

April 3, 2019



# Recro Pharma Restructures Acute Care Segment While Continuing To Execute on Strong CDMO Segment Performance

*Implements Plan to Reduce Acute Care Segment Staff*

*CDMO Segment Continues Strong Performance; Company Increases Revenue, Operating Income and EBITDA, as Adjusted\* Guidance for 2019*

*Expects to Become Cash Flow Breakeven During Q3; Cash Flow Positive Second Half of 2019*

*Plans to Seek Strategic Partner for Commercialization of IV Meloxicam*

MALVERN, Pa., April 03, 2019 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (Nasdaq:REPH), a revenue generating specialty pharmaceutical company with a high-performing contract development and manufacturing (CDMO) Segment, today announced an initiative that will reduce the operating expenses of its Acute Care Segment, including a reduction in staff of approximately 50 employees. Some Acute Care Segment employees engaged in efforts to select a partner for and in obtaining FDA approval of (IV) meloxicam were retained. This initiative is expected to significantly lower operating expenses following receipt of a second Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) Office of Drug Evaluation II regarding its New Drug Application (NDA). The headcount reduction will not affect Recro Pharma's CDMO Segment, which continues its strong performance, providing positive cash flow.

The workforce reduction was communicated today and the Company expects to incur the charges for expenses associated with the headcount reduction as well as additional restructuring costs during both the first and second quarter of 2019. Recro Pharma believes this plan significantly reduces the Company's 2019 planned cash burn and anticipates becoming cash flow breakeven during Q3 and cash flow positive in the second half of 2019 (excluding the impact from any potential partnering transactions).

"Recro Pharma has faced challenges while moving IV meloxicam through the regulatory process, making difficult decisions necessary to ensure shareholder value is preserved in the short term and can be built over the long term," said Gerri Henwood, President and Chief Executive Officer of Recro Pharma. "We continue to believe that IV meloxicam would be an attractive non-opioid pain management candidate for the hospital marketplace, and we believe it will ultimately be approved by FDA."

Recro Pharma plans to request a meeting with the FDA to determine a path forward for IV meloxicam, which may include dispute resolution. In light of the additional timing setback due to the second CRL, the Company also intends to seek a strategic partner for the commercialization of IV meloxicam.

"We sincerely thank those employees leaving the Company for their dedicated service. Following this restructuring, our resources will be laser-focused on growing the CDMO division, obtaining marketing approval for IV meloxicam from the FDA and securing a strategic commercialization partner," concluded Ms. Henwood.

## **Financial Guidance**

For 2019, Recro Pharma is increasing its revenue guidance from \$80 million to an anticipated \$85-87 million, Operating Income from \$23.5 million to \$28-30 million and EBITDA, as Adjusted\* from \$34 million to \$38-40 million, based on current trends including organic growth from existing customers and new business prospects. This guidance takes into consideration existing contracts and timing of customer order patterns, as well as the Company's experience with customer's product market estimations.

\*Operating Income, as Adjusted and EBITDA, as Adjusted is a non-GAAP financial measure (see reconciliation page of press release)

## **Non-GAAP Financial Measures**

To supplement our financial results determined by U.S. generally accepted accounting principles ("GAAP"), we have also disclosed in the table below the following non-GAAP information for our Contract Development and Manufacturing Organization (CDMO): "Operating Income, as Adjusted" which is Operating Income without the impact of ASU, No.2014-09 as to remove the variability of timing of revenue recognized and expected cash receipt, and "EBITDA, as Adjusted" which is "Operating Income, as Adjusted" before interest, taxes, depreciation, amortization and non-cash stock-based compensation. We believe these non-GAAP financial measures are helpful in understanding our CDMO Business as it is useful to investors in allowing for greater transparency of supplemental information used by management. "EBITDA, as Adjusted" is used by investors, as well as management in assessing our performance. Non-GAAP financial measures should be considered in addition to, but not as a substitute for, reported GAAP results. Further, Non-GAAP financial measures, even if similarly titled, may not be calculated in the same manner by all companies, and therefore should not be compared.

#### Reconciliation of Non-GAAP Financial Measures (unaudited)

CDMO Business (\$millions)	Full Year 2017	Full Year 2018	Full Year 2019 Estimate
<b>Operating Income</b>	\$ 25.4	\$ 24.9	\$28.0 – 30.0
less: Revenue recognition *	na	\$ 1.4	\$0.0
<b>Operating Income, as Adjusted</b>	\$ 25.4	\$ 23.5	\$28.0 – 30.0
Depreciation	\$ 4.8	\$ 4.8	\$5.6
Amortization of intangible assets	\$ 2.6	\$ 2.6	\$2.6
Non-Cash stock-based compensation	\$ 1.0	\$ 1.3	\$1.8
<b>EBITDA, as Adjusted</b>	\$ 33.8	\$ 32.2	\$38.0 - 40.0

\* Impact of adoption of ASU, No. 2014-09 starting January 2018

#### About Recro Pharma, Inc.

Recro Pharma 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 in Gainesville, GA. The Acute Care division is primarily focused on developing innovative products for the 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 has successfully completed two pivotal Phase III clinical efficacy trials, a large double-blind placebo-controlled Phase III safety trial and four Phase II clinical efficacy trials, as well as other safety studies. On March 22, 2019 Recro announced that FDA had provided a second CRL in response to the Company's NDA for IV meloxicam. The Company is evaluating the path forward for IV meloxicam and plans to schedule a meeting with the FDA. As injectable meloxicam is in the non-opioid class of drugs, if approved, the Company believes it has the potential to 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 and development-stage 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," "may," "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 Company's ability to manage costs and execute on its operational and budget plans, the Company's ability to achieve its financial goals, including financial guidance, the Company's ability to pay its debt under its credit agreement, the Company's ability to attract a strategic partner for the development and commercialization of IV meloxicam, the Company's ability to adequately resolve the deficiencies identified by the FDA in the second CRL for IV meloxicam, and the time frame associated with any such resolution, including whether the FDA will require additional clinical studies and the time and cost of such studies; whether the Company will prepare an amended new drug application (NDA) for IV meloxicam and, whether the FDA will accept and approve any such resubmitted NDA and the labeling under any such approval; the Company's ability to raise future financing for continued product development and IV meloxicam commercialization; with regard to the Company's clinical trial results, whether there may be changes in the interpretation by the FDA of the data of the Company's clinical trials and the length, cost and uncertain results and timing of our ongoing clinical trials; with regard to the potential commercial opportunity of IV meloxicam, whether any FDA approval of IV meloxicam will include labeling restrictions and the potential that IV meloxicam does not receive regulatory approval or does not receive reimbursement by third party payors, that IV meloxicam is not accepted by the medical community, including physicians, patients, health care providers and hospital formularies or that a commercial market for IV meloxicam does not develop; the Company's ability to maintain relationships with CDMO commercial partners; and the Company's ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection. 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](http://www.sec.gov).

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