
**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): August 7, 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

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 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.

Item 2.02 Results of Operations and Financial Condition.

On August 7, 2018, Recro Pharma, Inc. (the “Company”) issued a press release announcing its financial results for the second quarter ended June 30, 2018. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The Company has scheduled a conference call and webcast for 8:00 a.m. Eastern time on August 7, 2018 to discuss these financial results and business updates.

The information in Item 8.01 below regarding certain financial information contained in the slide attached hereto as Exhibit 99.2 is incorporated into this Item 2.02 by reference.

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 8.01 Other Events.

On August 7, 2018, the Company posted certain financial information on its website relating to the reconciliation of certain non-GAAP financial measures for the second quarter ended June 30, 2018 to the comparable measures calculated and presented in accordance with U.S. GAAP. A copy of the non-GAAP reconciliation slide is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. Representatives of the Company may use such financial information and the non-GAAP reconciliation slide in presentations and various meetings with investors from time to time.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits**

The following exhibits are being filed herewith:

<u>Exhibit No.</u>	<u>Document</u>
99.1	<u>Press release of Recro Pharma, Inc., dated August 7, 2018.</u>
99.2	<u>Non-GAAP Reconciliation Slide.</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: August 7, 2018



Recro Pharma Reports Second Quarter 2018 Financial Results

Company to Host Conference Call Today at 8:00 AM ET

MALVERN, Pa., August 7, 2018 (GLOBE NEWSWIRE) — Recro Pharma, Inc. (NASDAQ:REPH), a revenue generating specialty pharmaceutical company focused on therapeutics for the hospital and other acute care settings, today reported financial results for the three months and six months ended June 30, 2018.

“Our recent efforts have been focused on addressing the Complete Response Letter (CRL) received in May 2018 from the U.S. Food and Drug Administration (FDA) for the intravenous (IV) meloxicam New Drug Application,” said Gerri Henwood, President and Chief Executive Officer of Recro Pharma. “In July, a Type A meeting was held with the FDA, and we plan to provide an update on our path forward following receipt of the written meeting minutes. We remain fully committed to IV meloxicam and to addressing the significant need for new non-opioid treatment options for the management of moderate to severe pain. Our CDMO division maintained the strong performance observed in early 2018, with \$21.7 million generated in revenue during the second quarter, and we reiterate our 2018 CDMO guidance.”

Second Quarter 2018 and Recent Events

- **Strong CDMO Performance.** Recro’s contract manufacturing business continued to perform well, generating revenues of \$21.7 million for the second quarter of 2018.
- **Received CRL from FDA for IV Meloxicam.** In May 2018, Recro received a CRL from the FDA regarding its NDA for IV meloxicam. In July 2018, the Company participated in a Type A End-of-Review meeting with the FDA to discuss the topics covered in the CRL. Recro plans to provide an update on CRL potential pathway following the receipt of the written meeting minutes from the FDA.
- **Peer-Reviewed Publications and Presentations at Medical Meetings.** IV meloxicam clinical data was published in a peer-reviewed journal and presented at a medical meeting during the second quarter.
 - In June 2018, an article, titled “Efficacy and Safety of Intravenous Meloxicam in Subjects with Moderate to Severe Pain Following Abdominoplasty,” was published online in the Plastic and Reconstructive Surgery Global Open. The data describe previously reported results from Recro’s Phase III clinical trial evaluating IV meloxicam for the management of moderate to severe pain following abdominoplasty surgery.
 - In April 2018, Recro presented eight posters at the 43rd Annual Regional Anesthesiology and Acute Pain Medicine Meeting, co-hosted by the American Society of Regional Anesthesia and Pain Medicine. The data describe previously presented results from Recro’s Phase II and Phase III clinical development programs for IV meloxicam for the management of moderate to severe pain.

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- **Three New Patents Issued for IV Meloxicam.** In May 2018, Recro announced the issuance of three U.S. IV meloxicam patents which are exclusively licensed from Alkermes Pharma Ireland Limited. The patents relate to the reduced flake-like aggregates of the injectable nanoparticle meloxicam composition and methods of producing such compositions. The issuance of these patents marks a significant expansion of the IV meloxicam intellectual property portfolio, and the Company expects one of the newly issued patents to be Orange-Book listable, with a patent expiry of 2030.
- **Presented Preclinical Data on Neuromuscular Blocking and Reversal Agents at AUA 2018.** In April 2018, Recro presented preclinical data for its novel neuromuscular blocking and reversal agents at the Association of University Anesthesiologists (AUA) 2018 Annual Meeting. The data demonstrates rapid effect of the ultra-short acting neuromuscular blocking agent in a preclinical primate model, as well as the ability of the rapid-acting reversal agent to antagonize the neuromuscular blocking molecule and induce recovery.

Financial Results

As of June 30, 2018, Recro had cash, cash equivalents and short-term investments of approximately \$49.0 million.

Revenues were \$21.7 million and \$16.9 million for the three months ended June 30, 2018 and 2017, respectively. The increase of \$4.8 million in revenue includes the impact from the new revenue recognition Accounting Standards Update, or ASU, No. 2014-09 (ASU 2014-09), and was primarily due to increased profit sharing recognized from one of Recro's commercial partners and an increase in product sales to one of Recro's commercial partners. Revenues were \$41.3 million and \$35.7 million for the six months ended June 30, 2018 and 2017, respectively. The increase of \$5.6 million in revenue includes the impact from the new standard ASU 2014-09, and was primarily due to increased profit sharing recognized from one of Recro's commercial partners and an increase in product sales to one of Recro's commercial partners.

Cost of sales were \$12.1 million and \$10.4 million for the three months ended June 30, 2018 and 2017, respectively. Cost of sales were \$22.6 million and \$20.9 million for the six months ended June 30, 2018 and 2017, respectively. The increase in both periods was primarily due to increased product sales.

Research and development expenses were \$10.2 and \$7.1 for the three months ended June 30, 2018 and 2017, respectively. The increase of \$3.1 million was primarily due to an increase in pre-commercialization manufacturing costs for IV meloxicam, an increase in salaries and benefits expense, an increase in Phase IIIb clinical trials and related costs and a modest increase in development costs for other pipeline products. These increases were partially offset by a decrease in Phase III clinical trial costs. Research and development expenses were \$18.6 million and \$14.8 million for the six months ended June 30, 2018 and 2017, respectively. The increase of \$3.8 million was primarily due to an increase in pre-commercialization

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manufacturing costs for IV meloxicam, an increase in salaries and benefits expense, an increase in Phase IIIb clinical trials and a modest increase in development costs for other pipeline products. These increases were partially offset by a decrease in Phase III clinical trial costs.

General and administrative expenses were \$13.0 million and \$6.3 million for the three months ended June 30, 2018 and 2017, respectively. The increase of \$6.7 million was primarily due to increased commercial costs as well as increased legal and consulting fees associated with addressing the CRL issued by the FDA regarding the NDA for IV meloxicam. General and administrative expenses were \$22.5 million and \$10.4 million for the six months ended June 30, 2018 and 2017, respectively. The increase of \$12.1 million was primarily due to increased commercial costs as well as increased legal and consulting fees associated with addressing the CRL.

Amortization expense was \$0.6 million for each of the three months ended June 30, 2018 and 2017, and \$1.3 million for each of the six months ended June 30, 2018 and 2017. This expense was solely related to the amortization of Recro's royalties and contract manufacturing relationships intangible asset over its estimated useful life.

Interest expense, net, was \$2.1 million and \$1.1 million for the three months ended June 30, 2018 and 2017, and, \$4.0 million and \$2.2 million during the six months ended June 30, 2018 and 2017, respectively. The increase in both periods was primarily due to the higher principal balance on the Athyrium senior secured term loan and amortization of the related financing costs, which was partially offset by a lower interest rate on the Athyrium senior secured term loan versus Recro's previous loan with OrbiMed.

Income tax benefit was \$2.7 million and \$1.7 million for the three months ended June 30, 2018 and 2017, and, \$5.1 million and \$2.0 million during the six months ended June 30, 2018 and 2017, respectively, related exclusively to our U.S. operations. The increase in tax benefit for both periods was primarily due to increased losses in the United States.

For the three months ended June 30, 2018, Recro reported a net loss of \$12.7 million, or \$0.62 diluted loss per share, compared to net loss of \$8.9 million, or \$0.48 diluted loss per share, for the comparable period in 2017. For the six months ended June 30, 2018, Recro reported a net loss of \$25.2 million, or \$1.27 diluted loss per share, compared to net loss of \$16.9 million, or \$0.89 diluted loss per share, for the comparable period in 2017.

Financial Guidance

The Company reaffirms its 2018 CDMO guidance and believes it will generate approximately \$70 million in revenue 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.

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Conference Call and Webcast

Recro Pharma management will be hosting a conference call and webcast today beginning at 8:00 a.m. ET. To access the conference call, please dial (844) 243-4691 (local) or (225) 283-0379 (international) at least 10 minutes prior to the start time and refer to conference ID 8839159. A webcast will be available in the investor relations section of the Company’s website, www.recropharma.com. A live audio webcast of the call will be available under “Events” in the Investor section of the Company’s website, <https://ir.recropharma.com/events>. An archived webcast will be available on the Company’s website approximately two hours after the event and will be available for 30 days.

About IV/IM Meloxicam

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 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 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 once a day 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 May 2018, Recro received a complete response letter from the FDA regarding IV meloxicam which it is currently evaluating. 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 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.

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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 resolve the deficiencies identified by the FDA in the complete response letter for IV meloxicam and the time frame associated with such resolution, including whether the FDA will require additional clinical studies and the time and cost of such studies; whether the Company will be able to prepare an amended new drug application (NDA) for IV meloxicam and, if prepared, whether the FDA will accept and approve the NDA and the labeling under any such approval; the Company's ability to successfully launch and commercialize IV meloxicam, if approved; the length, cost and uncertain results and timing of the Company's clinical trials, including the Company's phase IIIb clinical trials and any additional clinical trials that the FDA may require in connection with IV meloxicam; the extent to which IV meloxicam, if approved, is accepted by the medical community, including physicians, patients, health care providers and hospital formularies; 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 third-party 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 at www.sec.gov.

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RECRO PHARMA, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
(Unaudited)

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

	<u>June 30, 2018</u>	<u>December 31, 2017</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 48,911	\$ 60,984
Short-term investments	—	3,498
Accounts receivable	11,671	9,686
Contract Asset	6,866	—
Inventory	8,113	9,839
Prepaid expenses and other current assets	3,468	3,276
Total current assets	<u>\$ 79,029</u>	<u>\$ 87,283</u>
Property, plant and equipment, net	38,740	39,074
Deferred income taxes	22,696	18,573
Intangible assets, net	33,558	34,850
Goodwill	6,446	6,446
Total assets	<u>\$ 180,469</u>	<u>\$ 186,226</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	6,357	7,954
Accrued expenses & other current liabilities	9,500	9,897
Current portion of contingent consideration	33,957	32,053
Total current liabilities	49,814	49,904
Long-term debt, net	54,316	53,598
Warrants & other long-term liabilities	481	3,516
Long-term portion of contingent consideration	51,372	50,360
Total liabilities	<u>155,983</u>	<u>157,378</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, 20,716,269 shares at June 30, 2018 and 19,127,435 shares at December 31, 2017	207	191
Additional paid in-capital	157,981	140,006
Accumulated deficit	(133,702)	(111,348)
Accumulated other comprehensive loss	—	(1)
Total shareholders' equity	<u>24,486</u>	<u>28,848</u>
Total liabilities and shareholders' equity	<u>\$ 180,469</u>	<u>\$ 186,226</u>

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,	
	2018	2017	2018	2017
Revenue	\$ 21,739	\$ 16,934	\$ 41,281	\$ 35,676
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	12,071	10,448	22,561	20,946
Research and development	10,157	7,073	18,599	14,836
General and administrative	12,955	6,322	22,473	10,354
Amortization of intangible assets	646	646	1,292	1,292
Change in warrant valuation	(1,139)	(1,084)	(365)	(793)
Change in contingent consideration valuation	396	2,959	2,916	5,773
Total operating expenses	<u>35,086</u>	<u>26,364</u>	<u>67,476</u>	<u>52,408</u>
Operating loss	(13,347)	(9,430)	(26,195)	(16,732)
Other income (expense):				
Interest income	114	117	255	222
Interest expense	(2,189)	(1,207)	(4,292)	(2,390)
Net loss before income taxes	\$ (15,422)	\$ (10,520)	\$ (30,232)	\$ (18,900)
Income tax benefit	2,707	1,665	5,060	1,958
Net loss	<u>\$ (12,715)</u>	<u>\$ (8,855)</u>	<u>\$ (25,172)</u>	<u>\$ (16,942)</u>
Per share information:				
Net loss per share of common stock, basic	<u>\$ (0.62)</u>	<u>\$ (0.46)</u>	<u>\$ (1.27)</u>	<u>\$ (0.89)</u>
Net loss per share of common stock, diluted	<u>\$ (0.62)</u>	<u>\$ (0.48)</u>	<u>\$ (1.27)</u>	<u>\$ (0.89)</u>
Weighted average common shares outstanding, basic	<u>20,410,615</u>	<u>19,052,430</u>	<u>19,818,227</u>	<u>19,050,931</u>
Weighted average common shares outstanding, diluted	<u>20,410,615</u>	<u>19,220,700</u>	<u>19,818,227</u>	<u>19,220,175</u>
Other comprehensive loss:				
Unrealized loss on available-for-sale securities	<u>1</u>	<u>(19)</u>	<u>1</u>	<u>(76)</u>
Comprehensive loss	<u>\$ (12,714)</u>	<u>\$ (8,874)</u>	<u>\$ (25,171)</u>	<u>\$ (17,018)</u>

Reconciliation of Non-GAAP Financial Measures (unaudited)

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): earnings before interest, taxes, depreciation and amortization ("EBITDA"). We believe this non-GAAP financial measure is helpful in understanding our Manufacturing Business as it is useful to investors in allowing for greater transparency of supplemental information used by management. EBITDA 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.

CDMO Business (\$millions)	Full Year 2017	Six Months Ended June 30, 2018	Full Year 2018 Estimate
Operating Income	\$25.4	\$13.9	\$22.6
Depreciation	\$4.8	\$2.3	\$4.8
Amortization of intangible assets	\$2.6	\$1.3	\$2.6
EBITDA	\$32.8	\$17.5	\$30.0