IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS

_____, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. REATA PHARMACEUTICALS, INC., J. WARREN HUFF, and MANMEET S. SONI, Defendants,	Case No. 4:21-cv-00987 **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**

Plaintiff _____ ("Plaintiff"), individually and on behalf of all others similarly situated, by and through his attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, his counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Reata Pharmaceuticals, Inc. ("Reata" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Reata; and (c) review of other publicly available information concerning Reata.

NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired Reata securities, and/or sold Reata put options, between November 9, 2020 and December 8, 2021, inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Reata is a clinical-stage biopharmaceutical company that focuses on small-molecule therapeutics. One of its two lead product candidates is bardoxolone methyl ("bardoxolone"), which is being developed for multiple indications, including chronic kidney disease caused by Alport syndrome.

3. On March 1, 2021, Reata announced that it had submitted its New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for bardoxolone as a treatment of chronic kidney disease ("CKD") caused by Alport syndrome ("AS"). The Phase 3 CARDINAL study was purportedly designed to measure the efficacy and safety of bardoxolone. The primary endpoint for Year 2 was the change from baseline in estimated glomerular filtration rate ("eGFR")

after 100 weeks of treatment (end-of-treatment). The key secondary endpoint for Year 2 was the change from baseline in eGFR at Week 104 (four weeks after last dose in second year of treatment).

4. On December 6, 2021, the FDA released briefing documents in advance of an Advisory Committee meeting for the Company's NDA for bardoxolone, stating that throughout the clinical development, the agency had repeatedly questioned the validity of Reata's study design because bardoxolone's pharmacodynamic effect on kidney function would make the results difficult to assess the effectiveness of the drug. Though the FDA agreed that Reata's Phase 3 study met its endpoints, "the FDA review team d[id] not believe the submitted data demonstrate that bardoxolone is effective in slowing the loss of kidney function in patients with AS and reducing the risk of progression to kidney failure."

5. On this news, the Company's stock price fell $29.77, or 38%, to close at $48.92 per share on December 6, 2021, on unusually heavy trading volume.

6. Then, on December 8, 2021, the FDA's Advisory Committee unanimously decided that bardoxolone was not effective based on the submitted data.

7. On this news, the Company's stock price fell $25.31, or 46%, to close at $29.11 per share on December 9, 2021, on unusually heavy trading volume.

8. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that the FDA had raised concerns regarding the validity of the clinical study designed to measure the efficacy and safety of bardoxolone for the treatment of chronic kidney disease caused by Alport syndrome; (2) that, as a result, there was a material risk that Reata's NDA would not be approved; and (3)

that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

9. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

10. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

12. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. In addition, the Company's principal executive offices are in this District.

13. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

14. Plaintiff _____, as set forth in the accompanying certification, incorporated by reference herein, purchased Reata securities during the Class Period, and suffered damages as a

result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

15. Defendant Reata is incorporated under the laws of Delaware with its principal executive offices located in Plano, Texas. Reata's Class A common stock trades on the NASDAQ exchange under the symbol "RETA."

16. Defendant J. Warren Huff ("Huff") was the Company's Chief Executive Officer ("CEO") at all relevant times.

17. Defendant Manmeet S. Soni ("Soni") was the Company's Chief Financial Officer ("CFO") at all relevant times.

18. Defendants Huff and Soni (collectively the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

19. Reata is a clinical-stage biopharmaceutical company that focuses on small-molecule therapeutics. One of its two lead product candidates is bardoxolone methyl

("bardoxolone"), which is being developed for multiple indications, including chronic kidney disease caused by Alport syndrome.

Materially False and Misleading

Statements Issued During the Class Period

20. The Class Period begins on November 9, 2020. On that day, Reata announced the results from Year 2 of the Phase 3 CARDINAL study in a press release that stated, in relevant part:

> Reata Pharmaceuticals, Inc. (Nasdaq:RETA) ("Reata" or the "Company," or "we"), a clinical-stage biopharmaceutical company, today announced that the ***Phase 3 CARDINAL study of bardoxolone methyl ("bardoxolone") in patients with chronic kidney disease ("CKD") caused by Alport syndrome met its primary and key secondary endpoints at the end of Year 2.*** At Week 100, in the intent-to-treat ("ITT") population, which included estimated glomerular filtration rate ("eGFR") values for patients who either remained on or discontinued study drug, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean change from baseline in eGFR of 7.7 mL/min/1.73 m2 (p=0.0005). In the modified ITT ("mITT") analysis, which assessed the effect of receiving treatment by excluding values after patients discontinued treatment, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean change from baseline in eGFR at Week 100 of 11.3 mL/min/1.73 m2 (p<0.0001). At Week 104 (four weeks after last dose in second year of treatment), patients in the ITT population treated with bardoxolone had a statistically significant improvement compared to placebo in mean change from baseline in eGFR of 4.3 mL/min/1.73 m2 (p=0.023). Bardoxolone treatment was generally reported to be well-tolerated. In the long-term extension study ("EAGLE"), for the 14 patients who completed three years of treatment, bardoxolone treatment resulted in a mean increase from baseline in eGFR of 11.0 mL/min/1.73 m2. ***Based on these positive results and following a recently completed pre-NDA meeting with the U.S. Food and Drug Administration ("FDA"), we plan to proceed with the submission of an NDA for full marketing approval in the United States in the first quarter of 2021.*** We also plan to pursue marketing approval outside of the United States and work has commenced on preparations to file for marketing approval in Europe.
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> * * *
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> "Chronic kidney disease caused by Alport syndrome is a serious, progressive disease with an urgent need for new therapeutic options. ***The two-year CARDINAL study, now complete, represents the first time that an investigational medicine has shown a significant clinical benefit in this disease***, and it marks an important step toward making a treatment available for patients with Alport syndrome. We look forward to submitting our New Drug Application for

bardoxolone in the first quarter of 2021. On behalf of everyone at Reata, I would like to express my sincere appreciation to all of the patients, families, and investigators who participated in the CARDINAL study," said Warren Huff, Reata's President and Chief Executive Officer.

* * *

In rare forms of CKD, the FDA has accepted the off-treatment endpoint as the basis for approval. Withdrawal of drug after long-term treatment provides evidence whether a drug either protected or harmed the kidney during treatment. If off-treatment changes in eGFR are higher than placebo, this is evidence that the drug protected the kidney during treatment, and, if off-treatment changes in eGFR are lower than placebo, this is evidence that the drug harmed the kidney during treatment. ***An off-treatment eGFR benefit relative to placebo provides evidence that drug treatment may delay kidney failure.***

21. Also on November 9, 2020, the Company filed its quarterly report on Form 10-Q for the period ended September 30, 2020, stating in relevant part:

Bardoxolone for CKD Caused by Alport Syndrome

On November 9, 2020, we announced that the ***Phase 3 CARDINAL study of bardoxolone in patients with CKD caused by Alport syndrome met its primary and key secondary endpoints at the end of Year 2.*** At Week 100, in the intent-to-treat (ITT) population, which included eGFR values for patients who either remained on or have discontinued study drug, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean change from baseline in estimated glomerular filtration rate (eGFR) of 7.7 mL/min/1.73 m2 (p=0.0005). In the modified ITT (mITT) analysis, which assessed the effect of receiving treatment by excluding values after patients discontinued treatment, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean change from baseline in eGFR at Week 100 of 11.3 mL/min/1.73 m2 (p<0.0001). At Week 104 (four weeks after last dose in second year of treatment), patients in the ITT population treated with bardoxolone had a statistically significant improvement compared to placebo in mean change from baseline in eGFR of 4.3 mL/min/1.73 m2 (p=0.023). Bardoxolone treatment was generally reported to be well-tolerated. ***Based on these positive results and following a recently completed pre-NDA meeting with the U.S. Food and Drug Administration (FDA), we plan to proceed with the submission of an NDA for full marketing approval in the United States in the first quarter of 2021.*** We also plan to pursue marketing approval outside of the United States and work has commenced on preparations to file for marketing approval in Europe.

22. On March 1, 2021, Reata announced that it had submitted its NDA for bardoxolone as a treatment of chronic kidney disease caused by Alport syndrome. The Company's press release stated, in relevant part:

> Reata Pharmaceuticals, Inc. (Nasdaq: RETA) ("Reata," the "Company," or "we"), a clinical-stage biopharmaceutical company, today announced that it has submitted a New Drug Application ("NDA") for bardoxolone methyl ("bardoxolone") for the treatment of chronic kidney disease ("CKD") caused by Alport syndrome to the U.S. Food and Drug Administration ("FDA").
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> ***This NDA submission is based on the efficacy and safety data from the CARDINAL Phase 3 clinical trial.*** The submission includes a request for Priority Review, which, if granted, would shorten the FDA's review of the NDA to eight months from the time of submission, versus a standard review timeline of 12 months. ***If approved, bardoxolone would become the first therapy specifically indicated for the treatment of CKD caused by Alport syndrome.***
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> "This NDA submission marks an important step toward making a treatment available for patients with Alport syndrome, a serious, progressive disease with an urgent need for new therapeutic options," said Warren Huff, Reata's President and Chief Executive Officer. "I want to thank all those who made this moment possible, especially Alport syndrome patients and their families. We look forward to next steps on the path to making bardoxolone available as a first-in-class therapy for Alport syndrome, pending NDA acceptance, review, and drug approval."

23. Also on March 1, 2021, Reata filed its annual report on Form 10-K for the period ended December 31, 2020. Regarding risks impacting regulatory approval of any of its product candidates, Reata stated, in relevant part:

> ***The clinical and commercial success of bardoxolone and omaveloxolone will depend on a number of factors, many of which are beyond our control.***
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> The clinical and commercial success of bardoxolone and omaveloxolone will depend on a number of factors, including the following, many of which are beyond our control:
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> - the timely initiation, continuation, and completion of our Phase 2 and Phase 3 clinical trials for bardoxolone and omaveloxolone, which will depend substantially upon requirements for such trials imposed by the FDA and other regulatory agencies and bodies;
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> - our ability to demonstrate the safety and efficacy of our product candidates to the satisfaction of the relevant regulatory authorities;

- whether the FDA or other regulatory authorities will accept NDAs for approval of our product candidates;

- whether we are required by the FDA or other regulatory authorities to conduct additional clinical trials, and the scope and nature of such clinical trials, prior to approval to market our products;

- the timely receipt of necessary marketing approvals from the FDA and foreign regulatory authorities, including pricing and reimbursement determinations;

- the ability to successfully commercialize our product candidates for marketing and sale, if approved by the FDA or foreign regulatory authorities, whether alone or in collaboration with others;

- our ability and the ability of third-party manufacturers to manufacture the quantities of our product candidates with quality attributes necessary to meet regulatory requirements and at a scale and yield sufficient to meet anticipated demand at a cost that allows us to achieve profitability;

- our success in educating health care providers and patients about the benefits, risks, administration, and use of our product candidates, if approved;

- acceptance of our product candidates, if approved, as safe and effective by patients and the healthcare community;

- the achievement and maintenance of compliance with all regulatory requirements applicable to our product candidates, our third-party manufacturers, and our internal operations;

- the maintenance of an acceptable safety profile of our products, if any, following any approval;

- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competitive treatments;

- our ability to provide approved product with a convenient and patient-friendly capsule configuration;

- our ability to successfully enforce our intellectual property rights for our product candidates and against the products of potential competitors; and

- our ability to avoid or succeed in third-party patent interference or patent infringement claims.

> We cannot assure you that we will ever be able to achieve profitability through the sale of, or royalties from, our product candidates. If we or our collaborators are not successful in obtaining approval for and commercializing our product candidates, or are delayed in completing those efforts, our business and operations would be adversely affected.

24. On April 26, 2021, Reata announced that the FDA had accepted the NDA submission and set an action date for February 25, 2022. Its press release stated, in relevant part:

> Reata Pharmaceuticals, Inc. (Nasdaq: RETA) ("Reata," the "Company," or "we"), a clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration ("FDA") accepted for filing the New Drug Application ("NDA") for bardoxolone methyl ("bardoxolone") for the treatment of patients with chronic kidney disease ("CKD") caused by Alport syndrome.
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> ***This NDA submission is based on the efficacy and safety data from the CARDINAL Phase 3 clinical trial.*** The FDA will review the application under a Standard Review timeline. The Prescription Drug User Fee Act ("PDUFA") date, the FDA action date for the application, is scheduled for February 25, 2022. The FDA also advised the Company that it is currently planning to hold an Advisory Committee meeting to discuss the application.
>
> "We are pleased with the FDA's decision to accept for filing our NDA for bardoxolone and look forward to continuing to work with the Division during the review process," said Warren Huff, Reata's President and Chief Executive Officer. "Alport syndrome is one of the most rapidly progressive forms of CKD and a truly devastating disease to those patients and the families who are affected by it. ***If approved, bardoxolone may be the first therapy to slow the progression of kidney disease in patients with this serious and debilitating disease.***"

25. On May 6, 2021, Reata announced its first quarter 2021 financial results and provided an update on its clinical development programs. The press release stated, among other things:

> **Recent Company Highlights**
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> *Bardoxolone Methyl ("Bardoxolone") in Patients with Alport Syndrome*
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> In April 2021, we announced that the U.S. Food and Drug Administration ("FDA") accepted for filing Reata's New Drug Application ("NDA") for bardoxolone for the treatment of patients with chronic kidney disease ("CKD") caused by Alport syndrome. The FDA will review the application under a Standard Review timeline. The Prescription Drug User Fee Act ("PDUFA") date, the FDA action date for the application, is scheduled for February 25, 2022. ***The FDA also advised us that it is***

currently planning to hold an Advisory Committee meeting to discuss the application. If approved, bardoxolone may become the first therapy specifically indicated for the treatment of CKD caused by Alport syndrome.

"We made significant progress during the first quarter of 2021 with the submission of our NDA for bardoxolone for the treatment of CKD caused by Alport syndrome coming less than four months after reporting positive results from Year 2 of our Phase 3 CARDINAL trial," said Warren Huff, Reata's President and Chief Executive Officer. "Alport syndrome is a devastating disease that affects 30,000 to 60,000 patients in the United States. We are pleased with the FDA's recent decision to accept our application for filing and look forward to continuing to work with the FDA during its review of our application."

26. On May 6, 2021, Reata filed its quarterly report on Form 10-Q for the period ended March 31, 2021, stating in relevant part:

Bardoxolone in Patients with CKD Caused by Alport Syndrome

On April 26, 2021, we announced that the U.S. Food and Drug Administration (FDA) accepted for filing the New Drug Application (NDA) for bardoxolone for the treatment of patients with CKD caused by Alport syndrome. The FDA will review the application under a Standard Review timeline. The Prescription Drug User Fee Act (PDUFA) date, the FDA action date for the application, is scheduled for February 25, 2022. The FDA also advised us that it is currently planning to hold an Advisory Committee meeting to discuss the application.

Our NDA submission was based on the results of Year 2 of the Phase 3 CARDINAL study of bardoxolone in patients with CKD caused by Alport syndrome announced in November 2020. The study met its primary and key secondary endpoints following two years of treatment (referred to as Year 2). Moreover, we also announced that patients who completed one year in the EAGLE long-term extension study and were treated with bardoxolone for a total of three years (n=14) showed a sustained and significant increase from baseline in estimated glomerular filtration rate (eGFR). ***Together, these data suggest that bardoxolone treatment has beneficial long-term effects on kidney function in patients with Alport syndrome.***

27. On August 9, 2021, Reata announced its second quarter 2021 financial results and provided an update on its clinical development programs. The press release stated that, during a mid-cycle communication meeting about the NDA, the FDA had "identified four significant clinical and statistical review issues" for Reata to address. Specifically, the Company stated:

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.

28. On August 9, 2021, Reata filed its quarterly report on Form 10-Q for the period ended June 30, 2021, stating in relevant part:

Bardoxolone in Patients with CKD Caused by Alport Syndrome

On April 26, 2021, we announced that the U.S. Food and Drug Administration (FDA) accepted for filing the NDA for bardoxolone for the treatment of patients with CKD caused by Alport syndrome, and the NDA 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. We believe each of these issues are addressable with additional data and analyses, and the FDA invited us to address its identified issues in follow-up submissions to the NDA.*** We plan to address each of the issues through the submission of additional data and analyses to the NDA. See *Programs in Chronic Kidney Disease – Bardoxolone in Patients with CKD Caused by Alport Syndrome below*.

The FDA made additional information requests and identified a few additional issues that were not deemed significant. 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. We were notified that we would be receiving comments in writing regarding Chemistry, Manufacturing, and Controls (CMC), and we will not be receiving any nonclinical comments. 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.

29. The above statements identified in ¶¶ 20-28 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that the FDA had raised concerns regarding the validity of the clinical study designed to measure the efficacy and safety of bardoxolone for the treatment of chronic kidney disease caused by Alport syndrome; (2) that, as a result, there was a material risk that Reata's NDA would not be approved; and (3) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

Disclosures at the End of the Class Period

30. On December 6, 2021, the FDA released briefing documents in advance of an Advisory Committee meeting for the Company's NDA for bardoxolone, stating that the agency had repeatedly questioned the validity of Reata's study design because bardoxolone's pharmacodynamic effect on kidney function would make the results difficult to assess the effectiveness of the drug. Specifically, the briefing document noted that, "[i]n September 2018, FDA encouraged [Reata] to request an end-of-phase 2 meeting to discuss the development program and ensure alignment," but Reata declined. Then, in February 2019, the FDA "emphasized the importance of obtaining FDA concurrence that a study intended to support a marketing application was adequate and acceptable for this purpose." The briefing document detailed the concerns the FDA had raised with Reata during the course of the clinical studies and NDA submission:

- *Bardoxolone's pharmacodynamic effect on eGFR and assessing for effects on disease progression*: At a preIND meeting held in October 2016, the Division indicated that because of bardoxolone's pharmacodynamic effect on kidney function, on-treatment assessments of kidney function would be difficult to interpret as a drug effect on disease progression. As such, a post-treatment assessment of creatinine should be used to assess bardoxolone's efficacy in treating the disease. Following submission of the IND in 2016, ***the Agency repeatedly voiced concerns about the time-course for resolution of bardoxolone's pharmacodynamic effect on creatinine/eGFR***

following discontinuation of treatment and whether the off-treatment values collected in CARDINAL Phase 3 were in fact capturing an effect on disease progression. The Agency ultimately recommended that the Applicant conduct a separate study to characterize the time course for resolution of bardoxolone's pharmacodynamic effect or modify CARDINAL Phase 3 to obtain the information (i.e., revise the protocol to include additional off-treatment eGFR measurements).

- *Accelerated Approval*: In January and September 2020, the Applicant met with Agency to discuss submission of an NDA for bardoxolone under the accelerated approval pathway based primarily on the Year 1 data on eGFR from CARDINAL Phase 3. ***The Division did not agree with the proposed approach, voicing concerns about the interpretability of the eGFR findings given the available information on the time course for resolution of bardoxolone's pharmacodynamic effect, as well as the amount of missing data in the bardoxolone arm and lack of clarity on how patients with missing data were handled in key analyses intended to disentangle the drug's pharmacodynamic effect on kidney function from its effect on the irreversible loss of kidney function.***

- *Bardoxolone's effects on blood pressure and albuminuria*: At the January and September 2020 meetings with the Applicant, the Agency voiced concern about bardoxolone's effects on blood pressure and albuminuria and whether, over the long term, these effects could accelerate progression to kidney failure.

- *Trial integrity*: In November 2020, the Applicant submitted an addendum to their SAP dated October 30, 2020, and an amended Data Access Plan dated August 28, 2020 for CARDINAL Phase 3. In its December 2020 response to the submission, the Agency expressed concern about the number of individuals with access to patient-level clinical data and individual treatment assignments following the interim analysis of data from Year 1, as well as the late changes to the study's SAP, and provided specific recommendations on additional information and analyses that should be included in the Applicant's marketing application to address the integrity of the trial data. [Footnote omitted.]

31. Though the FDA agreed that Reata's Phase 3 study met its endpoints, "the FDA review team d[id] not believe the submitted data demonstrate that bardoxolone is effective in slowing the loss of kidney function in patients with AS and reducing the risk of progression to kidney failure." Among other things, the FDA noted that a "treatment can have both reversible [pharmacodynamic] effects on kidney function as well as change the trajectory of the decline in

kidney function . . . , but it can be difficult to tease apart the contribution of each component in trials with short treatment duration and/or when off-treatment measurements of eGFR are obtained before the pharmacodynamic effect on eGFR has fully reversed." It further stated:

> The CARDINAL Phase 3 study consisted of two years of longitudinal on-treatment eGFR assessments with two 4-week washout periods, after Year 1 and Year 2, respectively. The time-course of eGFR changes in the bardoxolone and placebo groups is shown in Figure 4 [omitted]. eGFR increased compared to placebo while on treatment at Week 48 and Week 100, as evaluated by the primary efficacy endpoint; however, eGFR decreased during each of the 4-week washout periods, suggesting that the on-treatment increase in eGFR was, at least in part, a result of the reversible PD effect of bardoxolone on eGFR. If the duration of the washout was long enough to eliminate the reversible PD effect on eGFR, then changes in eGFR compared with placebo at the end of the Year-2 washout period could indicate bardoxolone's effect on slowing disease progression. ***A key issue was to determine if the study's 4-week washout was long enough for the reversible PD effect on eGFR to have resolved.***
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> [Reata] has justified the 4-week washout in CARDINAL Phase 3 based on: various pooled analyses of patients across studies with eGFR measurements collected up to 42 days off-treatment; off-treatment eGFR measurements for studies in patients with CKD with treatment duration ≤8 weeks; the pharmacokinetic (PK) profile of bardoxolone; exposure-response modeling; and time to return to baseline of other PD markers, such as liver enzymes. ***The FDA has not found these justifications compelling to support the adequacy of a 4-week washout in patients with AS***, as described in Appendix 6.4.

32. On this news, the Company's stock price fell $29.77, or 38%, to close at $48.92 per share on December 6, 2021, on unusually heavy trading volume.

33. Then, on December 8, 2021, the FDA's Advisory Committee unanimously decided that bardoxolone was not effective based on the submitted data.

34. On this news, the Company's stock price fell $25.31, or 46%, to close at $29.11 per share on December 9, 2021, on unusually heavy trading volume.

CLASS ACTION ALLEGATIONS

35. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased

or otherwise acquired Reata securities, and/or sold Reata put options, between November 9, 2020 and December 8, 2021, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

36. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Reata's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of Reata shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Reata or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

37. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

38. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

39. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Reata; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

40. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

UNDISCLOSED ADVERSE FACTS

41. The market for Reata's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Reata's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Reata's securities relying upon the integrity of the market price of the Company's securities and market information relating to Reata, and have been damaged thereby.

42. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Reata's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or

misleading because they failed to disclose material adverse information and/or misrepresented the truth about Reata's business, operations, and prospects as alleged herein.

43. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Reata's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

44. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

45. During the Class Period, Plaintiff and the Class purchased Reata's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS

46. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were

materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Reata, their control over, and/or receipt and/or modification of Reata's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Reata, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE

(FRAUD-ON-THE-MARKET DOCTRINE)

47. The market for Reata's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Reata's securities traded at artificially inflated prices during the Class Period. On November 10, 2020, the Company's share price closed at a Class Period high of $184.62 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Reata's securities and market information relating to Reata, and have been damaged thereby.

48. During the Class Period, the artificial inflation of Reata's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Reata's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Reata and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all

relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

49. At all relevant times, the market for Reata's securities was an efficient market for the following reasons, among others:

(a) Reata shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Reata filed periodic public reports with the SEC and/or the NASDAQ;

(c) Reata regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Reata was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

50. As a result of the foregoing, the market for Reata's securities promptly digested current information regarding Reata from all publicly available sources and reflected such information in Reata's share price. Under these circumstances, all purchasers of Reata's securities during the Class Period suffered similar injury through their purchase of Reata's securities at artificially inflated prices and a presumption of reliance applies.

51. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

52. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Reata who knew that the statement was false when made.

FIRST CLAIM

Violation of Section 10(b) of The Exchange Act and

Rule 10b-5 Promulgated Thereunder

Against All Defendants

53. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

54. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Reata's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

55. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Reata's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

56. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Reata's financial well-being and prospects, as specified herein.

57. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Reata's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Reata and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

58. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

59. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to

ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Reata's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

60. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Reata's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Reata's securities during the Class Period at artificially high prices and were damaged thereby.

61. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Reata was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Reata securities, or, if they had

acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

62. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

63. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM

Violation of Section 20(a) of The Exchange Act

Against the Individual Defendants

64. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

65. Individual Defendants acted as controlling persons of Reata within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

66. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

67. As set forth above, Reata and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.