UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 27, 2018

Recro Pharma, Inc.

(Exact name of registrant as specified in its charter)

Pennsylvania (State or other jurisdiction of incorporation or organization) 001-36329 (Commission File Number) 26-1523233 (I.R.S. Employer Identification No.)

490 Lapp Road, Malvern, Pennsylvania (Address of principal executive offices)

19355 (Zip Code)

Registrant's telephone number, including area code: (484) 395-2470

 $\label{eq:Notation} \textbf{Not Applicable} \\ \textbf{(Former name or former address, if changed since last report)}$

ck the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under of the following provisions (see General Instruction A.2. below):
Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
cate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 30.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ⊠

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. \boxtimes

Item 2.02 Results of Operations and Financial Condition.

On February 27, 2018, Recro Pharma, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2017. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information disclosed under Item 2.02, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are being filed herewith:

Exhibit

No. Document

99.1 <u>Press release of Recro Pharma, Inc., dated February 27, 2018.</u>

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Recro Pharma, Inc.

By: /s/ Gerri A. Henwood

Name: Gerri A. Henwood Title: Chief Executive Officer

Date: February 27, 2018



Recro Pharma Reports Year End 2017 Financial Results

IV Meloxicam NDA Submitted and PDUFA Action Date Set for May 26, 2018

Record CDMO Performance; 2017 Revenues of \$71.8 Million

MALVERN, PA, February 27, 2018 – 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 year ended December 31, 2017.

"As we await the upcoming review decision from the U.S. Food and Drug Administration (FDA) for intravenous (IV) meloxicam, we are building our commercial infrastructure and preparing for our first potential product launch during 2018," said Gerri Henwood, President and Chief Executive Officer of Recro Pharma. "We have designed an efficient commercialization team and strategy that we believe can successfully launch IV meloxicam, pending approval, and rapidly build physician awareness, drive adoption and create meaningful value for all of our stakeholders."

Ms. Henwood concluded, "For the Gainesville CDMO division, we achieved a record year generating \$71.8 million in revenue in 2017, with 2018 expected to be another strong year for our CDMO division, providing significant non-dilutive capital."

Fourth Quarter 2017 and Recent Highlights

- NDA Filing with the U.S. FDA for IV Meloxicam Accepted for Review and Filing and PDUFA Date Assigned. In July 2017, Recro filed the IV Meloxicam NDA and in October 2017, Recro announced the acceptance for review and filing of its NDA by the U.S. FDA 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 efficacy trials and other safety studies. The FDA assigned a PDUFA date of May 26, 2018.
- Commercial Teams and 'Go to Market Strategy' in Place for a Successful IV Meloxicam Launch, if Approved. In 2017 and early 2018, the Company has built its core commercial infrastructure and expanded its acute care commercial team in preparation for the potential launch of IV meloxicam, assuming a positive review by the FDA in late May 2018. This launch team is currently comprised of individuals in medical affairs, sales management, marketing, strategic accounts and reimbursement.
- Secured \$100 Million Credit Facility. In November 2017, Recro secured a \$100 million credit facility from funds managed by Athyrium Capital Management, LP, a leading healthcare-focused investment firm. The funds are structured in three tranches, with \$60 million drawn immediately upon closing of the transaction which was used to repay and refinance Recro's then outstanding OrbiMed debt. An additional \$20 million is available upon FDA approval of IV meloxicam subject to certain financial conditions. The final \$20 million is available after Recro demonstrates early IV meloxicam sales traction.



- Peer-Reviewed Publications and Presentations at Medical Meetings. IV meloxicam clinical data was published in two peer-reviewed journals and selected for presentation at a key medical meeting:
 - In February 2018, an article titled, "Evaluation of the safety and efficacy of an intravenous nanocrystal formulation of meloxicam in the management of moderate-to-severe pain after bunionectomy" was published online in the Journal of Pain Research.
 - In January 2018, an article titled, "A Randomized Double-Blind Controlled Trial of Intravenous Meloxicam in the Treatment of Pain Following Dental Impaction Surgery" was published online in the Journal of Clinical Pharmacology.
 - In October 2017, an oral presentation titled, "Efficacy and Safety of N1539, Intravenous Meloxicam, in a Phase 3 Study of Subjects with Moderate to Severe Pain following Abdominoplasty" was presented at Plastic Surgery The Meeting 2017, hosted by the American Society of Plastic Surgeons.

Financial Results

As of December 31, 2017, Recro had cash, cash equivalents and short-term investments of \$64.5 million.

Revenues were \$71.8 million and \$69.3 million for the years ended December 31, 2017 and 2016, respectively. Excluding the \$2.3 million, one-time, contractually based manufacturing revenue amount from one of our commercial partners in the year ended December 31, 2016, the \$4.8 million increase in 2017 revenue versus 2016 was primarily due to higher profit share revenue as a result of stronger sales volumes and pricing of Verapamil as well as increased manufacturing revenue. These increases were partially offset by decreased royalty revenue due to a change in the mix of generic and brand sales by another of our commercial partners.

Cost of sales were \$38.2 million and \$37.2 million for the year ended December 31, 2017 and 2016, respectively, and increased primarily due to the change in overall product mix.

Research and development expenses were \$33.1 million and \$33.3 million for the years ended December 31, 2017 and 2016, respectively. The decrease of \$0.2 million in 2017 was primarily due to lower IV meloxicam clinical trial expenses offset by increases in pre-commercialization IV meloxicam product validation, manufacturing and support costs, NDA filing fees and development costs for our other pipeline products.

General and administrative expenses were \$25.4 million and \$12.7 million for the year ended December 31, 2017 and 2016, respectively. The increase of \$12.7 million was primarily due to building of the IV meloxicam team.



Amortization expense was \$2.6 million for the year ended December 31, 2017 and 2016. This expense was solely related to the amortization of the Company's royalties and contract manufacturing relationships intangible asset over its estimated useful life.

Change in contingent consideration was \$12.8 million and \$9.7 million for the year ended December 31, 2017 and 2016, respectively. This non-cash expense was related to the change in fair value of the contingent consideration that would be due to Alkermes upon achievement of certain milestones. The increase in contingent consideration is primarily attributed to the estimated probability adjusted fair value as the Company gets closer to potential FDA approval.

Interest expense, net, was \$11.7 million and \$5.5 million during the years ended December 31, 2017 and 2016, respectively. The increase in interest expense, net, was due to the refinancing of our prior credit agreement with OrbiMed Royalty Opportunities (OrbiMed) in 2017 which resulted in a one-time, previously disclosed, charge totaling approximately \$6.8 million for fees related to early extinguishment of debt and the non-cash write-off of the related deferred financing costs.

Income tax benefit was \$1.9 million and \$1.1 million during the years ended December 31, 2017 and 2016, respectively. The increase in income tax benefit was primarily due to the increase in net loss before income taxes. As a result of the Tax Cuts and Jobs Act of 2017, included within income tax benefit for the year ended December 31, 2017 was a non-cash adjustment of \$7.9 million for the remeasurement of the deferred tax items using the new 21% statutory tax rate.

Net loss was \$50.1 million and \$30.2 million during the years ended December 31, 2017 and 2016, respectively. Net loss per share was \$2.63 and \$2.82 for the years ended December 31, 2017 and 2016, respectively. As noted above, increasing the net loss in the year ended December 31, 2017 was a \$7.9 million adjustment related to tax reform and \$6.8 million in charges related to the early extinguishment of the OrbiMed debt. Combined, the tax effected impact of these items was an increase in net loss of \$12.1 million. Adjusted net loss* for the year ended December 31, 2017 was \$38.0 million excluding the \$12.1 million tax reform adjustment and tax effected debt charges. Adjusted net loss per share* for the year ended December 31, 2017 was \$1.99.

* "Adjusted net loss" and "adjusted net loss per share" are non-GAAP financial measures (see "Non-GAAP Financial Measures").

Financial Guidance

For 2018, the Company expects revenue generated from its CDMO division to be approximately \$70 million, despite the anticipated unfavorable impact of the adoption of the new revenue recognition standard, and taking into consideration existing contracts and timing of customer order patterns, as well as our experience with customer's product market estimations.



Non-GAAP Financial Measures

In addition to the United States generally accepted accounting principles (GAAP) results, this earnings release includes adjusted net loss and adjusted net loss per share, non-GAAP financial measures. Management uses adjusted net loss and adjusted net loss per share (defined as net loss and net loss per share adjusted to exclude the change in tax benefit related to tax reform as well as the impact from the early extinguishment of debt) in its evaluation of the Company's core results of operations and trends between fiscal periods and believes that these measures are an important component of its internal performance measurement process. Management believes that this non-GAAP financial information reflects an additional way of viewing aspects of our business that, when viewed with our GAAP results, provides a more complete understanding of factors and trends affecting our business.

The presentation of non-GAAP financial measures is not intended to be considered in isolation or as a substitute for, or superior to, financial information prepared and presented in accordance with GAAP. Investors are cautioned that there are material limitations associated with the use of non-GAAP financial measures as an analytical tool. In addition, these measures may be different from non-GAAP financial measures used by other companies, limiting their usefulness for comparison purposes. Please see the section of this press release titled "Reconciliation of Adjusted Net Loss and Adjusted Net Loss Per Share" for a reconciliation of adjusted net loss per share to its most directly comparable GAAP financial measure.

About IV/IM Meloxicam

Meloxicam, as a molecule, 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 was developed using the proprietary NanoCrystal® platform, a technology that was designed to enable enhanced bioavailability of poorly water-soluble drug compounds. NanoCrystal® is a registered trademark of Alkermes Pharma Ireland Limited (APIL).

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 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, four Phase II clinical efficacy trials, as well as other safety studies. In 2017, Recro submitted the NDA for IV meloxicam to the FDA for review, it was accepted by the FDA and there is a late May 2018 PDUFA date. 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 Company's ability to obtain and maintain regulatory approval of IV meloxicam and the labeling under any such approval; the Company's ability to successfully launch and commercialize IV meloxicam, if approved; results and timing of the phase IIIb clinical trials of IV meloxicam; the extent to which IV meloxicam, if approved, is accepted by the medical community, including physicians, patients, health care providers and hospital fomularies; the availability of coverage and adequate and timely reimbursement for IV meloxicam, if approved; the Company's ability to raise future financing for continued product development, IV meloxicam commercialization and the payment of milestones; the Company's ability to achieve its financial goals, including financial guidance; the Company's ability to pay its debt; regulatory developments in the United States and foreign countries; customer product performance and ordering patterns, the performance of thirdparty suppliers and manufacturers; 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



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RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Balance Sheets (Unaudited)

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

	December 31, 2017		December 31, 2016	
Assets				_
Current assets:				
Cash and cash equivalents	\$	60,984	\$	64,483
Short-term investments		3,498		
Accounts receivable		9,686		10,411
Inventory		9,839		8,746
Prepaid expenses and other current assets		3,276		1,118
Total current assets	\$	87,283	\$	84,758
Property, plant and equipment, net		39,074		37,300
Deferred income taxes		18,573		17,060
Intangible assets, net		34,850		37,433
Goodwill		6,446		6,446
Total assets	\$	186,226	\$	182,997
Liabilities and Shareholders' Equity				
Current liabilities:				
Accounts payable		7,954		4,132
Accrued expenses & other liabilities		9,897		9,893
Current portion of contingent consideration		32,053		
Current portion of long-term debt, net				2,236
Total current liabilities	<u> </u>	49,904	<u> </u>	16,261
Long-term debt, net		53,598		22,152
Warrants & other long-term liabilities		3,516		3,397
Long-term portion of contingent consideration		50,360		69,574
Total liabilities		157,378		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, 19,127,435 shares at December 31, 2017 and 19,043,216 shares at				
December 31, 2016		191		190
Additional paid in-capital		140,006		132,691
Accumulated deficit		(111,348)		(61,268)
Accumulated other comprehensive loss		(1)		
Total shareholders' equity		28,848		71,613
Total liabilities and shareholders' equity	\$	186,226	\$	182,997

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

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

	Twelve Mo Decen	oths Ended ber 31,	
	2017	2016	
Revenue	\$ 71,834	\$ 69,337	
Operating expenses:			
Cost of sales (excluding amortization of intangible assets)	38,193	37,152	
Research and development	33,095	33,278	
General and administrative	25,426	12,742	
Amortization of intangible assets	2,583	2,583	
Change in warrant valuation	9	(373)	
Change in contingent consideration valuation	12,839	9,728	
Total operating expenses	112,145	95,110	
Operating loss	(40,311)	(25,773)	
Other income (expense):	· · · · · ·	, i	
Interest income	385	49	
Interest expense	(12,034)	(5,588)	
Net loss before income taxes	\$ (51,960)	\$ (31,312)	
Income tax benefit	1,880	1,107	
Net loss	\$ (50,080)	\$ (30,205)	
Per share information:			
Net loss per share of common stock, basic and diluted	<u>\$</u> (2.63)	\$ (2.82)	
Weighted average common shares outstanding, basic and diluted	19,070,983	10,721,928	
Other comprehensive loss:			
Net loss	\$ (50,080)	\$ (30,205)	
Unrealized loss on available-for-sale securities	(1)		
Comprehensive loss	\$ (50,081)	\$ (30,205)	

Reconciliation of Adjusted Net Loss and Adjusted Net Loss Per Share

Twelve Months Ended December 31, 2017 Adjusted Net Loss

(amounts in thousands)	Twelve Months Ended December 31, 2017	
As reported net loss	\$	(50,080)
Adjustment to tax benefit related to tax reform (a) Early extinguishment of debt charge, net of tax (b)		7,892 4,235
Adjusted net loss	\$	(37,953)

Twelve Months Ended December 31, 2017 Adjusted Net Loss per share

	Twelve Months Ended December 31, 2017	
Net loss per share of common stock, basic and diluted	\$	(2.63)
Adjustment to tax benefit related to tax reform (a)	\$	0.41
Early extinguishment of debt charge, net of tax (b)	\$	0.23
Adjusted net loss per share of common stock, basic and		
diluted	\$	(1.99)

- (a) Net loss and net loss per share of common stock, basic and diluted, for the twelve months ended December 31, 2017 includes a decrease to tax benefit related to tax reform of approximately \$7.9 million, or \$0.41 per share. The tax reform adjustment was a result of the Tax Cuts and Jobs Act of 2017 for the remeasurement of the deferred tax asset, net, items using the new 21% statutory tax rate.
- (b) Net Loss and net loss per share of common stock, basic and diluted, for the twelve months ended December 31, 2017 includes a one-time charge for fees related to early extinguishment of debt and the non-cash write-off of the related deferred financing costs of approximately \$6.8 million (\$4.2 million net of tax), or \$0.23 per share tax-effected.