
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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 28, 2019

Reata Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE
(State or Other Jurisdiction
of Incorporation)

001-37785

(Commission File Number)

11-3651945
(IRS Employer
Identification No.)

**2801 Gateway Drive; Suite 150
Irving, TX 75063**

(Address of Principal executive offices, including zip code)

(972) 865-2219

(Registrant's telephone number, including area code)

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 February 28, 2019, Reata Pharmaceuticals, Inc. (“the Company”) issued a press release announcing its financial results for the twelve months ended December 31, 2018 (the “Press Release”). A copy of the Press Release is furnished herewith as Exhibit 99.1.

The information set forth under Item 2.02 and in Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1*	Press Release, dated February 28, 2019

* Furnished herewith.

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.

Reata Pharmaceuticals, Inc.

Date: February 28, 2019

By: _____
/s/ Jason D. Wilson
Jason D. Wilson
Chief Financial Officer



REATA PHARMACEUTICALS, INC. ANNOUNCES FOURTH QUARTER AND FULL YEAR 2018 FINANCIALS AND OPERATING RESULTS

PIVOTAL TRIALS CARDINAL AND MOXIE FULLY ENROLLED WITH DATA EXPECTED SECOND HALF 2019

FALCON PIVOTAL PHASE 3 TRIAL TO INITIATE IN MID-2019

CONFERENCE CALL WITH MANAGEMENT SCHEDULED FOR TODAY, FEBRUARY 28, 2019

IRVING, Texas—February 28, 2019—Reata Pharmaceuticals, Inc. (Nasdaq: RETA), a clinical-stage biopharmaceutical company, today announced financial results for the fourth quarter and full year ended December 31, 2018, and provided an update on the Company's business and product development programs.

"2018 was a very significant year for Reata," said Warren Huff, Reata's Chief Executive Officer. "We completed enrollment in two pivotal studies, CARDINAL in Alport syndrome and MOXie in Friedreich's ataxia. We also reported positive data from three cohorts of the PHOENIX trial in rare forms of chronic kidney disease (CKD), and announced plans to launch FALCON, a Phase 3 trial of bardoxolone methyl (bardoxolone) in patients with autosomal dominant polycystic kidney disease (ADPKD) during mid-2019."

Pipeline Highlights

Phase 3 Portion of the CARDINAL Trial of Bardoxolone in Alport Syndrome

In the second half of 2018, we completed enrollment in the pivotal Phase 3 CARDINAL study of bardoxolone in patients with CKD caused by Alport syndrome. A total of 157 patients were enrolled. The FDA has provided us with written guidance that, in patients with CKD caused by Alport syndrome, an analysis of retained eGFR demonstrating an improvement versus placebo after one year of bardoxolone treatment may support accelerated approval. In July, we reported one-year retained eGFR data from the open-label Phase 2 portion of CARDINAL, which demonstrated a statistically significant increase from baseline in mean eGFR of 4.1 mL/min/1.73 m² (p<0.05) after 48 weeks of treatment and four weeks off-treatment in 25 patients. Available historical data for 22 of these patients showed an average annual decline in eGFR of 4.2 mL/min/1.73 m² in the three-year period prior to study entry. We expect to report top-line, one-year data from the pivotal Phase 3 portion of CARDINAL in the second half of this year.

Phase 2 PHOENIX Trial of Bardoxolone in Rare Forms of Chronic Kidney Disease

During 2018 and the first calendar quarter of this year, we fully enrolled and reported positive results for all cohorts of the Phase 2 PHOENIX study in patients with ADPKD, IgA nephropathy (IgAN), type 1 diabetic CKD (T1D CKD), and focal segmental glomerulosclerosis (FSGS). In the PHOENIX study population, bardoxolone demonstrated a statistically significant improvement from baseline in mean eGFR of 7.8 mL/min/1.73m² (p<0.00001; n=103) after 12

weeks of treatment. In addition, each individual cohort demonstrated statistically significant increases in mean eGFR that represent the recovery of multiple years of kidney function loss based on historical average eGFR decline. Based on the results of the ADPKD cohort, we announced the clinical trial design for FALCON, a Phase 3 study of bardoxolone for the treatment of patients with ADPKD, and we expect to dose the first patient in mid-2019. In addition, based on the eGFR improvements observed in patients across the other cohorts of PHOENIX, we plan to pursue IgAN, T1D CKD, and FSGS as commercial indications for bardoxolone.

Registrational Portion of MOXle Trial of Omaveloxolone in Friedrich's Ataxia

We also completed enrollment in the pivotal part 2 portion of the MOXle Phase 2 study of omaveloxolone in patients with Friedrich's ataxia. A total of 103 patients were enrolled. The FDA has provided us with written guidance that the mFARS score is acceptable as the primary endpoint for part 2 of MOXle and that it may consider either accelerated or full approval based on the overall results of the trial and strength of the data. We reported previously that omaveloxolone demonstrated a statistically significant improvement in modified Friedrich's Ataxia Rating Scale (mFARS) scores of 3.8 points ($p=0.0001$) at the optimal dose level versus baseline and a placebo-corrected improvement in mFARS scores of 2.3 points ($p=0.06$) in part 1 of the MOXle trial. We expect to report top-line data from the pivotal part 2 portion of MOXle in the second half of this year.

Registrational Phase 3 CATALYST Trial of Bardoxolone in CTD-PAH

The Phase 3 CATALYST study for bardoxolone in connective tissue disease-associated pulmonary arterial hypertension (CTD-PAH) is ongoing and is expected to enroll a total of approximately 200 patients. Based on discussion with the FDA, the primary endpoint of the study is the change from baseline in six-minute walk distance (6MWD) relative to placebo at Week 24. We expect to report top-line data from CATALYST in the first half of 2020.

Selected Clinical Milestones in 2019

- Initiation of the pivotal FALCON trial in ADPKD in mid-2019
- Pivotal CARDINAL data in the second half of 2019
- Pivotal MOXle data in the second half of 2019

Fourth Quarter Results

The Company incurred total expenses of \$33.4 million for the quarter ended December 31, 2018, with research and development accounting for \$25.3 million. This compares to total expenses of \$26.5 million for the same period of the year prior, when research and development accounted for \$20.4 million. We reported a net loss of \$25.6 million or \$0.86 per share for the quarter ended December 31, 2018. This compares to a net loss of \$16.7 million or \$0.64 per share in the same period of the year prior.

The increase in net loss for the three-month period is primarily driven by both an increase in expenses and a decrease in revenue. Higher expenses are driven by an increase in research and development expenses due to clinical and manufacturing activities, and an increase in personnel expenses to support expanded development activities. Revenue to date has primarily been related to license, and collaboration agreements entered into during 2009, 2010, and 2011. The decrease in revenue was caused primarily by the full recognition in 2017 of deferred revenue for a 2010 agreement and a decrease in the recognition of revenue for a 2009 agreement.

2018 Financial Results

The Company incurred total expenses of \$130.5 million for the twelve month period ended December 31, 2018, with research and development accounting for \$97.3 million. This compares to total expenses of \$95.0 million for the same period of the year prior, when research and development accounted for \$71.3 million. We reported a net loss of \$80.5 million or \$2.91 per share for the full year ended December 31, 2018. This compares to a net loss of \$47.7 million or \$1.99 per share in the same period of the year prior. The increase in net loss for the year is driven primarily by increased expenses due to greater clinical and manufacturing activities, development activities for earlier stage assets to expand our product candidate portfolio, and personnel expenses to support expanded development activities.

Our cash-based operating expenses, a non-GAAP measure, were \$30.5 million and \$119.5 million for the three months and full year ended December 31, 2018, respectively. This compares to \$24.6 million and \$88.0 million for the same periods in 2017. We expect our cash-based operating expenses to continue to increase in the future as we advance bardoxolone and omaveloxolone through ongoing and future clinical trials, scale manufacturing for registrational and validation purposes, advance other product candidates into mid- and later-stage clinical trials, expand our product candidate portfolio, increase both our research and development and administrative personnel, and plan for commercialization of our product candidates.

At December 31, 2018, we had \$337.8 million in cash and cash equivalents. We expect our current cash to fund our operations through data readouts for our three ongoing registrational clinical trials.



Non-GAAP Financial Measures

In addition to the U.S. generally accepted accounting principles (GAAP) financial highlights, this earnings release includes cash-based operating expenses, a non-GAAP financial measure, which the Company defines as total expenses excluding stock-based compensation expense and depreciation expense. A reconciliation of this non-GAAP financial measure to its most directly comparable GAAP financial measure is presented in the table below in this earnings release.

We believe that this non-GAAP financial measure, in addition to GAAP financial measures, provides a meaningful measure of our ongoing business and operating performance by allowing investors to analyze our financial results similarly to how management analyzes our financial results by viewing period expense totals more indicative of effort directly expended to advance the business and our product candidates. Non-GAAP financial measures should be considered in addition to, not in isolation or as a substitute for, GAAP financial measures. In addition, our non-GAAP financial measure may differ from similarly named measures used by other companies.

Reata management will host a conference call to discuss these results on Thursday, February 28, 2019, at 8:00 a.m. ET at the following:

CONFERENCE CALL INFORMATION

Date:	Thursday, February 28, 2019
Time:	8:00 a.m. ET
Audience Dial-in (toll-free):	(844) 348-3946
Audience Dial-in (international):	(213) 358-0892
Conference ID:	8569879
Webcast Link:	https://edge.media-server.com/m6/p/ovw35445

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Consolidated Statements of Operations				
(Unaudited)				
(in thousands, except share and per share data)				
Collaboration revenue				
License and milestone	\$ 7,898	\$ 9,509	\$ 52,351	\$ 47,103
Other revenue	553	454	1,238	955
Total collaboration revenue	8,451	9,963	53,589	48,058
Expenses				
Research and development	25,308	20,443	97,288	71,273
General and administrative	7,945	5,948	32,748	23,260
Depreciation	120	98	431	437
Total expenses	33,373	26,489	130,467	94,970
Other income (expense)				
Investment income	1,755	350	3,541	701
Interest expense	(2,404)	(498)	(6,176)	(1,454)
Loss on extinguishment of debt	-	-	(1,007)	-
Other income (expense)	-	-	-	(3)
Total other income (expense)	(649)	(148)	(3,642)	(756)
Loss before taxes on income	(25,571)	(16,674)	(80,520)	(47,668)
Provision (benefit) for taxes	11	-	26	3
Net loss	\$ (25,582)	\$ (16,674)	\$ (80,546)	\$ (47,671)
Net loss per share—basic and diluted	\$ (0.86)	\$ (0.64)	\$ (2.91)	\$ (1.99)
Weighted-average number of common shares used in net loss per share basic and diluted	29,716,666	26,120,324	27,701,783	23,933,309

	2018		2017	
	(in thousands)			
Condensed Consolidated Balance Sheet Data				
Cash and cash equivalents	\$	337,790	\$	129,780
Working capital		286,353		85,492
Total assets		345,208		135,337
Term loan		79,219		19,614
Deferred revenue (including current portion)		225,721		244,438
Accumulated deficit		(420,323)		(337,143)
Total stockholders' equity (deficit)	\$	15,159	\$	(146,973)

Reconciliation of GAAP to Non-GAAP Financial Measures

The following table presents results for the three months ending (in thousands) (unaudited):

	2018					2017				
	YTD Total	December 31	September 30	June 30	March 31	YTD Total	December 31	September 30	June 30	March 31
Total expenses - GAAP	\$ 130,467	\$ 33,373	\$ 34,735	\$ 34,223	\$ 28,136	\$ 94,970	\$ 26,489	\$ 24,575	\$ 24,000	\$ 19,906
Stock-based compensation expense	(10,550)	(2,768)	(2,745)	(2,552)	(2,485)	(6,530)	(1,800)	(1,545)	(1,582)	(1,603)
Depreciation and amortization	(431)	(120)	(105)	(105)	(101)	(437)	(100)	(98)	(109)	(130)
Cash-based operating expenses - Non-GAAP	\$ 119,486	\$ 30,485	\$ 31,885	\$ 31,566	\$ 25,550	\$ 88,003	\$ 24,589	\$ 22,932	\$ 22,309	\$ 18,173
Change from previous quarter	\$	(1,400)	\$ 319	\$ 6,016	\$ 961	\$	1,657	\$ 623	\$ 4,136	\$ 2,497
Percentage change from previous quarter		-4%	1%	24%	4%		7%	3%	23%	16%



About Reata Pharmaceuticals, Inc.

Reata is a clinical-stage biopharmaceutical company that develops novel therapeutics for patients with serious or life-threatening diseases by targeting molecular pathways involved in the regulation of cellular metabolism and inflammation. Reata's two most advanced clinical candidates, bardoxolone and omaveloxolone, target the important transcription factor Nrf2 that promotes the resolution of inflammation by restoring mitochondrial function, reducing oxidative stress, and inhibiting pro-inflammatory signaling.

Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements," including, without limitation, statements regarding the success, cost and timing of our product development activities and clinical trials, our plans to research, develop and commercialize our product candidates, and our ability to obtain and retain regulatory approval of our product candidates. You can identify forward-looking statements because they contain words such as "believes," "will," "may," "aims," "plans," and "expects." Forward-looking statements are based on Reata's current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, (i) the timing, costs, conduct, and outcome of our clinical trials and future preclinical studies and clinical trials, including the timing of the initiation and availability of data from such trials; (ii) the timing and likelihood of regulatory filings and approvals for our product candidates; (iii) the potential market size and the size of the patient populations for our product candidates, if approved for commercial use, and the market opportunities for our product candidates; and (iv) other factors set forth in Reata's filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K, under the caption "Risk Factors." The forward-looking statements speak only as of the date made and, other than as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.



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