



## **REATA PHARMACEUTICALS, INC. ANNOUNCES SECOND QUARTER 2021 FINANCIAL RESULTS AND PROVIDES AN UPDATE ON CLINICAL DEVELOPMENT PROGRAMS**

***PRE-NDA MEETING WITH FDA SCHEDULED FOR Q3 2021 ON OMAVELOXOLONE FOR PATIENTS WITH FA AND REATA ANNOUNCES PLAN TO FILE OMAVELOXOLONE NDA DURING Q1 2022***

***PROVIDES UPDATE FROM MID-CYCLE COMMUNICATION MEETING ON BARDOXOLONE FOR PATIENTS WITH CKD CAUSED BY ALPORT SYNDROME***

***PROVIDES UPDATE FROM TYPE B MEETING ON BARDOXOLONE FOR PATIENTS WITH ADPKD***

***ANNOUNCES COMPLETION OF ENROLLMENT IN PHASE 2 MERLIN TRIAL OF BARDOXOLONE IN PATIENTS WITH CKD AT RISK OF RAPID PROGRESSION***

***REAFFIRMS CASH RUNWAY THROUGH MID-2024***

***CONFERENCE CALL WITH MANAGEMENT ON AUGUST 9, 2021 AT 4:30 P.M. ET***

**PLANO, Texas—August 9, 2021 (BUSINESS WIRE)**—[Reata Pharmaceuticals, Inc.](https://www.reata.com) (Nasdaq: RETA) (“Reata,” the “Company,” “our,” “us,” or “we”), a clinical-stage biopharmaceutical company, today announced financial results for the quarter ended June 30, 2021, and provided an update on the Company’s business operations and clinical development programs.

### **Recent Company Highlights**

#### *Omaveloxolone in Patients with Friedreich’s Ataxia (“FA”)*

Based on a communication received from the U.S. Food and Drug Administration (“FDA”) regarding omaveloxolone for the treatment of FA, we withdrew our request for a Type C meeting and requested a pre-NDA meeting with the FDA. The pre-NDA meeting request has been granted, a pre-NDA meeting has been scheduled during the third quarter of this year, and we have submitted briefing materials for the meeting. We recently received a communication from the FDA requesting the estimated date of our New Drug Application (“NDA”) for its planning purposes. We plan to submit the NDA during the first quarter of 2022.

#### *Bardoxolone Methyl (“Bardoxolone”) in Patients with Alport Syndrome*

The NDA for bardoxolone for the treatment of patients with chronic kidney disease (“CKD”) caused by Alport syndrome is currently under review by the FDA. The FDA completed a bio-research monitoring inspection of Reata. We did not receive any observations. We also recently completed a mid-cycle communication meeting with the FDA. While we have not yet received formal minutes from the FDA, in the preliminary agenda for, and during, the meeting, the FDA identified four significant clinical and statistical review issues for us to address. The FDA invited us to respond to its identified issues in follow-up submissions to the NDA, and we believe each of the identified issues is addressable with additional data and analyses. The FDA did not designate any safety issues as significant issues, and it stated that,



based on its current review, it does not believe a Risk Evaluation and Mitigation Strategies (“REMS”) program is needed. The FDA also advised us that an Advisory Committee meeting is tentatively scheduled for December 8, 2021. The Prescription Drug User Fee Act (“PDUFA”) date, the FDA action date for the application, is scheduled for February 25, 2022.

We reaffirm our plan to submit a Marketing Authorization Application (“MAA”) with the European Medicines Agency (“EMA”) in the fourth quarter of 2021 for marketing approval of bardoxolone for the treatment of CKD caused by Alport syndrome in the European Union.

On July 27, 2021, Kyowa Kirin Co., Ltd. (“KKC”), our strategic collaborator in CKD in Japan, submitted an NDA in Japan to the Ministry of Health, Labour and Welfare (“MHLW”) for bardoxolone for the treatment of patients with CKD caused by Alport syndrome. Based on this submission, we have earned a milestone payment under the KKC license agreement.

#### *Bardoxolone in Patients with Autosomal Dominant Polycystic Kidney Disease (“ADPKD”)*

FALCON is an international, multi-center, randomized, double-blind, placebo-controlled, registrational Phase 3 trial studying the safety and efficacy of bardoxolone in patients with ADPKD randomized one-to-one to bardoxolone or placebo. We recently had a Type B meeting with the FDA regarding the ADPKD development program, and we have not yet received minutes from the meeting. Based on the discussion during the meeting, we plan to modify the protocol so that the primary endpoint will be the Year 2 off-treatment analysis. Additionally, we will not unblind the trial until after its completion, we will add an eight-week off-treatment visit to the study, and we will incorporate the FDA’s feedback on data related to patients who discontinued treatment early in the study. We may need to increase the patient enrollment sample size from the current target of 550 patients. More than 370 patients are currently enrolled in the study. We continue to expect to enroll 550 patients in the FALCON study by the end of 2021. However, if we decide to increase the target enrollment, we will provide updated guidance on our enrollment timeline.

#### *Bardoxolone in Patients with CKD at Risk of Rapid Progression*

MERLIN is a multi-center, double-blind, placebo-controlled, Phase 2 trial to evaluate the safety and efficacy of bardoxolone in patients with CKD due to multiple etiologies at meaningful risk of progression to end-stage kidney disease. We have completed enrollment in the MERLIN trial and expect to have top-line data in the fourth quarter of 2021. If the results of this study are positive, we may proceed to a larger Phase 3 with similar eligibility criteria.

## Recent Presentations

Abstracts highlighting results from our various programs in CKD and FA have been selected for presentation at recent international medical conferences. Posters that have been presented can be found on our website at <https://www.reatapharma.com/investors/>.

- Dr. David Lynch, MD, PhD, Director, Friedreich's Ataxia Program, Division of Neurology, Children's Hospital of Philadelphia, Philadelphia, PA, presented the talk *Efficacy of Omaveloxolone in Patients with Friedreich's Ataxia: Baseline-Controlled Study* at the National Ataxia Foundation's Ataxia Investigators Meeting 2021, which was held virtually from May 24 – 27, 2021.
- Dr. Bradley A. Warady, MD, Director, Division of Pediatric Nephrology, Children's Mercy Kansas City, Kansas City, MO presented the talk *Safety of Bardoxolone Methyl in Pediatric Patients with Alport Syndrome in CARDINAL Phase 3 Trial* at the 58th ERA-EDTA Congress, which was held virtually from June 5 – 8, 2021.
- Dr. Arlene Chapman, MD, Professor of Medicine, University of Chicago, Chicago, IL, presented the poster *Trial Design for Phase 3 FALCON: Evaluation of the Safety, Tolerability, and Efficacy of Bardoxolone Methyl in Patients with Autosomal Dominant Polycystic Kidney Disease* at the PKD CON:NECT Conference, which was held virtually from June 25 – 26, 2021.

## Second Quarter Financial Highlights

### *Cash and Cash Equivalents*

At June 30, 2021, we had cash and cash equivalents of \$755.7 million. The decrease in cash and cash equivalents during the second quarter of 2021 was \$21.9 million, as compared to \$40.5 million in the first quarter of 2021. This decrease in cash used is primarily due to a \$22.9 million tax refund related to the Coronavirus Aid, Relief and Economic Security Act that was received during the second quarter of 2021. We reaffirm our current cash runway to last through mid-2024.

### *Collaboration Revenue*

Collaboration revenue was \$2.2 million in the second quarter of 2021, as compared to \$3.1 million for the same period of the year prior.

### *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 \$40.1 million for the second quarter of 2021, as compared to \$36.8 million, for the same period of the year prior.



Non-GAAP R&D expenses were \$34.8 million for the second quarter of 2021, as compared to \$29.3 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 \$22.0 million for the second quarter of 2021, as compared to \$16.6 million, for the same period of the year prior.

Non-GAAP G&A expenses were \$14.0 million for the second quarter of 2021, as compared to \$9.3 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 2021 was \$72.7 million, or \$2.00 per share, on both a basic and diluted basis, as compared to a GAAP net loss of \$67.6 million, or \$2.03 per share, on both a basic and diluted basis, for the same period of the year prior.

The non-GAAP net loss for second quarter of 2021 was \$48.0 million, or \$1.32 per share on both a basic and diluted basis, as compared to a non-GAAP net loss of \$40.9 million, or \$1.23 per share, on both a basic and diluted basis, for the same period of the year prior.<sup>1</sup>

**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 increases in GAAP and non-GAAP net loss are driven primarily by increased clinical study and manufacturing activities, commercial launch readiness activities, and increased personnel and personnel-related costs to support the growth of our development activities compared to the same period of the year prior.

The Company defines non-GAAP R&D expenses as GAAP R&D expenses, excluding stock-based compensation expense; non-GAAP G&A expenses as GAAP G&A expenses, excluding stock-based compensation expense; non-GAAP operating expenses as GAAP operating expenses, excluding stock-based compensation expense; non-GAAP net loss as GAAP net loss, excluding stock-based compensation expense, non-cash interest expense from liability related to sale of future royalties, loss on extinguishment of debt, and gain on lease termination; and non-GAAP net

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<sup>1</sup> See “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.



loss per common share – basic and diluted as GAAP net loss per common share – basic and diluted, excluding stock-based compensation expense, non-cash interest expense from liability related to sale of future royalties, and loss on extinguishment of debt. 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 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 loss on extinguishment of debt and gain on lease termination as they are non-recurring transactions that make it difficult to compare its results to peer companies who also provide non-GAAP disclosures. The Company has excluded the impact of stock-based compensation expense, non-cash interest expense from liability related to sale of future royalties, loss on extinguishment of debt, and gain on lease termination 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, non-cash interest expense from liability related to sales of future royalties, loss on extinguishment of debt, and gain on lease termination, 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 9, 2021, at 4:30 pm ET. The conference call will be accessible by dialing (866) 270-1533 (toll-free domestic) or (412) 317-0797 (international) using the access code: 10157197. The webcast link is <https://event.on24.com/wcc/r/3196578/57A5A4A99C3D3BA0F2D6A7D9D86B06B7>.

Second quarter 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 <https://www.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 <https://www.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 that regulate cellular metabolism, inflammation, and the cellular response to injury. Reata's two most advanced clinical candidates, bardoxolone and omaxeloxolone, target the important transcription factor Nrf2 that promotes the resolution of inflammation by restoring mitochondrial function, reducing oxidative stress, and inhibiting pro-inflammatory signaling. We possess exclusive, worldwide rights to develop, manufacture, and commercialize bardoxolone, omaxeloxolone, and our next-generation Nrf2 activators, excluding certain Asian markets for bardoxolone in certain indications, which are licensed to Kyowa Kirin Co., Ltd. **Bardoxolone and omaxeloxolone 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, 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, 2020. 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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	Three Months Ended June 30		Six Months Ended June 30	
	2021	2020	2021	2020
<b>Consolidated Statements of Operations</b>				
(unaudited)				
(in thousands, except share and per share data)				
<b>Collaboration revenue</b>				
License and milestone	\$ 803	\$ 1,169	\$ 1,598	\$ 2,338
Other revenue	1,418	1,904	1,568	2,088
Total collaboration revenue	2,221	3,073	3,166	4,426
<b>Expenses</b>				
Research and development	40,066	36,783	74,946	84,436
General and administrative	21,998	16,600	42,703	37,387
Depreciation	287	284	561	562
Total expenses	62,351	53,667	118,210	122,385
<b>Other income (expense), net</b>	(13,223)	(16,990)	(25,780)	(20,804)
Loss before taxes on income	(73,353)	(67,584)	(140,824)	(138,763)
Benefit from (provision for) taxes on income	653	3	669	22,243
Net loss	\$ (72,700)	\$ (67,581)	\$ (140,155)	\$ (116,520)
Net loss per share—basic and diluted	\$ (2.00)	\$ (2.03)	\$ (3.87)	\$ (3.51)
Weighted-average number of common shares used in net loss per share basic and diluted	36,299,735	33,265,778	36,251,948	33,243,931

	As of June 30, 2021 (unaudited)	As of December 31, 2020
	(in thousands)	
<b>Condensed Consolidated Balance Sheet Data</b>		
Cash and cash equivalents	\$ 755,707	\$ 818,150
Income tax receivable	-	22,228
Working capital	646,575	728,136
Total assets	777,612	857,598
Liability related to sale of future royalties, net	337,808	315,454
Payable to collaborators	76,923	73,437
Deferred revenue	3,090	4,688
Accumulated deficit	(1,098,400)	(958,245)
Total stockholders' equity	\$ 313,829	\$ 417,431

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

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

	Three Months Ended June 30		Six Months Ended June 30	
	2021	2020	2021	2020
<b>Reconciliation of GAAP to Non-GAAP Research and development:</b>				
GAAP Research and development	\$ 40,066	\$ 36,783	\$ 74,946	\$ 84,436
Less: Stock-based compensation expense	(5,263)	(7,527)	(12,071)	(19,044)
Non-GAAP Research and development	<u>\$ 34,803</u>	<u>\$ 29,256</u>	<u>\$ 62,875</u>	<u>\$ 65,392</u>
<b>Reconciliation of GAAP to Non-GAAP General and administrative:</b>				
GAAP General and administrative	\$ 21,998	\$ 16,600	\$ 42,703	\$ 37,387
Less: Stock-based compensation expense	(7,981)	(7,269)	(15,852)	(15,060)
Non-GAAP General and administrative	<u>\$ 14,017</u>	<u>\$ 9,331</u>	<u>\$ 26,851</u>	<u>\$ 22,327</u>
<b>Reconciliation of GAAP to Non-GAAP Operating expenses:</b>				
GAAP Operating expense	\$ 62,351	\$ 53,667	\$ 118,210	\$ 122,385
Less: Stock-based compensation expense	(13,244)	(14,796)	(27,923)	(34,104)
Non-GAAP Operating expense	<u>\$ 49,107</u>	<u>\$ 38,871</u>	<u>\$ 90,287</u>	<u>\$ 88,281</u>
<b>Reconciliation of GAAP to Non-GAAP Net loss:</b>				
GAAP Net loss	\$ (72,700)	\$ (67,581)	\$ (140,155)	\$ (116,520)
Add: Stock-based compensation expense	13,244	14,796	27,923	34,104
Add: Non-cash interest expense from liability related to sale of future royalties	11,429	664	22,354	664
Add: Loss on extinguishment of debt	-	11,183	-	11,183
Non-GAAP Net loss	<u>\$ (48,027)</u>	<u>\$ (40,938)</u>	<u>\$ (89,878)</u>	<u>\$ (70,569)</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	\$ (2.00)	\$ (2.03)	\$ (3.87)	\$ (3.51)
Add: Stock-based compensation expense	0.36	0.44	0.77	1.03
Add: Non-cash interest expense from liability related to sale of future royalties	0.32	0.02	0.62	0.02
Add: Loss on extinguishment of debt	-	0.34	-	0.34
Non-GAAP Net loss per common share-basic and diluted	<u>\$ (1.32)</u>	<u>\$ (1.23)</u>	<u>\$ (2.48)</u>	<u>\$ (2.12)</u>



Reconciliation of GAAP to Non-GAAP Operating expenses	Three Months Ended			
	June 30, 2021	March 31, 2021	December 31, 2020	September 30, 2020
	(unaudited)			
GAAP Operating expenses	\$ 62,351	\$ 55,858	\$ 57,173	\$ 55,786
Less: Stock-based compensation expense	(13,244)	(14,679)	(11,950)	(11,580)
<b>Non - GAAP Operating expenses</b>	<b>\$ 49,107</b>	<b>\$ 41,179</b>	<b>\$ 45,223</b>	<b>\$ 44,206</b>
<b>Reconciliation of GAAP to Non-GAAP Net loss</b>				
GAAP Net loss	\$ (72,700)	\$ (67,455)	\$ (65,776)	\$ (65,456)
Add: Stock-based compensation expense	13,244	14,679	11,950	11,580
Add: Non-cash interest expense from liability related to sale of future royalties	11,429	10,925	10,807	10,413
Less: Gain on lease termination	-	-	(470)	(816)
<b>Non-GAAP Net loss</b>	<b>\$ (48,027)</b>	<b>\$ (41,851)</b>	<b>\$ (43,489)</b>	<b>\$ (44,279)</b>