August 10, 2017

Recro Pharma Reports Second Quarter 2017 Financial Results

Reports Second Quarter 2017 Revenues of $16.9 Million

NDA Submitted to U.S. FDA for IV Meloxicam

MALVERN, Pa., Aug. 10, 2017 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (Nasdaq:REPH), a revenue generating specialty pharmaceutical company focused on therapeutics for hospital and other acute care settings, today reported financial results for the three and six months ended June 30, 2017.

“We recently achieved a key milestone with the submission of our New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for intravenous (IV) meloxicam 30mg, a significant step in our commitment to providing a non-opioid alternative for the management of moderate to severe pain,” said Gerri Henwood, President and Chief Executive Officer of Recro Pharma. “Based on data from our two pivotal Phase III trials demonstrating efficacy in the moderate to severe, acute pain setting, we believe IV meloxicam 30mg has a unique profile as an effective and well tolerated long-acting therapeutic with the potential to benefit patients and provide physicians with new treatment options.”

“In parallel with filing the NDA package for IV meloxicam 30mg, we continued to build out our internal commercial and supply chain teams in advance of a potential approval and launch of IV meloxicam 30mg, as well as expanded our portfolio through the acquisition of two novel neuromuscular blocking (NMB) agent product candidates and companion reversal agent from Cornell University, all of which are meaningful steps in our efforts to strengthen our position as a developer and commercializer of hospital and acute care products,” Ms. Henwood concluded.

Second Quarter 2017 and Recent Highlights

- **Strong Gainesville Manufacturing Performance.** Recro’s manufacturing business continued to perform well with revenues of $16.9 million for the three months ended June 30, 2017. Revenues for the six months ended June 30, 2017, were $35.7 million.

- **Filed NDA with the U.S. FDA for IV Meloxicam 30mg.** In late July 2017, Recro submitted an NDA with the U.S. FDA for IV meloxicam 30mg for the management of moderate to severe pain. The NDA package includes data from two Phase III efficacy trials, one Phase III safety trial, four Phase II trials and other safety studies. The FDA has a 60-day review period to determine whether the NDA is complete and acceptable for filing.

- **Acquired Two Novel NMBs and a Novel Companion Reversal Agent Licensed from Cornell University.** In June 2017, Recro acquired exclusive global rights to one novel, clinical stage, intermediate-acting NMB, one novel, pre-IND stage, ultra-short-acting NMB and one rapid-acting reversal agent specific to these compounds, collectively referred to herein as the NMB Related Compounds. The two NMBs are being developed to permit a rapid induction of neuromuscular blockade and the reversal agent is being developed to provide rapid reversal of this blockade, which may meaningfully reduce the patient's post-procedure time in the operating room or post-acute care unit, with the potential to provide benefits to patients and valuable savings to hospitals and ambulatory surgical centers.

- **Expanded Team.** In June and July 2017, Recro added key personnel in the areas of reimbursement, pharmacovigilance, commercial analytics, acute care marketing, clinical development, manufacturing, regulatory affairs and finance. These new hires are part of Recro's preparation for the medical, commercial and supply chain teams for IV meloxicam 30mg.

- **Presented Phase III Bunionectomy Clinical Data for IV Meloxicam 30mg at the APS Annual Meeting.** In May 2017, Recro presented clinical data from its Phase III study evaluating IV meloxicam 30mg for the management of moderate to severe pain in patients following bunionectomy surgery at the American Pain Society 36th Annual Scientific Meeting. The poster presentation highlighted the clinical performance of IV meloxicam 30mg, including achievement of the study's primary endpoint, a statistically significant difference in Summed Pain Intensity Difference (SPID) over 48 hours (SPID48) compared to placebo, along with multiple secondary endpoints and safety results.

- **Reported Successful Top-Line Results from the IV Meloxicam 30mg Phase III Safety Study.** The primary objective of the safety study following major surgery was to evaluate the safety and tolerability of IV meloxicam 30mg compared to placebo through Day 28 following treatment. The study demonstrated that the adverse event profile of IV meloxicam 30mg was consistent with previously completed studies. In addition, the study demonstrated overall opioid use was lower, and "time to first use" of opioids was significantly longer, in the IV meloxicam 30mg treatment arm, compared to placebo.

Financial Results

As of June 30, 2017, Recro had cash, cash equivalents and short-term investments of $50.2 million.

Revenues were $16.9 million and $17.3 million for the three months ended June 30, 2017 and 2016, respectively. The decrease of $0.3 million in revenue, or 2%, for this quarter year-over-year, was primarily the result of a decrease in royalty revenue due to a change in the mix of generic and brand sales by our partners offset by an increase in profit sharing revenue due to increased sales volumes and pricing by our partner. Revenues were $35.7 million and $35.0 million for the six months ended June 30, 2017 and 2016, respectively. The year-over-year increase of $0.7 million, or 2%, was primarily the result of increased profit

share revenue due to increased volumes and pricing by our partner. This was partially offset by a decrease in manufacturing revenue due to a change in the timing of product shipments compared to prior year and decreased royalty revenue due to a change in the mix of generic and brand sales by our partners.

Cost of sales were $10.4 million and $9.5 million for the three months ended June 30, 2017 and 2016, respectively. Cost of sales were $20.9 million and $19.8 million for the six months ended June 30, 2017 and 2016, respectively. Cost of sales increased in both periods due to changes in the product mix of manufacturing revenue.

Research and development expenses were $7.1 million and $8.3 million for the three months ended June 30, 2017 and 2016, respectively. Lower IV meloxicam clinical trial expenses of $4.3 million were offset by increases of $1.6 million of pre-commercialization manufacturing and other development costs for IV meloxicam, $0.8 million in costs to acquire the NMB Related Compounds and $0.5 million of salaries and benefits expense due to increased clinical headcount in our Acute Care division. Research and development expenses were $14.8 million and $16.1 million for the six months ended June 30, 2017 and 2016. Lower IV meloxicam clinical trial expenses of $5.5 million were offset by increases of $2.5 million of pre-commercialization manufacturing and other development costs for IV meloxicam, $0.8 million in costs to acquire the NMB Related Compounds and $0.9 million of salaries and benefits expense due to increased clinical headcount in our Acute Care division.

General and administrative expenses were $6.3 million and $2.8 million for the three months ended June 30, 2017 and 2016, respectively. The increase of $3.6 million was primarily due to increased headcount in our Acute Care division and pre-commercialization and medical affairs expenses. General and administrative expenses were $10.4 million and $5.4 million for the six months ended June 30, 2017 and 2016, respectively. The increase of $5.0 million was primarily due to increased headcount in our Acute Care division and pre-commercialization and medical affairs expenses.

Amortization expense was $0.6 million for each of the three months ended June 30, 2017 and 2016, and $1.3 million for each of the six months ended June 30, 2017 and 2016. This expense was solely related to the amortization of the Company's royalties and contract manufacturing relationships intangible asset over its six-year estimated useful life.

Interest expense, net was $1.1 million and $1.3 million during the three months ended June 30, 2017 and 2016, and, $2.2 million and $2.8 million during the six months ended June 30, 2017 and 2016, respectively. The decrease in interest expense, net, was due to a lower principal balance on the Company's OrbiMed senior secured term loan and amortization of the related financing costs.

Financial Guidance

The Company is raising its guidance for 2017 revenue from a range of $55-$60 million to $60-$63 million, as a result of strong performance through June and our expectation of customer ordering patterns and product market performance for the balance of the year.

About IV/IM Meloxicam 30mg

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 (COX) and subsequent reduction in prostaglandin biosynthesis. IV meloxicam 30mg 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 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 at the Company's Gainesville facility. 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 30mg has successfully completed two pivotal Phase III clinical efficacy trials in patients following bunionectomy and abdominoplasty surgeries, a large double blind Phase III safety trial, four Phase II clinical trials for the management of moderate to severe post-operative pain, as well as other safety studies. 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 ability to obtain and maintain regulatory approval of injectable meloxicam and, and the labeling under any such approval, regulatory developments in the United States and foreign countries; results and timing of the clinical trials of injectable meloxicam; the Company's ability to achieve its financial goals, including financial guidance; the Company's ability to raise future financing for continued development and the payment of milestones; the Company's ability to pay its debt; 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; and the successful commercialization of injectable meloxicam. In addition, 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. Recro 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	**June 30, 2017**	**December 31, 2016**
Current assets:		
Cash and cash equivalents	$ 8,728	$ 64,483
Short-term investments	41,517	—
Accounts receivable	10,102	10,411
Inventory	6,888	8,746
Prepaid expenses and other current assets	2,572	1,118
Total current assets	$ 69,807	$ 84,758
Property, plant and equipment, net	37,638	37,300
Deferred income taxes	19,777	17,060
Intangible assets, net	36,141	37,433
Goodwill	6,446	6,446
Total assets	$ 169,809	$ 182,997
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	3,421	4,132
Accrued expenses & other liabilities	6,551	9,893
Current portion of long-term debt, net	2,057	2,236
Total current liabilities	12,029	16,261
Long-term debt, net	22,657	22,152
Warrants & other long-term liabilities	2,788	3,397
Contingent consideration	75,347	69,574
Total liabilities	112,821	111,384
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, 19,054,566 shares at June 30, 2017 and 19,043,216 shares at December 31, 2016	191	190
Additional paid in-capital	135,083	132,691
Accumulated deficit	(78,210)	(61,268)
Accumulated other comprehensive loss	(76)	—
Total shareholders' equity	56,988	71,613
Total liabilities and shareholders' equity	$ 169,809	$ 182,997

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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue:				
Manufacturing, royalty and profit sharing revenue	$ 16,750	$ 16,933	$ 34,878	$ 34,072
Research and development revenue	184	346	798	949
Total revenue	16,934	17,279	35,676	35,021
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	10,448	9,547	20,946	19,818
Research and development	7,073	8,320	14,836	16,129
General and administrative	6,322	2,763	10,354	5,421
Amortization of intangible assets	646	646	1,292	1,291
Change in warrant valuation	(1,084)	1,240	(793)	(354)
Change in contingent consideration valuation	2,959	1,534	5,773	4,512
Total operating expenses	26,364	24,050	52,408	46,817
Operating loss	(9,430)	(6,771)	(16,732)	(11,796)
Other income (expense):				
Interest income	117	8	222	17
Interest expense	(1,207)	(1,317)	(2,390)	(2,829)
Net loss before income taxes	$ (10,520)	$ (8,080)	$ (18,900)	$ (14,608)
Income tax benefit	1,665	195	1,958	184
Net loss	$ (8,855)	$ (7,885)	$ (16,942)	$ (14,424)
Per share information:				
Net loss per share of common stock, basic	$ (0.46)	$ (0.83)	$ (0.89)	$ (1.53)
Net loss per share of common stock, diluted	$ (0.48)	$ (0.83)	$ (0.89)	$ (1.53)
Weighted averagecommon shares outstanding, basic	19,052,430	9,544,629	19,050,931	9,398,288
Weighted averagecommon shares outstanding, diluted	19,220,700	9,544,629	19,220,175	9,398,288
Other comprehensive loss:				
Unrealized loss on available-for-sale securities	(19)	—	(76)	—
Comprehensive loss	$ (8,874)	$ (7,885)	$ (17,018)	$ (14,424)

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Source: Recro Pharma, Inc.