



## **REATA PHARMACEUTICALS, INC. ANNOUNCES SECOND QUARTER 2020 FINANCIAL RESULTS AND PROVIDES AN UPDATE ON BUSINESS OPERATIONS AND CLINICAL DEVELOPMENT PROGRAMS**

***PRE-NDA (NEW DRUG APPLICATION) MEETING GRANTED FOR BARDOXOLONE***

***REGULATORY UPDATE ON OMAVELOXOLONE***

***YEAR 2 DATA FROM CARDINAL TRIAL EXPECTED IN FOURTH QUARTER 2020***

***ENROLLMENT RESUMED IN FALCON TRIAL***

**PLANO, Texas—August 10, 2020 (GLOBE NEWSWIRE)**—Reata Pharmaceuticals, Inc. (Nasdaq: RETA) (“Reata,” the “Company,” or “we”), a clinical-stage biopharmaceutical company, today announced financial results for the quarter ended June 30, 2020, and provided an update on the Company’s business operations and clinical development programs.

### **Regulatory Update**

*Bardoxolone Methyl (“Bardoxolone”) for Alport Syndrome*

Since the announcement of positive, Year 1 data from the Phase 3 CARDINAL study, we have been engaged in discussions with the U.S. Food and Drug Administration (“FDA”) regarding the Year 1 efficacy and safety results. We have had a Type C meeting and have provided written responses to the FDA’s questions and comments. We believe that we have addressed the FDA’s questions and comments regarding the Year 1 results, and, accordingly, we recently requested and were granted a pre-NDA meeting by the FDA to discuss the NDA submission content and plans.

One of the key questions to be resolved in the pre-NDA meeting is how the data from Year 2 of the CARDINAL study should be handled during the NDA review process. Our plan has been, and continues to be, to submit the NDA for bardoxolone in Alport syndrome during fourth quarter of 2020 for accelerated approval based on the one-year data from the Phase 3 portion of CARDINAL. If the second-year results are available during an acceptable time frame, we may be able to submit the second-year data to the NDA during the review process and before the FDA makes a determination about accelerated approval. This may extend the PDUFA date, but could also result in consideration of full approval, rather than accelerated approval. The FDA could recommend that we wait for the second-year data from CARDINAL to file the NDA. This would permit us to file for full approval but would delay the filing until the first quarter of 2021, compared to our current guidance of filing by the end of this year.

### *Omaveloxolone for Friedreich's Ataxia*

Following the announcement of the positive data from the MOXle Part 2 study in October 2019, we have planned, subject to discussion with regulatory authorities, to proceed with a submission for marketing approval of omaveloxolone for the treatment of Friedreich's ataxia ("FA") in the United States. We recently completed a Type C meeting in which the FDA provided us with guidance that it does not have any concerns with the reliability of the mFARS primary endpoint results in the MOXle Part 2 study. Nevertheless, the FDA is not convinced that the MOXle Part 2 results will support a single study approval without additional evidence that lends persuasiveness to the results. In preliminary comments for the meeting, the FDA stated that we will need to conduct a second pivotal trial that confirms the mFARS results of the MOXle Part 2 study with a similar magnitude of effect.

In response to the preliminary comments, the Friedreich's Ataxia Research Alliance ("FARA"), key FA clinicians, and we provided the FDA with information to demonstrate that it will be difficult to conduct an additional, prospective clinical trial in FA because of the very slow progression rate of FA, the limited number of FA patients available for clinical research, the small number of clinical trial investigators who can conduct the mFARS exam, and the impact of the COVID-19 pandemic on the ability to conduct neuroscience clinical trials. Thus, conducting an additional pivotal study would result in a long delay in the availability of a potentially effective therapy to patients with a progressive, life-threatening disease with no treatment options. The FDA acknowledged the unmet need of patients with FA, reiterated its commitment to facilitate the development of omaveloxolone within the constraints of the regulatory standards, and emphasized its willingness to consider all available options to meet the regulatory standards. The FDA also acknowledged that launching a new, neuroscience clinical trial now may not be possible because of the COVID-19 pandemic.

At the Type C meeting, to address the FDA's requirement, FARA, key opinion leaders, and Reata proposed a second study (the "crossover study") to provide additional evidence of effectiveness. The study would measure the effect of omaveloxolone on mFARS in patients who were previously randomized to placebo in the MOXle Part 2 study and are being treated with omaveloxolone in the MOXle open-label extension study. The FDA acknowledged that a study like the proposed crossover study could provide important additional information and asked us to submit a design for the crossover study for their consideration.

If the FDA accepts this approach, we expect to complete the crossover study as early as the fourth quarter of this year. Assuming that the FDA views the crossover study data as sufficiently positive to provide confirmatory evidence, our plan would be to submit an NDA during the first quarter of 2021. If the FDA rejects the proposal or if the data are not supportive, we will evaluate whether it is feasible to conduct a second pivotal study in FA patients as suggested by the FDA. Regardless of the interaction with the FDA, we plan to pursue marketing approval outside of the United States.



## **Clinical Development Update**

### *CARDINAL Phase 3 Study of Bardoxolone in Alport Syndrome*

We are in the process of completing the second year of CARDINAL and anticipate that the study will be completed this year. The last study visits are anticipated to occur during the fourth quarter of 2020, which is consistent with our pre-COVID-19 trial timeline. As a result of the measures taken in response to the pandemic, at this time we believe that the timeline for Year 2 data availability is unlikely to be affected by COVID-19.

### *FALCON Phase 3 Study of Bardoxolone in Autosomal Dominant Polycystic Kidney Disease (“ADPKD”)*

In March 2020, we temporarily paused screening and enrollment of new patients in the FALCON Phase 3 study due to the emergence of COVID-19. We began to lift the screening hold in June 2020, and currently all sites are able to screen patients and approximately one-half of all sites are able to randomize patients. The measures we implemented to the conduct of FALCON in response to COVID-19 have been effective, and we anticipate no meaningful impact on data integrity due to COVID-19.

### *BARCONA Study of Bardoxolone in Patients with COVID-19*

Reata recently announced the start of an investigator-sponsored trial, led by researchers at New York University’s (“NYU”) Grossman School of Medicine, to study the effect of bardoxolone in patients with COVID-19. The Phase 2 BARCONA study is a randomized, placebo-controlled, double-blind trial that will enroll 40 patients with a primary endpoint of safety and a treatment duration of up to 29 days. Reata was involved in the design of the trial, has a representative on the study’s executive steering committee, and is providing drug supply for the study, as requested by NYU.

## **Second Quarter Financial Highlights**

Reata recently announced a strategic investment from Blackstone Life Sciences (“Bxls”) of \$350 million, which includes \$300 million in return for various percentage royalty payments by the Company on worldwide net sales of bardoxolone by the Company and its licensees, other than Kyowa Kirin Co., Ltd (“KKC”), and a \$50 million investment in 340,793 shares of Reata’s Class A common stock at \$146.72 per share. The royalty percentage will initially be in the mid-single digits and in future years can vary between higher-mid single digit percentages to low-single digit percentages depending on various milestones, including indication approval dates, cumulative royalty payments, and cumulative net sales.

In connection with the closing of the Bxls investment, the Company paid off in full its senior loan with Oxford Finance LLC and Silicon Valley Bank, which included \$155.0 million in principal and \$12.1 million in exit and prepayment fees, and which resulted in a charge for extinguishment of debt of \$11.2 million.



### *Cash and Cash Equivalents*

On June 30, 2020, we had cash and cash equivalents of \$610.4 million, as compared to \$664.3 million at December 31, 2019.

### *Collaboration Revenue*

Collaboration Revenue was \$3.1 million in the second quarter of 2020, as compared to \$7.8 million for the same period of the year prior. Revenue for the second quarter of 2020 included \$1.2 million from the KKC license agreement and \$1.9 million in reimbursements of expenses from KKC.

### *GAAP and Non-GAAP Research and Development (“R&D”) Expenses*

R&D expenses according to generally accepted accounting principles in the U.S. (“GAAP”) were \$36.8 million for the second quarter of 2020, as compared to \$29.6 million for the same period of the year prior.

Non-GAAP R&D expenses were \$29.3 million for the second quarter of 2020, as compared to \$27.9 million for the same period of the year prior.<sup>1</sup>

### *GAAP and Non-GAAP General and Administrative (“G&A”) Expenses*

GAAP G&A expenses were \$16.6 million for the second quarter of 2020, as compared to \$11.7 million for the same period of the year prior.

Non-GAAP G&A expenses were \$9.3 million for the second quarter of 2020, as compared to \$8.9 million for the same period of the year prior.<sup>1</sup>

### *GAAP and Non-GAAP Net Loss*

The GAAP net loss for the second quarter of 2020 was \$67.6 million, or \$2.03 per share, on both a basic and diluted basis, as compared to a GAAP net loss of \$34.4 million, or \$1.14 per share, on both a basic and diluted basis, for the same period of the year prior.

The increase in GAAP net loss for the second quarter of 2020 is driven primarily by the loss on extinguishment of debt related to the payoff of our loan to Oxford Finance LLC and Silicon Valley Bank, higher stock-based compensation expense, and decreased collaboration revenue related to AbbVie since the reacquisition of licensing rights.

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<sup>1</sup> See “Use of Non-GAAP Financial Measures” below for a description of non-GAAP financial measures and a reconciliation between GAAP and non-GAAP R&D expenses, GAAP and non-GAAP G&A expenses, and GAAP and non-GAAP net loss, respectively, appearing later in the press release.



The non-GAAP net loss for the second quarter of 2020 was \$40.9 million, or \$1.23 per share on both a basic and diluted basis, as compared to a non-GAAP net loss of \$29.9 million, or \$0.99 per share, on both a basic and diluted basis, for the same period of the year prior.<sup>1</sup>

#### *Reiterates Cash Guidance*

The Company reiterated that it expects existing cash and cash equivalents will be sufficient to enable it to fund operations through the end of 2023.

#### **Non-GAAP Financial Measures**

This press release contains non-GAAP financial measures, including non-GAAP R&D expenses, non-GAAP G&A expenses, non-GAAP operating expenses, non-GAAP net loss and non-GAAP net loss per common share – basic and diluted. These measures are not in accordance with, or an alternative to, GAAP, and may be different from non-GAAP financial measures used by other companies.

The Company defines non-GAAP R&D expenses as GAAP R&D expenses less stock-based compensation expense; non-GAAP G&A expenses as GAAP G&A expenses less stock-based compensation expense; non-GAAP operating expenses as GAAP operating expenses less stock-based compensation expense; non-GAAP net loss as GAAP net loss plus stock-based compensation expense, loss on extinguishment of debt, and non-cash interest expense from liability related to sale of future royalties; and non-GAAP net loss per common share – basic and diluted as GAAP net loss per common share – basic and diluted plus stock-based compensation expense, loss on extinguishment of debt, and non-cash interest expense from liability related to sale of future royalties. During the three and six months ended June 30, 2020 and 2019, the Company did not incur any reacquired license rights expense; therefore, this expense is not included in the reconciliations below for the measures for non-GAAP operating expenses, non-GAAP net loss, and non-GAAP net loss per common share – basic and diluted for these periods. The Company has excluded the impact of stock-based compensation expense, which may fluctuate from period to period based on factors including the variability associated with performance-based grants for stock options and restricted stock units and changes in the Company's stock price, which impacts the fair value of these awards. The Company has excluded the impact of loss on extinguishment of debt in connection with the Term Loan payoff because the Company has no other similar loan obligation and we believe it is a non-recurring transaction, that makes it difficult to compare its results to peer companies who also provide non-GAAP disclosures. The Company has excluded the impact of accreted non-cash interest expense from liability related to sale of future royalties as it may be calculated differently from, and therefore may not be comparable to peer companies who also provide non-GAAP disclosures. The Company has excluded the impact of stock-based compensation expense, loss on extinguishment of debt, non-cash interest expense from liability related to sale of future royalties, and reacquired license rights expense because the Company believes its impact makes it difficult to compare its results to prior periods and anticipated future periods.



Because management believes certain items, such as stock-based compensation expense, loss on extinguishment of debt, non-cash interest expense from liability related to sales of future royalties, and reacquired license rights expense can distort the trends associated with the Company's ongoing performance, the following measures are often provided, excluding special items, and utilized by the Company's management, analysts, and investors to enhance consistency and comparability of year-over-year results, as well as to industry trends, and to provide a basis for evaluating operating results in future periods: non-GAAP net loss; non-GAAP net loss per common share – basic and diluted; non-GAAP R&D expenses; non-GAAP G&A expenses; and non-GAAP operating expenses.

The Company believes the presentation of these non-GAAP financial measures provides useful information to management and investors regarding the Company's financial condition and results of operations. When GAAP financial measures are viewed in conjunction with these non-GAAP financial measures, investors are provided with a more meaningful understanding of the Company's ongoing operating performance and are better able to compare the Company's performance between periods. In addition, these non-GAAP financial measures are among those indicators the Company uses as a basis for evaluating performance, allocating resources and planning and forecasting future periods. These non-GAAP financial measures are not intended to be considered in isolation or as a substitute for GAAP financial measures. A reconciliation between these non-GAAP measures and the most directly comparable GAAP measures is provided later in this press release.

#### **Conference Call Information**

Reata's management will host a conference call on August 10, 2020 at 8:30 a.m. ET. The conference call will be accessible by dialing (800) 708-4539 (toll-free domestic) or (847) 619-6396 (international) using the access code: 49873533. The webcast link is <https://edge.media-server.com/mmc/p/hr8ew88f>.

Second quarter 2020 financial results to be discussed during the call will be included in an earnings press release that will be available on the company's website shortly before the call at <http://reatapharma.com/investors/> and will be available for 12 months after the call. The audio recording and webcast will be accessible for at least 90 days after the event at <http://reatapharma.com/investors/>.

#### **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.**



**Contact:**

Reata Pharmaceuticals, Inc.  
(972) 865-2219  
<http://reatapharma.com>

**Investors:**

Vinny Jindal  
Vice President, Corporate Communications and Strategy  
(469) 374-8721  
[ir@reatapharma.com](mailto:ir@reatapharma.com)  
<http://reatapharma.com/contact-us/>

**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, our plans to submit regulatory filings, 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,” “model,” 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) whether regulatory authorities determine that additional trials or data are necessary in order to obtain approval; (iv) 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 (v) other factors set forth in Reata’s filings with the U.S. Securities and Exchange Commission, including the detailed factors discussed under the caption “Risk Factors.” in its Annual Report on Form 10-K for the fiscal year ended December 31, 2019. 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.*



	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
(unaudited)				
(in thousands, except share and per share data)				
<b>Consolidated Statements of Operations</b>				
<b>Collaboration revenue</b>				
License and milestone	\$ 1,169	\$ 7,813	\$ 2,338	\$ 15,539
Other revenue	1,904	20	2,088	64
Total collaboration revenue	3,073	7,833	4,426	15,603
<b>Expenses</b>				
Research and development	36,783	29,554	84,436	55,668
General and administrative	16,600	11,706	37,387	21,744
Depreciation	284	232	562	401
Total expenses	53,667	41,492	122,385	77,813
<b>Other income (expense), net</b>	(16,990)	(701)	(20,804)	(1,301)
Loss before taxes on income	(67,584)	(34,360)	(138,763)	(63,511)
(Benefit from) provision for taxes on income	(3)	20	(22,243)	23
Net loss	<u>\$ (67,581)</u>	<u>\$ (34,380)</u>	<u>\$ (116,520)</u>	<u>\$ (63,534)</u>
Net loss per share—basic and diluted	\$ (2.03)	\$ (1.14)	\$ (3.51)	\$ (2.12)
Weighted-average number of common shares used in net loss per share basic and diluted	33,265,778	30,069,048	33,243,931	29,950,241

	As of June 30, 2020 (unaudited)		As of December 31, 2019	
	(in thousands)			
<b>Condensed Consolidated Balance Sheet Data</b>				
Cash and cash equivalents	\$	610,419	\$	664,324
Working capital		593,282		477,262
Total assets		652,404		682,420
Term loan (including current portion, net of issuance cost)		-		155,017
Liability related to sale of future royalties, net		294,234		-
Payable to collaborators		70,055		216,862
Deferred revenue (including current portion)		7,051		9,389
Accumulated deficit		(827,013)		(710,493)
<b>Total stockholders' equity</b>	\$	231,627	\$	256,857



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

The following table presents reconciliations of non-GAAP financial measures to the most directly comparable GAAP financial measures (in thousands, except for per share data) (unaudited):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
<b>Reconciliation of GAAP to Non-GAAP Research and development:</b>				
GAAP Research and development	\$ 36,783	\$ 29,554	\$ 84,436	\$ 55,668
Less: Stock-based compensation expense	(7,527)	(1,659)	(19,044)	(3,350)
Non-GAAP Research and development	<u>\$ 29,256</u>	<u>\$ 27,895</u>	<u>\$ 65,392</u>	<u>\$ 52,318</u>
<b>Reconciliation of GAAP to Non-GAAP General and administrative:</b>				
GAAP General and administrative	\$ 16,600	\$ 11,706	\$ 37,387	\$ 21,744
Less: Stock-based compensation expense	(7,269)	(2,824)	(15,060)	(5,360)
Non-GAAP General and administrative	<u>\$ 9,331</u>	<u>\$ 8,882</u>	<u>\$ 22,327</u>	<u>\$ 16,384</u>
<b>Reconciliation of GAAP to Non-GAAP Operating expenses:</b>				
GAAP Operating expenses	\$ 53,667	\$ 41,492	\$ 122,385	\$ 77,813
Less: Stock-based compensation expense	(14,796)	(4,483)	(34,104)	(8,710)
Non-GAAP Operating expenses	<u>\$ 38,871</u>	<u>\$ 37,009</u>	<u>\$ 88,281</u>	<u>\$ 69,103</u>
<b>Reconciliation of GAAP to Non-GAAP Net loss:</b>				
GAAP Net loss	\$ (67,581)	\$ (34,380)	\$ (116,520)	\$ (63,534)
Add: Stock-based compensation expense	14,796	4,483	34,104	8,710
Add: Loss on extinguishment of debt	11,183	-	11,183	-
Add: Non-cash interest expense from liability related to sale of future royalties	664	-	664	-
Non-GAAP Net loss	<u>\$ (40,938)</u>	<u>\$ (29,897)</u>	<u>\$ (70,569)</u>	<u>\$ (54,824)</u>
<b>Reconciliation of GAAP to Non-GAAP Net loss per common share-basic and diluted:</b>				
GAAP Net loss per common share-basic and diluted	\$ (2.03)	\$ (1.14)	\$ (3.51)	\$ (2.12)
Add: Stock-based compensation expense	0.44	0.15	1.03	0.29
Add: Loss on extinguishment of debt	0.34	-	0.34	-
Add: Non-cash interest expense from liability related to sale of future royalties	0.02	-	0.02	-
Non-GAAP Net loss per common share-basic and diluted	<u>\$ (1.23)</u>	<u>\$ (0.99)</u>	<u>\$ (2.12)</u>	<u>\$ (1.83)</u>

	Three Months Ended		
	June 30, 2020	March 31, 2020	December 31, 2019
<b>Reconciliation of GAAP to Non-GAAP Operating expenses</b>			
GAAP - Operating expenses	\$ 53,667	\$ 68,718	\$ 187,103
Less: Stock-based compensation expense	(14,796)	(19,307)	(12,291)
Less: Reacquired license rights expense	-	-	(124,398)
Non - GAAP - Operating expenses	<u>\$ 38,871</u>	<u>\$ 49,411</u>	<u>\$ 50,414</u>
<b>Reconciliation of GAAP to Non-GAAP Net loss</b>			
GAAP - Net loss	\$ (67,581)	\$ (48,939)	\$ (186,942)
Add: Stock-based compensation expense	14,796	19,307	12,291
Add: Loss on extinguishment of debt	11,183	-	-
Add: Non-cash interest expense from liability related to sale of future royalties	664	-	-
Add: Reacquired license rights expense	-	-	124,398
Non-GAAP Net loss	<u>\$ (40,938)</u>	<u>\$ (29,632)</u>	<u>\$ (50,253)</u>