief Commercial Officer:** Dr. McCallum, who joined Recro in December 2015, is a highly accomplished, board certified physician and surgeon who comes to Recro with a proven track record in drug development, both in industry and as a primary investigator at Stanford University. Mr. Graff joined the Company in February 2016 and brings over 20 years of senior commercial leadership, expertise in building high-performance sales organizations and launching new products.

Financial Results

As of December 31, 2015, Recro Pharma had cash and cash equivalents of $19.8 million.

Pursuant to the terms of the 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 year ended December 31, 2015, Recro Pharma reported net income applicable to common shareholders of $3.0 million, or $0.36 per share, compared to a net loss applicable to common shareholders of $17.4 million, or $2.79 per share, for the comparable period in 2014.

Revenues and COGS for the period from April 10, 2015 through December 31, 2015 were $52.0 million and $28.1 million, respectively. There were no revenues and COGS in the comparable period in 2014. 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 year ended December 31, 2015 were $12.3 million, compared to $7.9 million for the same period in 2014. General and administrative expenses for the year ended December 31, 2015, were $13.0 million, compared to $4.0 million for the same period in 2014. 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. This increase in general and administrative expenses was due to costs associated with the acquisition of the worldwide rights to injectable meloxicam and the contract manufacturing facility, Recro Gainesville, an increase in management's salaries to market compensation rates, an increase in benefits and stock compensation, and increased consulting and legal fees associated with being a public company and management of Recro Gainesville.

Amortization of intangibles for the year ended December 31, 2015, was $1.9 million. There

was no amortization of intangibles for the comparable period in 2014.

Interest expense for the year ended December 31, 2015, was $5.6 million and consists of interest incurred on our OrbiMed senior secured term loan. Interest expense for the year ended December 31, 2014, was $4.3 million which included a non-cash interest charge of approximately $4.1 million for the conversion of the 8% Convertible Promissory Notes to common stock.

About Recro Pharma, Inc.

Recro Pharma is a revenue generating specialty pharmaceutical company developing multiple non-opioid therapeutics 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 an 87,000 square foot, DEA-licensed facility that manufactures five commercial products and receives manufacturing revenues and royalties associated with the sales of these products. The campus includes an additional 10,000 square feet of administrative space and certain utility areas.

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

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

Assets	**December 31, 2015**	**December 31, 2014**
Current assets:		
Cash and cash equivalents	$ 19,779	$ 19,682
Accounts receivable	8,580	—
Other receivables	36	90
Inventory	8,982	—
Prepaid expenses	757	602
Deferred equity costs	542	—
Total current assets	38,676	20,374
Property, plant and equipment, net	37,922	—
Deferred income taxes	15,637	—
Intangible assets, net	40,016	—
Goodwill	6,446	—
Total assets	$ 138,697	$ 20,374
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,553	$ 870
Accrued expenses	3,418	576
Current portion of long-term debt	4,516	—
Total current liabilities	9,487	1,446
Long-term debt	25,244	—
Warrants	3,770	—
Contingent consideration	59,846	—
Total liabilities	98,347	1,446
Commitments and contingencies (Note 12)		
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, 9,224,315 shares at December 31, 2015 and 7,707,600 shares at December 31, 2014	92	77
Additional paid in-capital	71,321	52,947
Accumulated deficit	(31,063)	(34,096)
Total shareholders' equity	40,350	18,928
Total liabilities and shareholders' equity	$ 138,697	$ 20,374

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

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

	Year Ended December 31,	
	2015	**2014**
Revenue:		
Manufacturing, royalty and profit sharing revenue	$ 49,284	$ —
Research and development revenue	2,668	—
Total revenues	51,952	—
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	28,054	—
Research and development	12,281	7,874
General and administrative	13,017	3,998
Amortization of intangible assets	1,884	—
Change in warrant valuation	(1,560)	—
Change in contingent consideration valuation	5,246	—
Total operating expenses	58,922	11,872
Operating loss	(6,970)	(11,872)
Other income (expense):		
Interest income	12	11
Interest expense	(5,560)	(4,273)
Loss before income taxes	(12,518)	(16,134)
Income tax benefit	15,551	—
Net income (loss)	3,033	(16,134)
Accretion of redeemable convertible preferred stock	—	(1,270)
Net income (loss) applicable to common shareholders	$ 3,033	$ (17,404)
Basic net income (loss) per common share	$ 0.36	$ (2.79)
Diluted net income (loss) per common share	$ 0.21	$ (2.79)
Weighted average basic common shares outstanding	8,491,025	6,238,581
Weighted average diluted common shares outstanding	8,749,234	6,238,581

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Source: Recro Pharma, Inc.