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Recro Pharma Reports Third Quarter 2015 Financial Results

MALVERN, Pa., Nov. 13, 2015 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (Nasdaq:REPH), a revenue generating specialty pharmaceutical company developing multiple non-opioid therapeutics for the treatment of pain, today reported financial results for the third quarter ended September 30, 2015.

"Over the last several months, the team at Recro Pharma has taken important steps to advance our non-opioid product candidates for the treatment of acute pain and achieve our overall business objectives," said Gerri Henwood, Recro Pharma's President and Chief Executive Officer. "During the third quarter, we strengthened the balance sheet, reported Phase II Dex-IN results, and gained important clarity from the U.S. Food and Drug Administration (FDA) for our pipeline assets. Looking forward, we are diligently working toward a first quarter 2016 start to our pivotal Phase III clinical program for intravenous (IV) meloxicam. Assuming positive outcomes, we expect the results from this Phase III program will be the basis of our New Drug Application (NDA) submission for marketing authorization. We look forward to updating you on our progress in the coming months and quarters."

Third Quarter 2015 and Recent Highlights

- ***Provided Clinical Pipeline Update:*** In October 2015, Recro reported that it will be advancing IV meloxicam, a long-acting, preferential COX-2 inhibitor, for the treatment of moderate to severe acute post operative pain, into a pivotal Phase III clinical development program in the first quarter of 2016. The Phase III program is expected to be comprised of two pivotal clinical trials, as well as other trials, including a safety trial. The Company expects that a total of approximately 1,300 patients will be enrolled in these anticipated trials. For Dex-IN, Recro's intranasal formulation of the selective alpha-2 agonist analgesic, dexmedetomidine, the Company obtained feedback from the FDA and intends to pursue a program in peri-procedural pain including Phase II dose finding trials.
- ***Presented IV Meloxicam Data at PainWeek® 2015:*** In September 2015, Recro presented two posters at PAINWeek®, the National Conference on Pain for Frontline Practitioners. The poster presentations highlighted efficacy and safety data from two trials for the Company's novel intravenous (IV) formulation of NanoCrystal Colloidal Dispersion® meloxicam, being developed for the management of acute moderate to severe pain. These presented data support the Company's lead product candidate, IV/IM meloxicam, which has successfully completed multiple Phase II clinical trials.
- ***Expanded Board and Leadership Team:*** During the third quarter, Recro appointed Karen A. Flynn to the Company's Board of Directors and Audit Committee and named Scott Rizzo as General Manager of the Company's contract manufacturing facility located in Gainesville, Georgia.

- ***Announced Results from Phase II Dex-IN Clinical Trial:*** In July 2015, Recro Pharma reported safety data and efficacy results from its Phase II Dex-IN (REC-14-013) clinical trial. In this trial, Dex-IN met the primary endpoint of demonstrating significant pain relief compared with placebo over 48 hours, SPID48, (p=0.0214).
- ***Completed Private Common Stock Placement:*** In July 2015, Recro Pharma announced the closing of a $16.0 million private common stock placement with a group of institutional accredited investors led by Broadfin Capital, LLC. The Company issued 1,379,311 shares of common stock in the placement, resulting in net proceeds of $14.8 million.

Third Quarter 2015 Financial Results

As of September 30, 2015, Recro Pharma had cash and cash equivalents of $28.3 million. On July 7, 2015, the Company raised net proceeds of $14.8 million in a private common stock placement.

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 Gainesville contract manufacturing facility.

For the three months ended September 30, 2015, Recro Pharma reported a net loss applicable to common shareholders of $2.2 million, or $0.24 per share, compared to a net loss applicable to common shareholders of $4.7 million, or $0.61 per share, for the comparable period in 2014. For the nine months ended September 30, 2015, Recro Pharma reported a net loss applicable to common shareholders of $7.6 million, or $0.92 per share, compared to a net loss applicable to common shareholders of $13.9 million, or $2.42 per share, for the comparable period in 2014.

Revenues and costs of sales for the three months ended September 30, 2015, were $16.5 million and $10.0 million, respectively. Revenues and costs of sales for the nine months ended September 30, 2015, were $35.2 million and $19.2 million, respectively. There were no revenues and costs of sales in the comparable periods in 2014. The increases in revenues and costs of sales were the result of the acquired manufacturing business from Alkermes on April 10, 2015.

Research and development expenses for the three months ended September 30, 2015, were $2.7 million, compared to $3.6 million for the same period in 2014. Research and development expenses for the nine months ended September 30, 2015, were $7.3 million, compared to $5.6 million for the same period in 2014.

General and administrative expenses for the three months ended September 30, 2015, were $3.5 million, compared to $1.1 million for the same period in 2014. General and administrative expenses for the nine months ended September 30, 2015, were $8.5 million, compared to $2.8 million for the same period in 2014.

Amortization of intangibles for the three and nine months ended September 30, 2015, was $0.6 million and $1.2 million, respectively. There was no amortization of intangibles for the comparable periods in 2014.

Interest expense for the three and nine months ended September 30, 2015, was $2.0 million

and $3.9 million, respectively and consists of interest incurred on our OrbiMed senior secured term loan. Interest expense for the nine months ended September 30, 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 pain. Recro Pharma is currently developing IV/IM meloxicam, a proprietary, long-acting preferential COX-2 inhibitor for treatment of acute post-operative 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 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 IV/IM meloxicam and Dex-IN; the ability to obtain and maintain regulatory approval of IV/IM 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; the successful commercialization of IV/IM 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	September 30, 2015	December 31, 2014
Current assets:		
Cash and cash equivalents	$ 28,275	$ 19,682
Accounts receivable	9,572	—
Other recievables	29	90
Inventory	8,571	—
Prepaid expenses	1,456	602
Deferred equity costs	542	—
Total current assets	48,445	20,374
Property, plant and equipment,net	38,659	—
Intangible assets,net	40,662	—
Goodwill	6,744	—
Total assets	$ 134,510	$ 20,374
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 781	$ 871
Accrued expenses	4,695	575
Current portion of long-term debt	13,662	—
Total current liabilities	19,138	1,446
Long-term debt	24,360	—
Warrants	5,450	—
Contingent consideration	57,186	—
Total liabilities	106,134	1,446
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 September 30, 2015 and 7,707,600 shares at December 31, 2014	92	77
Additional paid in-capital	69,982	52,947
Accumulated deficit	(41,698)	(34,096)
Total shareholders' equity	28,376	18,928
Total liabilities and shareholders' equity	$ 134,510	$ 20,374

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

(unaudited)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	**2014**	**2015**	**2014**
Revenue:				
Manufacturing, royalty and profit sharing revenue	$ 16,120	$ —	$ 32,824	$ —
Research and development revenue	419	—	2,375	—
Total revenue	16,539	—	35,199	—
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	10,039	—	19,228	—
Research and development	2,716	3,634	7,260	5,619
General and administrative	3,478	1,084	8,492	2,768
Amortization of intangible assets	646	—	1,238	—
Change in warrant valuation	(762)	—	119	—
Change in contingent consideration valuation	586	—	2,586	—
Total operating expenses	16,703	4,718	38,923	8,387
Operating (loss)	(164)	(4,718)	(3,724)	(8,387)
Other income (expense):				
Interest income	2	5	10	7
Interest expense	(1,990)	—	(3,888)	(4,273)
Net loss	(2,152)	(4,713)	(7,602)	(12,653)
Accretion of redeemable convertible preferred stock	—	—	—	(1,270)
Net loss applicable to common shareholders	$ (2,152)	$ (4,713)	$ (7,602)	$ (13,923)
Basic and diluted net loss per common share	$ (0.24)	$ (0.61)	$ (0.92)	$ (2.42)
Weighted average basic and diluted common shares outstanding.	9,118,664	7,707,600	8,243,909	5,743,527

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Source: Recro Pharma