



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

NDA FOR OMAVELOXOLONE FOR PATIENTS WITH FRIEDREICH'S ATAXIA UNDER REVIEW WITH PDUFA DATE OF FEBRUARY 28, 2023

FDA DOES NOT PLAN TO HOLD AN ADVISORY COMMITTEE MEETING TO DISCUSS THE OMAVELOXOLONE NDA AND THE LATE CYCLE MEETING HAS BEEN COMPLETED

PROVIDES UPDATE ON COMMERCIAL PREPARATION

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

PLANO, Texas—November 8, 2022 (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 third 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

In May 2022, the U.S. Food and Drug Administration (“FDA”) accepted our New Drug Application (“NDA”) for filing and granted Priority Review for omaveloxolone for patients with Friedreich’s ataxia. We completed a Mid-Cycle Communication Meeting with the FDA and submitted additional data and analyses to the FDA after the meeting. The FDA determined that these submissions were a major amendment to our NDA and extended the Prescription Drug User Fee Act (“PDUFA”) date by three months to provide time for a full review of the new data and analyses. The PDUFA date is now February 28, 2023.

We recently completed a Late-Cycle Meeting with the FDA. The purpose of the Late-Cycle Meeting is for the FDA to discuss any substantive issues identified, and the Division’s objectives for the remainder of the review. The meeting does not address the final regulatory decision for the NDA. While we have not received formal minutes from the FDA, in the preliminary agenda for, and during, the Late-Cycle Meeting, the FDA stated that they continue to review the analyses and data included in the recent NDA submissions. The FDA made no request for additional data or analyses but stated that additional data may be requested as reviews are ongoing. The FDA confirmed that no information requests were outstanding. The FDA reiterated that they do not currently plan to hold an advisory committee meeting.

The FDA stated that no issues related to risk management have been identified to date. During the meeting, the FDA indicated that post-marketing requirements and label review are ongoing. With respect to post-marketing requirements and commitments, FDA stated that if omaveloxolone is approved, they anticipate requiring a drug-drug interaction trial

with CYP3A4 modulators, a thorough QT trial, and an evaluation of pregnancy outcomes. FDA stated that other post-marketing requirements and commitments may be considered depending on the findings of the review. With respect to label review, during the meeting we noted that the original proposed label language did not reflect the data and analyses included in the amendments to the NDA and that we have updated it in connection with the planned filing of our Marketing Authorization Application (“MAA”) in Europe later this year. We committed to submit the updated proposed label language to the NDA. The FDA indicated that post-marketing requirements and label comments will be communicated in early in 2023.

We have advanced our commercial launch preparations in the United States and are building the infrastructure necessary to support the commercialization of omaveloxolone for the treatment of Friedreich’s ataxia, if and when we receive regulatory approval. We have designed our patient access programs and our product distribution network. The payer field team has been hired and deployed. Hiring of the sales leadership team is underway and we intend to onboard our sales organization and reimbursement specialists in the first quarter of 2023, pending regulatory advancement.

We plan to submit an MAA to the European Medicines Agency (“EMA”) for omaveloxolone this year.

Third Quarter Financial Highlights

Cash and Cash Equivalents

On September 30, 2022, we had cash and cash equivalents and marketable securities of \$435.9 million, as compared to \$590.3 million of cash and cash equivalents 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 \$43.5 million for the third quarter of 2022, as compared to \$39.4 million for the same period of the year prior.

Non-GAAP R&D expenses were \$36.8 million for the third quarter of 2022, as compared to \$34.0 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 \$27.3 million for the third quarter of 2022, as compared to \$25.7 million, for the same period of the year prior.

Non-GAAP G&A expenses were \$19.5 million for the third quarter of 2022, as compared to \$17.5 million for the same period of the year prior.¹

GAAP and Non-GAAP Net Loss



The GAAP net loss for the third quarter of 2022, was \$79.0 million, or \$2.16 per share, on both a basic and diluted basis, as compared to a GAAP net loss of \$71.8 million, or \$1.97 per share, on both a basic and diluted basis, for the same period of the year prior.

The non-GAAP net loss for the third quarter of 2022, was \$53.9 million, or \$1.47 per share on both a basic and diluted basis, as compared to a non-GAAP net loss of \$46.2 million, or \$1.27 per share, on both a basic and diluted basis, for the same period of the year prior.¹

⁽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.

Cash Guidance

The Company reaffirms that its existing cash and 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, 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 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, excluding 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 November 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 756839. The webcast link is <https://events.q4inc.com/attendee/378624120>.

Third quarter 2022 financial results to be discussed during the call 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.

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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 September 30		Nine Months Ended September 30	
	2022	2021	2022	2021
Consolidated Statements of Operations				
(unaudited)				
(in thousands, except share and per share data)				
Collaboration revenue				
License and milestone	\$ -	\$ 5,529	\$ 1,648	\$ 7,127
Other revenue	540	1,862	568	3,430
Total collaboration revenue	540	7,391	2,216	10,557
Expenses				
Research and development	43,485	39,430	122,620	114,377
General and administrative	27,270	25,736	77,254	68,440
Depreciation	272	320	853	880
Total expenses	71,027	65,486	200,727	183,697
Other income (expense), net	(8,515)	(13,751)	(27,858)	(39,530)
Loss before taxes on income	(79,002)	(71,846)	(226,369)	(212,670)
Benefit from (provision for) taxes on income	-	-	(30)	669
Net loss	\$ (79,002)	\$ (71,846)	\$ (226,399)	\$ (212,001)
Net loss per share—basic and diluted	\$ (2.16)	\$ (1.97)	\$ (6.21)	\$ (5.84)
Weighted-average number of common shares used in net loss per share basic and diluted	36,536,919	36,387,560	36,472,903	36,297,766

	As of September 30, 2022		As of December 31, 2021	
	(unaudited)			
(in thousands)				
Condensed Consolidated Balance Sheet Data				
Cash and cash equivalents and marketable debt securities	\$	435,875	\$	590,258
Working capital		394,393		542,481
Operating lease right-of-use assets		127,135		126,777
Total assets		583,644		735,016
Liability related to sale of future royalties, net		392,953		362,142
Operating lease liabilities		140,713		136,033
Deferred revenue		-		1,648
Accumulated deficit		(1,482,030)		(1,255,631)
Total stockholders' equity	\$	4,516	\$	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 September 30		Nine Months Ended September 30	
	2022	2021	2022	2021
Reconciliation of GAAP to Non-GAAP Research and development:				
	(unaudited)			
GAAP Research and development	\$ 43,485	\$ 39,430	\$ 122,620	\$ 114,377
Less: Stock-based compensation expense	(6,684)	(5,403)	(20,635)	(17,474)
Non-GAAP Research and development	<u>\$ 36,801</u>	<u>\$ 34,027</u>	<u>\$ 101,985</u>	<u>\$ 96,903</u>
Reconciliation of GAAP to Non-GAAP General and administrative:				
GAAP General and administrative	\$ 27,270	\$ 25,736	\$ 77,254	\$ 68,440
Less: Stock-based compensation expense	(7,762)	(8,254)	(23,119)	(24,106)
Non-GAAP General and administrative	<u>\$ 19,508</u>	<u>\$ 17,482</u>	<u>\$ 54,135</u>	<u>\$ 44,334</u>
Reconciliation of GAAP to Non-GAAP Operating expenses:				
GAAP Operating expense	\$ 71,027	\$ 65,486	\$ 200,727	\$ 183,697
Less: Stock-based compensation expense	(14,446)	(13,657)	(43,754)	(41,580)
Non-GAAP Operating expense	<u>\$ 56,581</u>	<u>\$ 51,829</u>	<u>\$ 156,973</u>	<u>\$ 142,117</u>
Reconciliation of GAAP to Non-GAAP Net loss:				
GAAP Net loss	\$ (79,002)	\$ (71,846)	\$ (226,399)	\$ (212,001)
Add: Stock-based compensation expense	14,446	13,657	43,754	41,580
Add: Non-cash interest expense from liability related to sale of future royalties	10,664	11,958	30,812	34,312
Non-GAAP Net loss	<u>\$ (53,892)</u>	<u>\$ (46,231)</u>	<u>\$ (151,833)</u>	<u>\$ (136,109)</u>
Reconciliation of GAAP to Non-GAAP Net loss per common share-basic and diluted:				
GAAP Net loss per common share-basic and diluted	\$ (2.16)	\$ (1.97)	\$ (6.21)	\$ (5.84)
Add: Stock-based compensation expense	0.40	0.38	1.20	1.15
Add: Non-cash interest expense from liability related to sale of future royalties	0.29	0.32	0.84	0.94
Non-GAAP Net loss per common share-basic and diluted	<u>\$ (1.47)</u>	<u>\$ (1.27)</u>	<u>\$ (4.17)</u>	<u>\$ (3.75)</u>

	Three Months Ended			
	September 30, 2022	June 30, 2022	March 31, 2022	December 31, 2021
(unaudited)				
Reconciliation of GAAP to Non-GAAP Operating expenses				
GAAP Operating expenses	\$ 71,027	\$ 64,747	\$ 64,953	\$ 72,503
Less: Stock-based compensation expense	(14,446)	(13,864)	(15,444)	(15,226)
Non - GAAP Operating expenses	<u>\$ 56,581</u>	<u>\$ 50,883</u>	<u>\$ 49,509</u>	<u>\$ 57,277</u>
Reconciliation of GAAP to Non-GAAP Net loss				
GAAP Net loss	\$ (79,002)	\$ (73,555)	\$ (73,842)	\$ (85,385)
Add: Stock-based compensation expense	14,446	13,864	15,444	15,226
Add: Non-cash interest expense from liability related to sale of future royalties	10,664	10,277	9,871	12,376
Non-GAAP Net loss	<u>\$ (53,892)</u>	<u>\$ (49,414)</u>	<u>\$ (48,527)</u>	<u>\$ (57,783)</u>