



## **REATA PHARMACEUTICALS, INC. ANNOUNCES FIRST QUARTER 2019 FINANCIAL RESULTS AND AN UPDATE ON DEVELOPMENT PROGRAMS**

***PIVOTAL TRIALS CARDINAL AND MOXIE FULLY ENROLLED AND DATA EXPECTED IN THE SECOND HALF OF 2019***

***FALCON PIVOTAL PHASE 3 TRIAL TO INITIATE IN MAY 2019***

***CONFERENCE CALL WITH MANAGEMENT SCHEDULED FOR TODAY, MAY 9, 2019***

**IRVING, Texas—May 9, 2019**—Reata Pharmaceuticals, Inc. (Nasdaq: RETA), a clinical-stage biopharmaceutical company, today announced financial results for the first quarter ended March 31, 2019, and provided an update on the Company's business and product development programs.

### **Product Development Updates**

#### *Phase 2/3 CARDINAL Trial of Bardoxolone in Alport Syndrome*

Enrollment in the pivotal Phase 3 portion of the CARDINAL trial of bardoxolone methyl (bardoxolone) in patients with chronic kidney disease (CKD) caused by Alport syndrome is complete at 157 patients. Alport syndrome is a rare and serious hereditary disease that affects approximately 30,000 to 60,000 patients in the United States. There are no approved therapies for Alport syndrome anywhere in the world. We expect to have one-year top-line results available in the second half of 2019.

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

In the first quarter of 2019, we announced final data from the cohort of patients with focal segmental glomerulosclerosis (FSGS) from the Phase 2 PHOENIX study of bardoxolone in rare forms of CKD, as well as aggregate data across all four cohorts of PHOENIX. PHOENIX was an open-label, multi-center Phase 2 trial evaluating the safety and efficacy of bardoxolone in 103 patients, including 31 patients with autosomal dominant polycystic kidney disease (ADPKD), 26 with IgA nephropathy, 28 with CKD caused by type 1 diabetes, and 18 with FSGS. Patients were treated with bardoxolone for 12 weeks, and each cohort showed statistically significant increases in mean estimated glomerular filtration rate (eGFR) at Week 12. The mean change in eGFR from baseline across all four cohorts was 7.8 mL/min/1.73 m<sup>2</sup> (n=103; p<0.00001). Of the patients that reached Week 12, 88% experienced increases in eGFR. Bardoxolone significantly reduced mean systolic blood pressure by 3.8 mmHg (n=103; p=0.002) and mean diastolic blood pressure by 2.8 mmHg (n=103; p=0.0009). Urinary albumin excretion was low upon study entry and remained unchanged by bardoxolone treatment (n=103; p=0.6). No severe adverse events were reported related to bardoxolone treatment.



### *Phase 3 FALCON Trial of Bardoxolone in Autosomal Dominant Polycystic Kidney Disease*

Based on the results from the ADPKD cohort of PHOENIX, we announced in January of 2019 that we will initiate a registrational Phase 3 trial called FALCON in patients with ADPKD. ADPKD is the most common single-gene disorder of the kidneys, and there are an estimated 400,000 patients in the United States, with approximately 140,000 diagnosed. The only therapy currently approved for the treatment of ADPKD is tolvaptan, which was approved in the United States in 2018.

FALCON is an international, multi-center, randomized, double-blind, placebo-controlled trial studying the safety and efficacy of bardoxolone in approximately 300 patients with ADPKD randomized one-to-one to active drug or placebo. The primary efficacy endpoint is the retained eGFR benefit, defined as the change from baseline in eGFR compared to placebo after 48 weeks of treatment and a four-week drug withdrawal period. Based upon guidance from the FDA, the 52-week retained eGFR benefit data may support accelerated approval under subpart H. After Week 52, patients will be restarted on study drug with their original treatment assignments and will continue on study for a second year. The second-year retained eGFR benefit will be measured at Week 104 after withdrawal of drug for four weeks. Based upon guidance from the FDA, the year-two retained eGFR benefit data may support full approval. We plan to enroll the first ADPKD patient in FALCON in May 2019.

### *Pivotal MOXle Trial of Omaveloxolone in Friedreich's Ataxia*

We are conducting the pivotal part 2 of the MOXle Phase 2 trial of omaveloxolone in Friedreich's ataxia, an inherited, debilitating, and degenerative neuromuscular disorder. Enrollment in part 2 of the MOXle trial is complete at 103 patients, and top-line data are expected in the second half of 2019.

### *Phase 3 CATALYST Trial of Bardoxolone in Connective Tissue Disease-Associated Pulmonary Arterial Hypertension*

We are conducting the pivotal Phase 3 CATALYST trial of bardoxolone in patients with pulmonary arterial hypertension associated with connective tissue disease (CTD-PAH), an often fatal manifestation of many types of autoimmune disease, including systemic sclerosis (scleroderma) and systemic lupus erythematosus. The trial will enroll approximately 200 patients, with top-line data expected in the first half of 2020.

### **Selected Clinical Milestones in 2019**

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



## **First Quarter Results**

The Company incurred total expenses of \$36.3 million for the quarter ended March 31, 2019, with research and development accounting for \$26.1 million. This compares to total expenses of \$28.1 million for the same period of the year prior, when research and development accounted for \$21.4 million. We reported a net loss of \$29.2 million or \$0.98 per share for the quarter ended March 31, 2019. This compares to net income of \$4.1 million or \$0.16 per share in the same period of the year prior.

The net loss for the three-month period compared to the prior year is primarily driven by both an increase in expenses and a decrease in revenue. Higher expenses were 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 primarily due to an increase in revenue in the first quarter of 2018 from the portion of a \$30 million milestone from KHK that related to the period of time from execution of the KHK agreement until the three months ended March 31, 2018. There was no such catch-up revenue recognition in the first quarter of 2019.

Our cash-based operating expenses, a non-GAAP measure, were \$31.9 million for the three months ended March 31, 2019. This compares to \$25.6 million for the same period in 2018. 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 March 31, 2019, we had \$313.1 million in cash and cash equivalents. We expect our current cash to fund our operations through data readouts for CARDINAL, MOXle, and CATALYST.

## **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.

### CONFERENCE CALL INFORMATION

Date: Thursday, May 9, 2019  
 Time: 8:00 a.m. ET  
 Audience Dial-in (toll-free): 844-348-3946  
 Audience Dial-in (international): 213-358-0892  
 Conference ID: 5177169  
 Webcast Link: <https://edge.media-server.com/m6/p/cwm9hw5f>

	Three Months Ended March 31,	
	2019	2018
<b>Consolidated Statements of Operations</b>		
	(Unaudited)	
	(in thousands, except share and per share data)	
<b>Collaboration revenue</b>		
License and milestone	\$ 7,726	\$ 32,168
Other revenue	44	224
Total collaboration revenue	<u>7,770</u>	<u>32,392</u>
<b>Expenses</b>		
Research and development	26,114	21,407
General and administrative	10,038	6,628
Depreciation	170	101
Total expenses	36,322	28,136
<b>Other income (expense)</b>		
Investment income	1,797	335
Interest expense	(2,397)	(509)
Total other income (expense)	(600)	(174)
(Loss) income before taxes on income	(29,152)	4,082
Provision for taxes on income	2	-
Net (loss) income	<u>\$ (29,154)</u>	<u>\$ 4,082</u>
Net (loss) income per share—basic	\$ (0.98)	\$ 0.16
Net (loss) income per share—diluted	\$ (0.98)	\$ 0.15
Weighted-average number of common shares used in net (loss) income per share basic	29,830,114	26,155,141
Weighted-average number of common shares used in net (loss) income per share diluted	29,830,114	26,633,521

	As of March 31, 2019 (unaudited)	As of December 31, 2018
	(in thousands)	
<b>Condensed Consolidated Balance Sheet Data</b>		
Cash and cash equivalents	\$ 313,056	\$ 337,790
Working capital	256,267	286,353
Total assets	331,285	345,208
Term loan	79,558	79,219
Deferred revenue (including current portion)	217,995	225,721
Accumulated deficit	(449,477)	(420,323)
<b>Total stockholders' equity (deficit)</b>	<b>\$ (4,610)</b>	<b>\$ 15,159</b>

### Reconciliation of GAAP to Non-GAAP Financial Measures

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

	2019		2018		
	March 31	December 31	September 30	June 30	March 31
<b>Total expenses - GAAP</b>	<b>\$ 36,322</b>	<b>\$ 33,373</b>	<b>\$ 34,735</b>	<b>\$ 34,223</b>	<b>\$ 28,136</b>
Stock-based compensation expense	(4,227)	(2,768)	(2,745)	(2,552)	(2,485)
Depreciation	(170)	(120)	(105)	(105)	(101)
<b>Cash-based operating expenses - Non-GAAP</b>	<b>\$ 31,925</b>	<b>\$ 30,485</b>	<b>\$ 31,885</b>	<b>\$ 31,566</b>	<b>\$ 25,550</b>
<b>Change from previous quarter</b>	<b>\$ 1,440</b>	<b>\$ (1,400)</b>	<b>\$ 319</b>	<b>\$ 6,016</b>	<b>\$ 961</b>
<b>Percentage change from previous quarter</b>	<b>5%</b>	<b>-4%</b>	<b>1%</b>	<b>24%</b>	<b>4%</b>

### 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. Bardoxolone and omaveloxolone are investigational drugs, and their safety and efficacy have not been established by any agency.

### 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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