REATA PHARMACEUTICALS, INC. ANNOUNCES SECOND QUARTER 2022 FINANCIAL RESULTS AND PROVIDES AN UPDATE ON CLINICAL DEVELOPMENT PROGRAMS

RECEIVED PRIORITY REVIEW AND ACCEPTANCE FOR FILING OF THE NDA FOR OMAVELOXOLONE FOR TREATMENT OF PATIENTS WITH FRIEDREICH'S ATAXIA

PROVIDES UPDATE FROM FDA MID-CYCLE COMMUNICATION MEETING ON OMAVELOXOLONE FOR PATIENTS WITH FRIEDREICH'S ATAXIA

ANNOUNCES RESULTS OF NEW DATA AND ANALYSES SUBMITTED TO FDA

CONFERENCE CALL WITH MANAGEMENT ON AUGUST 8, 2022, AT 8:30 A.M. ET

PLANO, Texas—August 8, 2022 (BUSINESS WIRE)—Reata Pharmaceuticals, Inc. (Nasdaq: RETA) ("Reata," the "Company," "our," "us," or "we"), a clinical-stage biopharmaceutical company, today announced financial results for the second quarter of 2022 and provided an update on the Company's business operations and clinical development programs.

Recent Company Highlights

Omaveloxolone in Patients with Friedreich's Ataxia

Following the announcement of the positive data from the MOXIe Part 2 study in October 2019, the U.S. Food and Drug Administration ("FDA") stated that it did not have any concerns with the reliability of the modified Friedreich's ataxia rating scale ("mFARS") primary endpoint results in the MOXIe Part 2 study and requested additional evidence of persuasiveness to support a New Drug Application ("NDA") filing. We then began a series of interactions with the FDA to provide additional evidence of effectiveness to support a single study approval. This ultimately led to a pre-NDA meeting and subsequent NDA submission in March 2022 after FDA's review of our Delayed-Start Analysis, which it had requested.

In May 2022, the FDA accepted for filing our NDA for omaveloxolone for the treatment of patients with Friedreich's ataxia and granted Priority Review. The FDA has granted Fast Track Designation, Orphan Drug Designation, and Rare Pediatric Disease Designation to omaveloxolone for the treatment of Friedreich's ataxia. The FDA advised us that it is planning to hold an advisory committee meeting to discuss the application, and our application has been assigned a Prescription Drug User Fee Act ("PDUFA") target action date of November 30, 2022.

We recently completed a mid-cycle communication meeting with the FDA. The purpose of the mid-cycle communication meeting is for the FDA to provide the sponsor with an update of the status of the NDA review, including any issues identified. While we have not received formal minutes from the FDA, in the preliminary agenda for, and during, the mid-cycle communication meeting, the FDA stated that it has not identified any new significant issues, but it continues

to have concerns regarding the strength of the efficacy evidence. The FDA did not identify any significant clinical safety issues. The FDA stated that the safety review is ongoing, and they are continuing to evaluate the cardiac safety of omaveloxolone in patients with Friedreich's ataxia. They have not identified any other major safety concerns at this stage of their review.

During the mid-cycle meeting, we proposed to address FDA's concerns in three ways. First, we presented updated results from the Delayed-Start Analysis using a March 2022 data cut-off, which contain new, later time points and increased numbers of patients at later time points than the prior analysis. Second, we proposed to submit a new propensity-matched matched analysis of MOXIe Extension data using the largest, most robust Friedreich's ataxia natural history study to provide additional clinical data that could be considered confirmatory evidence. Third, we discussed an additional NDA amendment containing compelling mechanistic evidence in the setting of Friedreich's ataxia's well-understood disease pathophysiology, which could also serve as confirmatory evidence. The FDA acknowledged these data and agreed that we could submit the updated data to the NDA. We have submitted the following additional data and analyses to the FDA.

Results from March 2022 Data Cut-Off of MOXIe Extension

Results of the updated Delayed-Start Analysis from the March 2022 data cut-off demonstrated that the between-group difference in mFARS observed at the end of the placebo-controlled MOXIe Part 2 treatment period (LS mean difference = -2.17 ± 1.09) was preserved at MOXIe Extension Week 72 in the delayed-start period (LS mean difference = -2.91 ± 1.44). Consistent with a persistent treatment effect on disease, the upper limit of the 90% Confidence Interval ("CI") for the difference estimate was less than zero (-0.09), meeting the threshold for demonstrating significant evidence of non-inferiority. Additionally, the between group difference in mFARS was maintained at Extension Week 96, 120, and 144 (LS mean difference = -2.19 ± 1.38, -2.74 ± 1.26, and -2.58 ± 1.47 respectively), and the threshold for non-inferiority was met at Extension Week 120 with an upper limit of the 90% CI of -0.106.

Post Hoc Propensity-Matched Analysis of MOXIe Extension

We recently completed a post hoc analysis comparing the mFARS progression of omaveloxolone-treated patients in the open-label MOXIe Extension trial to the progression of propensity score-matched untreated patients in the largest natural history study of Friedreich's ataxia, Clinical Outcome Measures in Friedreich's ataxia ("FA-COMS"). All patients enrolled in the MOXIe Extension study with at least one post-baseline assessment (n=136) were matched one to one with patients from the FA-COMS study (n=136) using five baseline characteristics, or covariates, including sex, baseline age, age of Friedreich's ataxia onset, baseline mFARS score, and baseline gait score, which have been demonstrated to be predictive of disease progression. Demographics and baseline characteristics were highly comparable between MOXIe Extension patients and the matched FA-COMS external control group.

In the Primary Pooled Population (n=136 per group), patients in the matched FA-COMS group progressed 6.61 mFARS points at Year 3, whereas patients treated with omaveloxolone in MOXIe Extension progressed 3.00 points for a difference of -3.61 mFARS points (nominal p=0.0001). In this analysis, progression in mFARS was 55% slower in MOXIe Extension patients treated with omaveloxolone compared to matched untreated patients in the FA-COMS study.

Mechanistic Validation of Nrf2 Target Biomarkers in Friedreich's Ataxia

We have provided additional pharmacodynamic information to the FDA including an integrated and detailed presentation of the disease pathophysiology of Friedreich's ataxia, a review of the available pharmacodynamic data, justification of the relevance of these data in Friedreich's ataxia and an explanation of the relationship between the mechanistic data and the observed biomarker and clinical treatment effects in patients treated with omaveloxolone. Substantial evidence demonstrates that Nrf2 levels and activity are suppressed in cells from patients with Friedreich's ataxia and in preclinical animal models of the disease. Omaveloxolone restores Nrf2 levels and increases the expression of Nrf2 target genes, including those that encode ferritin and gamma-glutamyl transferase ("GGT"), in nonclinical models. Treatment with omaveloxolone in MOXIe Part 1 resulted in dose-dependent increases in Nrf2 activity, as assessed by serum ferritin and GGT levels. Data from MOXIe Part 2 showed an association between omaveloxolone-induced Nrf2 activity and measures of neurological function, with larger increases in Nrf2 target levels associated with larger improvements in mFARS scores.

"We look forward to continuing to work with FDA on its review of our NDA for omaveloxolone for the treatment of patients with Friedreich's ataxia, a rare, genetic, debilitating, and degenerative neuromuscular disorder with no approved therapies," said Warren Huff, Reata's Chief Executive Officer. "We have submitted these additional data and analyses to the FDA and are continuing to prepare for the upcoming Advisory Committee meeting."

Bardoxolone Methyl in Patients with Chronic Kidney Disease Caused by Alport Syndrome

We received a Complete Response Letter ("CRL") from the FDA in February 2022 with respect to its review of our NDA for bardoxolone methyl ("bardoxolone") in the treatment of patients with chronic kidney disease caused by Alport syndrome. The CRL indicated the FDA cannot approve the NDA in its present form. We have recently requested a Type C meeting to discuss the program and continue to work with the FDA to confirm our next steps on our Alport syndrome program.

Second Quarter Financial Highlights

Cash and Cash Equivalents

On June 30, 2022, we had cash and cash equivalents and marketable securities of $481.5 million, as compared to $590.3 million on December 31, 2021.

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 $39.3 million for the second quarter of 2022, as compared to $40.1 million for the same period of the year prior.

Non-GAAP R&D expenses were $33.0 million for the second quarter of 2022, as compared to $34.8 million, for the same period of the year prior.[1]

GAAP and Non-GAAP General and Administrative ("G&A") Expenses

GAAP G&A expenses were $25.1 million for the second quarter of 2022, as compared to $22.0 million, for the same period of the year prior.

Non-GAAP G&A expenses were $17.6 million for the second quarter of 2022, as compared to $14.0 million for the same period of the year prior.[1]

GAAP and Non-GAAP Net Loss

The GAAP net loss for the second quarter of 2022, was $73.6 million, or $2.02 per share, on both a basic and diluted basis, as compared to a GAAP net loss of $72.7 million, or $2.00 per share, on both a basic and diluted basis, for the same period of the year prior.

[1] 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.

The non-GAAP net loss for second quarter of 2022, was $49.4 million, or $1.36 per share on both a basic and diluted basis, as compared to a non-GAAP net loss of $48.0 million, or $1.32 per share, on both a basic and diluted basis, for the same period of the year prior.[1]

Cash Guidance

The Company reaffirms its existing cash & cash equivalents and marketable debt securities will be sufficient to enable it to fund operations through the end of 2024.

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, which exclude stock-based compensation expense; non-GAAP G&A expenses as GAAP G&A expenses, which exclude stock-based compensation expense; non-GAAP operating expenses as GAAP operating expenses, which exclude stock-based compensation expense; non-GAAP net loss as GAAP net loss, which excludes stock-based compensation expense 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, which excludes stock-based compensation expense and non-cash interest expense from liability related to sale of future royalties. 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 of stock options and restricted stock units and changes in the Company's stock price, which impact 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 stock-based compensation expense and non-cash interest expense from liability related to sale of future royalties 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 and non-cash interest expense from liability related to sales of future royalties, 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 8, 2022, at 8:30 am ET. The conference call will be accessible by dialing (844) 200-6205 (toll-free domestic) or (929) 526-1599 (international) using access code 964090. The webcast link is https://event.choruscall.com/mediaframe/webcast.html?webcastid=ai4Jk1V6.

Second quarter 2022 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 of the conference call will be accessible for at least 90 days after the event at https://www.reatapharma.com/investors/.

About Reata

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, omaveloxolone and bardoxolone, target the important transcription factor Nrf2 that promotes the resolution of inflammation by restoring mitochondrial function, reducing oxidative stress, and inhibiting pro-inflammatory signaling. **Omaveloxolone and bardoxolone 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 its Annual Report on Form 10-K for the fiscal year ended December 31, 2021, 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.

# # #

Contact:
Reata Pharmaceuticals, Inc.
(972) 865-2219
https://www.reatapharma.com/

Investor Relations & Media Relations:
John Hunter ir@reatapharma.com
Wendy Segal media@reatapharma.com
https://www.reatapharma.com/contact-us/

	Three Months Ended June 30		Six Months Ended June 30	
	2022	2021	2022	2021
Consolidated Statements of Operations	(unaudited) (in thousands, except share and per share data)			
Collaboration revenue				
License and milestone	$ 754	$ 803	$ 1,648	$ 1,598
Other revenue	8	1,418	29	1,568
Total collaboration revenue	762	2,221	1,677	3,166
Expenses				
Research and development	39,331	40,066	79,136	74,946
General and administrative	25,143	21,998	49,984	42,703
Depreciation	273	287	581	561
Total expenses	64,747	62,351	129,701	118,210
Other income (expense), net	(9,571)	(13,223)	(19,343)	(25,780)
Loss before taxes on income	(73,556)	(73,353)	(147,367)	(140,824)
Benefit from (provision for) taxes on income	1	653	(30)	669
Net loss	$ (73,555)	$ (72,700)	$ (147,397)	$ (140,155)
Net loss per share—basic and diluted	$ (2.02)	$ (2.00)	$ (4.04)	$ (3.87)
Weighted-average number of common shares used in net loss per share basic and diluted	36,467,802	36,299,735	36,440,364	36,251,948

	As of June 30, 2022	As of December 31, 2021
	(unaudited)	
	(in thousands)	
Condensed Consolidated Balance Sheet Data		
Cash and cash equivalents and marketable debt securities	$ 481,471	$ 590,258
Working capital	444,885	542,481
Operating lease right-of-use assets	129,159	126,777
Total assets	631,549	735,016
Liability related to sale of future royalties, net	382,290	362,142
Operating lease liabilities	142,512	136,033
Deferred revenue	-	1,648
Accumulated deficit	(1,403,028)	(1,255,631)
Total stockholders' equity	$ 68,636	$ 185,989

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):

	Three Months Ended June 30		Six Months Ended June 30	
	2022	2021	2022	2021
Reconciliation of GAAP to Non-GAAP Research and development:		(unaudited)		
GAAP Research and development	$ 39,331	$ 40,066	$ 79,136	$ 74,946
Less: Stock-based compensation expense	(6,344)	(5,263)	(13,951)	(12,071)
Non-GAAP Research and development	**$ 32,987**	**$ 34,803**	**$ 65,185**	**$ 62,875**
Reconciliation of GAAP to Non-GAAP General and administrative:				
GAAP General and administrative	$ 25,143	$ 21,998	$ 49,984	$ 42,703
Less: Stock-based compensation expense	(7,520)	(7,981)	(15,357)	(15,852)
Non-GAAP General and administrative	**$ 17,623**	**$ 14,017**	**$ 34,627**	**$ 26,851**
Reconciliation of GAAP to Non-GAAP Operating expenses:				
GAAP Operating expense	$ 64,747	$ 62,351	$ 129,701	$ 118,210
Less: Stock-based compensation expense	(13,864)	(13,244)	(29,308)	(27,923)
Non-GAAP Operating expense	**$ 50,883**	**$ 49,107**	**$ 100,393**	**$ 90,287**
Reconciliation of GAAP to Non-GAAP Net loss:				
GAAP Net loss	$ (73,555)	$ (72,700)	$ (147,397)	$ (140,155)
Add: Stock-based compensation expense	13,864	13,244	29,308	27,923
Add: Non-cash interest expense from liability related to sale of future royalties	10,277	11,429	20,148	22,354
Non-GAAP Net loss	**$ (49,414)**	**$ (48,027)**	**$ (97,941)**	**$ (89,878)**
Reconciliation of GAAP to Non-GAAP Net loss per common share-basic and diluted:				
GAAP Net loss per common share-basic and diluted	$ (2.02)	$ (2.00)	$ (4.04)	$ (3.87)
Add: Stock-based compensation expense	0.38	0.36	0.80	0.77
Add: Non-cash interest expense from liability related to sale of future royalties	0.28	0.32	0.55	0.62
Non-GAAP Net loss per common share-basic and diluted	**$ (1.36)**	**$ (1.32)**	**$ (2.69)**	**$ (2.48)**

	Three Months Ended			
	June 30, 2022	March 31, 2022	December 31, 2021	September 30, 2021
Reconciliation of GAAP to Non-GAAP Operating expenses			(unaudited)	
GAAP Operating expenses	$ 64,747	$ 64,953	$ 72,503	$ 65,486
Less: Stock-based compensation expense	(13,864)	(15,444)	(15,226)	(13,657)
Non - GAAP Operating expenses	**$ 50,883**	**$ 49,509**	**$ 57,277**	**$ 51,829**
Reconciliation of GAAP to Non-GAAP Net loss				
GAAP Net loss	$ (73,555)	$ (73,842)	$ (85,385)	$ (71,846)
Add: Stock-based compensation expense	13,864	15,444	15,226	13,657
Add: Non-cash interest expense from liability related to sale of future royalties	10,277	9,871	12,376	11,958
Non-GAAP Net loss	**$ (49,414)**	**$ (48,527)**	**$ (57,783)**	**$ (46,231)**