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# Recro Pharma Reports Third Quarter 2016 Financial Results

*Announced Positive Phase III Results from Pivotal Trial of IV Meloxicam Following Bunionectomy Surgery*

*Pivotal Phase III Trial of IV Meloxicam Following Mini Abdominoplasty Surgery Ongoing; Top-line Data Expected by Year End*

MALVERN, Pa., Nov. 10, 2016 (GLOBE NEWSWIRE) -- Recro Pharma, Inc (Nasdaq:REPH), a revenue generating specialty pharmaceutical company focused on products for hospital and ambulatory care settings, currently developing non-opioid products for the treatment of serious acute pain, today reported financial results for the third quarter ended September 30, 2016.

“During the third quarter, we made significant progress advancing our lead candidate, IV meloxicam, with positive top-line data from the first of two pivotal Phase III efficacy trials, and we remain on track to report top-line data from the second pivotal trial by year end,” said Gerri Henwood, President and Chief Executive Officer of Recro Pharma. “With the acute pain space currently dominated by opioids, which can cause addiction and other serious side effects, there exists an urgent medical need for non-opioid options that provide patients with rapid and sustained pain relief. We look forward to sharing future clinical updates as we work toward a possible NDA filing for IV meloxicam in mid-summer 2017.”

## Third Quarter 2016 and Recent Highlights

- **Announced Positive Data from Pivotal Phase III Trial of IV Meloxicam Following Bunionectomy Surgery.** Recro reported positive data from the first of two pivotal efficacy Phase III clinical trials of IV meloxicam. In this multicenter, randomized, double-blind, placebo-controlled trial, IV meloxicam achieved its primary endpoint of a statistically significant reduction in Summed Pain Intensity Difference (SPID) over 48 hours (SPID48) versus placebo. The study also achieved 15 of 19 secondary endpoints. Since enrollment is now completed, Recro remains on track to report top-line data from its second pivotal Phase III trial of IV meloxicam following mini abdominoplasty surgery by the end of 2016.
- **Strengthened Balance Sheet with Underwritten Common Stock Offering.** In August, Recro completed an underwritten public offering of 1,986,666 shares of its common stock at a price of \$7.50 per share, from which the Company raised a total of approximately \$13.4 million in net proceeds.
- **Strong Gainesville Manufacturing Performance.** Recro’s manufacturing business

continued to perform well with revenues of \$52 million for the nine months ended September 30, 2016, generating positive cash flow for the Company. We now anticipate 2016 full year revenue from our manufacturing business to exceed approximately \$60 million (our most recent guidance had been for revenues of approximately \$55-60 million), reflecting the benefit of a positive one-time revenue adjustment occurring in the third quarter of 2016. For 2017, we currently expect revenues of approximately \$55 to \$60 million, consistent with our expectations of the manufacturing business recurring revenue level.

## **Financial Results**

As of September 30, 2016, Recro Pharma had cash and cash equivalents of \$24.8 million.

For the three months ended September 30, 2016, Recro Pharma reported a net loss of \$5.4 million, or \$(0.50) per share, compared to a net loss of \$2.2 million, or \$(0.24) per share, for the comparable period in 2015. For the nine months ended September 30, 2016, Recro Pharma reported a net loss of \$19.8 million, or \$(2.01) per share, compared to a net loss of \$7.6 million, or \$(0.92) per share, for the comparable period in 2015.

Revenues for the three months ended September 30, 2016 were \$17.0 million, compared to \$16.5 million for the same period in 2015. Current year revenues included \$2.3 million related to a one-time, contractually based manufacturing revenue from one of our commercial partners, and \$1.1 million higher profit-share revenue from another commercial partner's new customer base, offset primarily by lower product shipment revenue. COGS for the three months ended September 30, 2016 were \$5.7 million, compared to \$10.0 million for the same period in 2015 due to lower product shipments.

Revenues and COGS for the nine months ended September 30, 2016 were \$52.0 million and \$25.6 million, respectively, which were higher than revenues and COGS of \$35.2 million and \$19.2 million, respectively, for the comparable period in 2015, as we owned the manufacturing business for six months through September 30, 2015 compared to nine months in 2016.

Research and development expenses for the three months ended September 30, 2016 were \$7.0 million, compared to \$2.7 million for the same period in 2015. Research and development expenses for the nine months ended September 30, 2016 were \$23.2 million, compared to \$7.3 million for the same period in 2015. The increases in research and development expenses were primarily due to the Company's IV meloxicam Phase III clinical trial expenses as well as increased research and development costs incurred at the Recro Gainesville facility, partially offset by a decrease in Dex clinical expenses.

General and administrative expenses for the three months ended September 30, 2016 were \$3.9 million, compared to \$3.5 million for the same period in 2015. General and administrative expenses for the nine months ended September 30, 2016 were \$9.3 million, compared to \$8.5 million for the same period in 2015. The increases in general and administrative expenses were primarily due to an increase in salaries, benefits and stock compensation as a result of additional headcount and pre-commercialization marketing expenses.

Amortization of intangibles for the three months ended September 30, 2016 and 2015 was \$0.6 million. Amortization of intangibles for the nine months ended September 30, 2016 was \$1.9 million, compared to \$1.2 million for the same period in 2015, as we owned the manufacturing business for six months through September 30, 2015 compared to nine months in 2016.

Interest expense was \$1.5 million for the three months ended September 30, 2016, compared to \$2.0 million for the same period in 2015. Interest expense for the nine months ended September 30, 2016 was \$4.3 million, compared to \$3.9 million for the same period in 2015, as we owned the manufacturing business for six months through September 30, 2015 compared to nine months in 2016. Interest expense consists of interest incurred on our OrbiMed senior secured term loan used to purchase the manufacturing business and amortization of related financing costs.

### **About IV/IM Meloxicam**

Meloxicam is a long-acting, preferential COX-2 inhibitor that possesses anti-inflammatory, analgesic, and antipyretic activities, which are believed to be related to the inhibition of cyclooxygenase (COX) and subsequent reduction in prostaglandin biosynthesis. Meloxicam has been marketed by Boehringer Ingelheim Pharmaceuticals, Inc. since the 1990's as an oral agent, Mobic<sup>®</sup>. IV/IM meloxicam was designed using NanoCrystal<sup>®</sup> platform, a technology that enables enhanced bioavailability of poorly water-soluble drug compounds. Recro acquired IV/IM meloxicam from Alkermes in April 2015.

### **About Recro Pharma, Inc.**

Recro Pharma is a revenue generating specialty pharmaceutical company focused on products for hospital and ambulatory care settings, 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, which has completed four successful Phase II clinical trials in postoperative pain conditions and has reported positive results from its first pivotal Phase III clinical trial in patients following bunionectomy surgery. An additional development candidate, Dex-IN, a proprietary intranasal formulation of dexmedetomidine, is being pursued for the treatment of peri-procedural pain, and has had a past successful Phase II trial in bunionectomy. 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**

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, clinical development plans and other statements containing the words "anticipate,"

"believe," "estimate," "upcoming," "plan," "target," "intend," "expect" and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: results and timing of the clinical trials of IV meloxicam and Dex-IN; unfavorable new clinical data and additional analyses of existing clinical data; whether results of early clinical trials will be indicative of the results of future trials and whether interim results from a clinical trial will be predictive of the final results of the trial; the ability to obtain and maintain regulatory approval of IV 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 meloxicam and Dex-IN and other factors discussed in the Risk Factors set forth in the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission (SEC) and in other filings the Company makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent the Company's views only as of the date of this press release. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements, and as such we anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

### RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Balance Sheets  
(unaudited)

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

<b>Assets</b>	<b>September 30, 2016</b>	<b>December 31, 2015</b>
Current assets:		
Cash and cash equivalents	\$ 24,752	\$ 19,779
Accounts receivable	12,400	8,580
Other receivables	60	36
Inventory	9,812	8,982
Prepaid expenses	1,668	757
Deferred equity costs	316	542
Total current assets	49,008	38,676
Property, plant and equipment, net	36,487	37,922
Deferred income taxes	15,989	15,637
Intangible assets, net	38,079	40,016
Goodwill	6,446	6,446
Total assets	\$ 146,009	\$ 138,697
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,917	\$ 1,553
Accrued expenses	7,857	3,418

Current portion of long-term debt	1,498	4,516
Total current liabilities	<u>11,272</u>	<u>9,487</u>
Long-term debt	22,738	25,244
Warrants	3,817	3,770
Contingent consideration	67,551	59,846
Total liabilities	<u>105,378</u>	<u>98,347</u>
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, 11,863,660 shares at September 30, 2016 and 9,224,315 shares at December 31, 2015	119	92
Additional paid-in capital	91,378	71,321
Accumulated deficit	<u>(50,866 )</u>	<u>(31,063 )</u>
Total shareholders' equity	<u>40,631</u>	<u>40,350</u>
Total liabilities and shareholders' equity	<u>\$ 146,009</u>	<u>\$ 138,697</u>

### RECRO PHARMA, INC. AND SUBSIDIARIES

#### Consolidated Statements of Operations (unaudited)

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Revenue:				
Manufacturing, royalty and profit sharing revenue	\$ 16,188	\$ 16,120	\$ 50,260	\$ 32,824
Research and development revenue	763	419	1,713	2,375
Total revenue	<u>16,951</u>	<u>16,539</u>	<u>51,973</u>	<u>35,199</u>
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	5,745	10,039	25,563	19,228
Research and development	7,046	2,716	23,175	7,260
General and administrative	3,841	3,478	9,263	8,492
Amortization of intangible assets	646	646	1,937	1,238
Change in warrant valuation	402	(762 )	47	119
Change in contingent consideration valuation	3,192	586	7,705	2,586
Total operating expenses	<u>20,872</u>	<u>16,703</u>	<u>67,690</u>	<u>38,923</u>
Operating loss	<u>(3,921 )</u>	<u>(164 )</u>	<u>(15,717 )</u>	<u>(3,724 )</u>
Other income (expense):				
Interest income	10	2	27	10
Interest expense	<u>(1,450 )</u>	<u>(1,990 )</u>	<u>(4,279 )</u>	<u>(3,888 )</u>
Net loss before income taxes	<u>(5,361 )</u>	<u>\$ (2,152 )</u>	<u>(19,969 )</u>	<u>(7,602 )</u>
Income tax benefit (expense)	<u>(18 )</u>	<u>—</u>	<u>166</u>	<u>—</u>
Net loss	<u>\$ (5,379 )</u>	<u>\$ (2,152 )</u>	<u>(19,803 )</u>	<u>(7,602 )</u>
Basic and diluted net loss per common share	<u>\$ (0.50 )</u>	<u>\$ (0.24 )</u>	<u>\$ (2.01 )</u>	<u>\$ (0.92 )</u>

Weighted average basic and diluted common  
shares outstanding

10,780,911

9,118,664

9,862,526

8,243,909

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Source: Recro Pharma, Inc.