UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS

TIM DOYLE, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. REATA PHARMACEUTICALS, INC., J. WARREN HUFF, MANMEET S. SONI, and COLIN J. MEYER, Defendants.	Case No. 4:21-cv-00987-ALM LEAD CLASS ACTION **CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

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TABLE OF DEFINED TERMS

Term	Meaning
10-14 Day Washout Representations	Representations that bardoxolone ("Bard") and/or its pharmacodynamic ("PD") effects on estimated glomerular filtration rate ("eGFR") were fully washed out within fourteen (14) days after stopping treatment
2019 Offering	November 14, 2019 secondary public offering of 2.76 million shares (following underwriters' full exercise of the over-allotment option) of Reata common stock at $183.00 per share
2019 Offering Documents	Shelf Registration Statement, 2019 Offering ProSupp, and 2019 Offering Incorporated Documents
2019 Offering Incorporated Documents	2018 10-K, Q1 2019 10-Q, Q2 2019 10-Q, Q3 2019 10-Q, and Form 8-K filed with the SEC on November 12, 2019
2019 Offering ProSupp	Prospectus supplement filed with the U.S. Securities Exchange Commission ("SEC") on Form 424B5, dated November 13, 2019
2019 Offering Underwriter Defendants	Defendants Citigroup, Jefferies, Leerink, Stifel, Baird, Cantor, and LT&Co
2020 Offering	December 1, 2020 secondary public offering of 2.0 million shares of Reata common stock at $140.85 per share
2020 Offering Documents	Shelf Registration Statement, 2020 Offering ProSupp, and 2020 Offering Incorporated Documents
2020 Offering Incorporated Documents	2019 10-K, Q1 2020 10-Q, Q2 2020 10-Q, Q3 2020 10-Q, and two Forms 8-K filed with the SEC on November 9, 2020
2020 Offering ProSupp	Prospectus supplement filed with the SEC on Form 424B5, dated December 1, 2020
2020 Offering Underwriter Defendants	Defendants Barclays and Goldman
AdCom	U.S. Food and Drug Administration ("FDA") Cardiovascular and Renal Drugs Advisory Committee
AdCom Meeting	December 8, 2021 AdCom meeting to consider the Bard NDA
Albuminuria	The presence of albumin in the urine, often understood as a sign of kidney disease
Alport	Alport syndrome
Baird	Robert W. Baird & Co., Inc.
Barclays	Barclays Capital Inc.
Bard	Bardoxolone methyl

Bard NDA	New Drug Application ("NDA") submitted by Reata to the FDA on or about February 25, 2021 for approval of Bard as treatment for Alport, based on efficacy and safety data from CARDINAL
Bard NDA Representations	Representations concerning the intended filing, filing and progress of the Bard NDA
Bard NDA Release	March 1, 2021 Reata press release titled "Reata Pharmaceuticals, Inc. Submits NDA for Company's Lead Program: Bardoxolone in Alport Syndrome"
Bard Pathway Conference Call	November 14, 2016 conference call
Bard Pathway Press Release	November 14, 2016 Reata press release titled "Reata Announces Plan for Global Phase 2/3 Trial in Chronic Kidney Disease Caused by Alport Syndrome"
Bass	James E. Bass, Reata director from July 2004 until August 26, 2020
BEACON	Reata phase III trial of Bard as treatment for Stage 4 chronic kidney disease ("CKD") and type 2 diabetes, conducted in 2011-2012 and discontinued after indication that Bard caused elevated risk of heart failure
Board	Board of Directors
Cantor	Cantor Fitzgerald & Co.
CARDINAL	Reata pivotal phase 2/3 trial to evaluate Bard's efficacy and safety as a treatment for Alport CKD, first announced in November 2016 and conducted between 2017 and 2020, with on-treatment eGFR at 1 and 2 years as its primary endpoint and retained eGFR, measured after a four (4)-week washout period at the end of years 1 and 2, as its key secondary endpoint
CARDINAL Design Representations	Representations that CARDINAL was designed to measure, and was measuring, retained eGFR
CARDINAL Phase 2 Initial Results Conference Call	Reata July 24, 2017 conference call
CARDINAL Phase 2 Initial Results Release	July 24, 2017 Reata press release titled "Reata's Bardoxolone Methyl Demonstrated Improved Kidney Function in Patients with Alport Syndrome in Ongoing Phase 2 Portion of Phase 2/3 CARDINAL Study"

CARDINAL Phase 2 Results Release	July 23, 2018 Reata press release titled "Reata Announces Positive Phase 2 Data for Bardoxolone Methyl in CKD Caused by Alport Syndrome and Autosomal Dominant Polycystic Kidney Disease"
CARDINAL Phase 2 Results Conference Call	Reata July 23, 2018 conference call
CARDINAL Phase 3 Results Conference Call	Reata November 12, 2019 conference call
CARDINAL Phase 3 Results Release	November 11, 2019, Reata press release titled "Reata Announces Positive Topline Year One Results from Pivotal Phase 3 Cardinal Study of Bardoxolone Methyl in Patients with Alport Syndrome"
CARDINAL Retained eGFR Representations	Representations that CARDINAL results had demonstrated a statistically significant retained eGFR benefit following 1 or 2 years of treatment
CARDINAL Year 2 Results Release	November 9, 2020 Reata press release titled "Reata Announces Positive Results from Year 2 of the Pivotal Phase 3 CARDINAL Study of Bardoxolone Methyl in Patients with Alport Syndrome"
CEO	Chief Executive Officer
CFO	Chief Financial Officer
Citigroup	Citigroup Global Markets Inc.
CKD	Chronic kidney disease
Class Period	November 14, 2016 through December 6, 2021, inclusive
Company	Reata Pharmaceuticals, Inc.
COO	Chief Operating Officer
CRL	Complete Response Letter, provided by FDA to NDA sponsor, rejecting sponsor's NDA and identifying its deficiencies and information required for any later reconsideration
December 2016 Advice Letter	December 2016 letter from FDA to Reata containing "extensive written feedback" on CARDINAL's design
Defendants	Reata Defendants and Underwriter Defendants
Director Defendants	Defendants McGaughy, Nielsen, Rose, McClellan, and Bass
eGFR	Estimated glomerular filtration rate
EOP	End of Phase
ESKD	End stage kidney disease
Exchange Act	Securities Exchange Act of 1934
FDA	U.S. Food and Drug Administration

FDA AdCom Slides	Presentation slides prepared by the FDA for the AdCom Meeting and published on December 6, 2021
FDA Briefing Book	Report on the Bard NDA, prepared by the FDA for the AdCom Meeting and published on December 6, 2021
FDA Guidance Representations	Representations concerning Reata's receipt of "guidance" from the FDA concerning (i) how CARDINAL should be designed (including, specifically, measurement of retained eGFR after one-year and two-year treatment periods followed by a four (4)-week washout period), and (ii) what CARDINAL results could serve as a basis for FDA approval (specifically, that such retained eGFR measurements, if showing a retained benefit after one year of treatment and a four (4)-week washout, could support accelerated FDA approval, while a retained eGFR benefit after two years of treatment and a four (4)-week washout could support full FDA approval)
GFR	Glomerular filtration rate
Goldman	Goldman Sachs & Co. LLC
Huff	J. Warren Huff, founder of Reata in 2002 and Reata's sole CEO and Chairman from 2002 onwards
Hyperfiltration	Short-term eGFR boost caused by increase in intra-kidney blood pressure, with potentially negative longer-term effects on kidney function and eGFR
IND	Investigational New Drug
Individual Defendants	Officer Defendants and Director Defendants
January 2020 FDA Meeting	Reata meeting with the FDA in January 2020, described in the FDA Briefing Book (at p. 39) and omitted/misdescribed in Reata's public statements, in which the FDA "did not agree" with Reata's proposal to submit an NDA under the accelerated approval pathway, and voiced "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"
Jefferies	Jefferies LLC
July 2017 Offering	July 26, 2017 secondary public offering of 3,737,500 shares (following underwriters' full exercise of the over-allotment option) of Reata common stock at $31.00 per share
July 2017 Offering Documents	July 2017 Offering Registration Statement and July 2017 Offering Prospectus

July 2017 Offering Prospectus	July 26, 2017 prospectus supplement
July 2017 Offering Registration Statement	Reata registration statement on Form S-3 filed with the SEC on June 23, 2017, as amended on July 10, 2017 and declared effective on July 14, 2017
July 2018 Offering	July 25, 2018 secondary public offering of 3.45 million shares (following underwriters' full exercise of the over-allotment option) of Reata common stock at $72.00 per share
July 2018 Offering Documents	Shelf Registration Statement and July 2017 Offering Prospectus
July 2018 Offering Prospectus	July 24, 2018 prospectus supplement
Kyowa Kirin	Kyowa Kirin Co., Ltd. (f/k/a Kyowa Hakko Kirin Co., Ltd.), a large, global pharmaceutical company organized and headquartered in Japan, which in 2009 agreed to pay Reata as much as $272 million to obtain the right to develop and commercialize Bard in certain regions in Asia
Lead Plaintiff	Court-appointed Lead Plaintiff UMC Benefit Board, Inc., US Equity Fund-P Series, a series of the Wespath Funds Trust, US Equity Index Fund-P Series, a series of the Wespath Funds Trust, Wespath Institutional Investments LLC, US Equity Fund-I Series, a series of the Wespath Funds Trust, and US Equity Index Fund-I Series, a series of the Wespath Funds Trust
Leerink	SVB Securities LLC, f/k/a SVB Leerink LLC
Leerink Partners	Leerink Partners LLC
LT&Co	Ladenburg Thalmann & Co., Inc.
McClellan	William D. McClellan, Jr., Reata director from March 2017 onwards
McGaughy	R. Kent McGaughy, Jr., Reata director from December 2004 onwards
Meyer	Colin J. Meyer, who joined Reata in 2003 as one of its first employees, and served as Reata's Chief Medical Officer from 2013 until July 7, 2020; Chief R&D Officer from July 7, 2020 until February 7, 2022; and Chief Innovation Officer from February 7, 2022 onwards
NDA	New Drug Application
Nielsen	Jack B. Nielsen, Reata director from June 2006 onwards
Officer Defendants	Defendants Huff, Meyer, and Soni
Offerings Subclass	Persons or entities who purchased or otherwise acquired Reata common stock pursuant and/or traceable to Reata's 2019 Offering and/or 2020 Offering, and were damaged thereby
Omav	Omaveloxolone

PD	Pharmacodynamic: biochemical, physiologic, and molecular effects of drugs on the body
PDUFA Date	Typically 10 months from the date of an NDA submission, once the submission is accepted, the FDA informs the applicant of the specific date by which the FDA intends to complete its review, which is the PDUFA Date
PK	Pharmacokinetic: a drug's absorption, distribution, metabolism, and excretion by the body
Pre-IND meetings	Type B meetings used to ensure sponsor/FDA alignment prior to IND applications
Pre-NDA meetings	Type B meetings used to ensure sponsor/FDA alignment prior to NDAs
Prior Study Retained eGFR Representations	Representations that results from Reata's older BEAM and BEACON studies also demonstrated sizable, statistically significant retained eGFR benefits for Bard
Reata	Reata Pharmaceuticals, Inc.
Reata AdCom Slides	Presentation slides prepared by Reata for the AdCom Meeting on December 8, 2021
Reata Defendants	Reata, Officer Defendants, and Director Defendants
REMS	Risk Evaluation and Mitigation Strategy
Retained eGFR	eGFR change over baseline eGFR, if any, following: (i) cessation of further drug treatment, and (ii) an adequate washout period that allows PD effects to extinguish, which, if present, indicates that treatment had not only PD effects, but also disease-modifying effects
Risk Factor Disclosures	Various "risk factors" contained in the 2016 10-K purporting to disclose the material risks Reata faced
Rose	William E. Rose, Reata director from February 2016 onwards
R&D	Research and Development
SEC	U.S. Securities and Exchange Commission
Secondary Public Offerings	2019 Offering and 2020 Offering
Securities Act	Securities Act of 1933
Shelf Registration Statement	Reata registration statement filed with the SEC on Form S-3 on July 23, 2018 and used for 2019 Offering and 2020 Offering
Soni	Manmeet Soni, Reata's Chief Financial Officer since August 28, 2019, Chief Operating Officer since June 2020, and President since February 27, 2022
Stifel	Stifel, Nicolaus & Company, Incorporated

TSUBAKI	Kyowa Kirin Phase 2 study of Bard as a treatment for type 2 diabetes CKD, conducted between 2014-2016, with results reported September 2017, where GFR was directly measured by inulin clearance, and where serial measures of GFR were obtained after cessation of treatment
Underwriter Defendants	the 2020 Offering Underwriter Defendants and the 2019 Offering Underwriter Defendants: Jeffries, Leerink, Stifel, Baird, LT&Co, Cantor, Citigroup, Barclays, and Goldman
U.S.	United States
Washout / Washout Period	The length of time necessary for a drug's PD effects to extinguish following discontinuation of drug treatment
Wespath	Court-appointed Lead Plaintiff UMC Benefit Board, Inc., US Equity Fund-P Series, a series of the Wespath Funds Trust, US Equity Index Fund-P Series, a series of the Wespath Funds Trust, Wespath Institutional Investments LLC, US Equity Fund-I Series, a series of the Wespath Funds Trust, and US Equity Index Fund-I Series, a series of the Wespath Funds Trust

Court-appointed Lead Plaintiff UMC Benefit Board, Inc., US Equity Fund-P Series, a series of the Wespath Funds Trust, US Equity Index Fund-P Series, a series of the Wespath Funds Trust, Wespath Institutional Investments LLC, US Equity Fund-I Series, a series of the Wespath Funds Trust, and US Equity Index Fund-I Series, a series of the Wespath Funds Trust (collectively, "Wespath" or "Lead Plaintiff"), individually and on behalf of all others similarly situated, by and through Lead Plaintiff's attorneys, alleges the following upon information and belief, except as to those allegations concerning Lead Plaintiff, which are alleged upon personal knowledge. Lead Plaintiff's information and belief is based upon, among other things, Lead Plaintiff's 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; (c) review of reports issued by industry and securities analysts; and (d) review of other publicly available information concerning Reata, including information from the U.S Food and Drug Administration ("FDA").

I. NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of the following class (the "Class"): all persons or entities who purchased or otherwise acquired the publicly traded common stock of Reata between November 14, 2016 and December 8, 2021, inclusive (the "Class Period"), and were damaged thereby, including all persons or entities who purchased or otherwise acquired Reata common stock pursuant and/or traceable to Reata's 2019 Offering and/or 2020 Offering, and were damaged thereby (the "Offerings Subclass").

2. This action is brought on behalf of the Class for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("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, and Sections 11,

12(a)(2), and 15 and the Securities Act of 1933 ("Securities Act"), 15 U.S.C. §§ 77k, 77l(a)(2), and 77o.

3. Reata is a clinical-stage biopharmaceutical company headquartered in Plano, Texas. During the Class Period, Reata sought to develop its most important drug candidate, bardoxolone methyl ("Bard"), as a treatment for Alport syndrome ("Alport"), a form of chronic kidney disease ("CKD"). To market Bard for Alport, Reata needed FDA approval, which required a clinical study demonstrating Bard's efficacy and safety in treating Alport.

4. A key measure of efficacy for CKD is "retained eGFR." Estimated glomerular filtration rate ("eGFR") measures kidney function. Drugs may generate a short-term boost to eGFR so long as the drug continues to be given and active in the patient's body. These are known as the drug's "pharmacodynamic" effects. However, such short-term effects may not indicate that the drug has any long-term effect on treating the disease. Evidence of such long-term, disease-modifying effects can be provided by measuring retained eGFR – a patient's eGFR measured after the patient stops taking the drug for a sufficient amount of time to allow the pharmacodynamic effects to wash out (known as the "washout period"). **Valid measurement of retained eGFR is predicated on an adequate washout period**.

5. The Class Period began on November 14, 2016, when Reata announced that it had received FDA "guidance" on how such a study should be designed and what results the FDA would deem to support approval. Per Defendants' account of the FDA's guidance: (i) to approve Bard, the FDA needed evidence of success on retained eGFR; and (ii) to generate such evidence, the study should be designed to measure eGFR levels following extended treatment with Bard (one (1) and two (2) years) **and a four (4)-week washout period**. For example, as stated in Reata's Form 10-K for 2017:

> The U.S. Food and Drug Administration (FDA) has provided us with guidance that, in patients with CKD caused by Alport syndrome, an analysis of retained eGFR, which is the eGFR change after a four week withdrawal of drug, demonstrating an improvement versus placebo after one year of bardoxolone methyl treatment may support accelerated approval [and] . . . after two years of treatment may support full approval.

See Reata 2017 10-K at 3 (March 2, 2018); *see also id*. at 6, 11, 80 (same).

6. Reata commenced that clinical study, named CARDINAL, in early 2017 and completed it in late 2020, with retained eGFR measurements taken following a four (4)-week washout period designated as CARDINAL's "key secondary endpoint," and FDA approval requiring success on that endpoint. Throughout, Defendants represented that CARDINAL was based on and faithfully reflected FDA guidance. Indeed, Defendants affirmatively insisted that they had been "transparent" with investors concerning Reata's communications with the FDA:

> I think that we've been transparent with our discussions with the agency dating back to our pre-IND meeting with Alport syndrome, which we had in 2016. They gave us the design for the Alport syndrome trial, which we've executed. . .
>
> And so from our perspective, the design is what they told us to do. We've executed it. We don't believe there is any discrepancies between what they told us to do and what we've executed . . .

Q1 2021 Conference Call, Bloomberg transcript at 17.[1]

7. Put simply, Defendants represented throughout the Class Period they had placed CARDINAL's goalposts exactly where the FDA said they needed to be for FDA approval.

8. Thereafter, each set of CARDINAL results that Defendants announced – including, most crucially, purported "retained" eGFR – suggested that Reata had kicked the ball straight through the FDA's goalposts.

9. Further Defendants' representations indicated that Reata's goals were: (i) scored

[1] In quotations, bold and italics are present in the original; underlining is added for emphasis.

from fair play rather than an offsides position (for example, repeated representations that Bard's "washout" required no more than ten to fourteen (10-14) days, which made CARDINAL's four (4)-week washout period appear conservative); and (ii) consistent with historical precedent (for example, representations that prior Bard studies had also purportedly evidenced "retained eGFR" benefits).

10. As CARDINAL's results **appeared** time after time to demonstrate successfully and consistently what the FDA needed for Bard's approval, Reata's share price **more than sextupled, rising from below $30 per share to above $200 per share**. Taking advantage of Reata's share price inflation, Defendants conducted four secondary public offerings during the Class Period, in which they sold more than 11.9 million Reata shares for total proceeds **exceeding $1.1 billion**. Certain Individual Defendants, together with other Reata officers, realized a further $50 million from selling personal Reata shareholdings as Reata shares neared their peak prices.

11. Shortly after (i) announcing successful CARDINAL retained eGFR results following two years of treatment on November 9, 2020, which caused Reata shares to leap 32.4% that day, from $131.89 to $174.66, and (ii) completing its fourth and last secondary public offering on December 1, 2020 (in which Reata sold 2.0 million shares for net proceeds of approximately $277.8 million), Reata submitted a New Drug Application ("NDA") with the FDA in February 2021, with the CARDINAL results as its centerpiece (the "Bard NDA").

12. The FDA scheduled a public Advisory Committee ("AdCom") meeting to consider the Bard NDA (the "AdCom Meeting") for December 8, 2021. On December 6, 2021, in connection with and three (3) days prior to the AdCom Meeting, the FDA released a 96-page report concerning the Bard NDA (the "FDA Briefing Book").

13. The FDA Briefing Book revealed, to considerable market shock, that Reata had not

been "transparent" with investors concerning its interactions with the FDA.

14. First, the FDA Briefing Book explained that Reata had **not** obtained FDA concurrence on CARDINAL's design – most specifically, on CARDINAL's four-week washout period. Throughout the Class Period, the FDA had in fact "repeatedly voiced concerns" to Reata – in December 2016, September 2018, February 2019, January 2020, and September 2020 – concerning the basis for and adequacy of CARDINAL's four-week washout period, and the validity of retained eGFR measurements premised on it. Although the FDA had repeatedly advised and invited Reata to address these issues and/or meet to discuss them, Reata had consistently declined to do so. Likewise, although the FDA had recommended that Reata either pause CARDINAL to determine an adequate washout period or amend CARDINAL's design to include additional measurements of retained eGFR (for example, not just at four weeks after cessation of treatment, but also at six weeks, eight weeks, etc.), Reata had declined and/or ignored these recommendations. While the FDA's "repeated[] . . . concerns" were raised **privately** with Reata, Defendants did not disclose those concerns to investors during the Class Period, and instead continued to assert, misleadingly, that CARDINAL's design and conduct reflected FDA guidance.

15. Second, the FDA Briefing Book revealed that CARDINAL's retained eGFR results, which Defendants had previously represented to be successful (demonstrating a retained eGFR benefit) and legitimate (premised on a purported FDA-approved washout period of four weeks, which was significantly longer than the 10-14 days that Reata represented was needed for washout), were neither. In fact, as the FDA Briefing Book explained, Bard required eight (8) weeks for washout. CARDINAL's purported retained eGFR data, measured only four weeks into the necessary eight-week washout period, was therefore **not retained eGFR at all**, but instead was contaminated and inflated by the very pharmacodynamic effects it purported, and needed, to

exclude. Notwithstanding their facial success in meeting CARDINAL's key secondary endpoint, these results did not actually measure truly retained eGFR and thus provided no basis for FDA approval.

16. Put simply, the FDA Briefing Book revealed that Defendants' claims to have conducted CARDINAL in accord with FDA guidance, and that CARDINAL's results had successfully met the FDA's threshold for approval, had been a mirage.

17. Consequently, following the FDA Briefing Book's publication on December 6, 2021, Reata's shares lost 37.8% of their value **that same day**, falling from $78.69 to $48.92 per share, on trading volume of 5.5 million shares (more than 19 times Reata's daily average) – the second most active trading day in Reata's existence. Three days later, on December 9, 2021, Reata shares fell further still, declining by $25.31 per share, or 46.5%, to close at $29.11 per share, on even heavier trading volume (9.8 million shares, Reata's most active trading day ever), after the AdCom Meeting showed the Advisory Committee to credit the FDA Briefing Book and vote unanimously against Bard approval.

18. Throughout the Class Period and as detailed herein, Defendants made materially false and/or misleading statements – including in connection with Reata's secondary public stock offerings – concerning, *inter alia*, the FDA guidance, CARDINAL's design, CARDINAL's results, Bard's washout period, and the Bard NDA. As a result, Lead Plaintiff and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

19. 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), as well as under Sections 11, 12(a)(2) and 15 of the Securities Act, 15 U.S.C. §§ 77k, 77l(a)(2), and 77o.

20. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, Section 27 of the Exchange Act (15 U.S.C. § 78aa), and Section 22 of the Securities Act (15 U.S.C. § 77v).

21. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b), Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)) and Section 22 of the Securities Act (15 U.S.C. § 77v). Substantial acts in furtherance of the alleged violations of the securities laws or their effects 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 located in this District.

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

III. PARTIES

A. Lead Plaintiff

23. Lead Plaintiff supervises and administers retirement plans, investment funds, and health and welfare benefit plans for active and retired clergy and lay employees of the United Methodist Church. As set forth in the certification previously filed with the Court (ECF No. 20-2)[2], incorporated by reference herein, Lead Plaintiff purchased a significant number of shares of Reata common stock during the Class Period and suffered damages resulting from the federal securities law violations, false and/or misleading statements, and/or material omissions alleged herein. Lead Plaintiff purchased Reata common stock pursuant and traceable to the Shelf Registration Statement, including 4,300 shares purchased in the 2019 Offering from Defendant

[2] All references to "ECF No. __" refer to documents filed in the above-captioned action.

Citigroup and 2,177 shares purchased in the 2020 Offering from Defendant Barclays.

B. Corporate Defendant

24. Defendant Reata is incorporated under the laws of Delaware with its principal executive offices located at 5320 Legacy Drive, Plano, Texas 75024. Reata's common stock trades on the NASDAQ exchange under the symbol "RETA." Reata, the Officer Defendants and the Director Defendants are referred to herein as the "Reata Defendants."

C. Officer Defendants

25. Defendant J. Warren Huff ("Huff") founded Reata in 2002 and has served as Reata's Chief Executive Officer ("CEO") and as Chairman of Reata's Board of Directors (the "Board") ever since. Until February 7, 2022, Huff served as Reata's President. Defendant Huff signed or authorized the signing of the Shelf Registration Statement for the Secondary Public Offerings.

26. Defendant Colin J. Meyer, M.D. ("Meyer") joined Reata in 2003 as one of its first employees. Defendant Meyer served as Reata's Chief Medical Officer ("CMO") from 2013 to July 7, 2020, and thereafter as Reata's Chief Research and Development ("R&D") Officer from July 7, 2020 to February 7, 2022. Defendant Meyer received a B.S. in chemistry with a specialization in biochemistry and a B.A. in biology from the University of Virginia, an M.D. from the University of Texas Southwestern Medical School, and an M.B.A. from Southern Methodist University Cox's School of Business.

27. Defendant Manmeet Soni ("Soni") joined Reata in August 2019 and has served as Reata's Chief Financial Officer ("CFO") since August 28, 2019. In June 2020, Soni also became Reata's Chief Operating Officer ("COO"). In those roles, Defendant Soni oversaw and, continues to oversee, Reata's manufacturing, quality assurance, global alliances, business development, corporate strategy, finance, accounting, treasury, tax, corporate communications, investor

relations, and information technology. On February 27, 2022, Defendant Soni succeeded Defendant Huff as Reata's President and gained additional responsibilities for Reata's operational excellence initiatives, program management, and quality assurance.

28. Defendants Huff, Meyer, and Soni are referred to as the "Officer Defendants."

29. The Officer 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 Officer 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, the Officer Defendants knew, or were reckless in disregarding, 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 Officer Defendants are liable for the false statements and omissions of fact pleaded herein, as well as others that may be revealed as such with the benefit of further investigation and discovery.

D. Director Defendants

30. Defendant R. Kent McGaughy, Jr. ("McGaughy") has served since December 2004 as a director on Reata's Board. Defendant McGaughy signed or authorized the signing of the Shelf Registration Statement for the Secondary Public Offerings.

31. Defendant Jack B. Nielsen ("Nielsen") has served since June 2006 as a director on Reata's Board. Following the Class Period, Reata announced that Defendant Nielsen would retire from Reata's Board in June 2022. Defendant Nielsen signed or authorized the signing of the Shelf Registration Statement for the Secondary Public Offerings.

32. Defendant William E. Rose ("Rose") has served since February 2016 as a director on Reata's Board. Defendant Rose signed or authorized the signing of the Shelf Registration Statement for the Secondary Public Offerings.

33. Defendant William D. McClellan, Jr. ("McClellan") has served since March 2017 as a director on Reata's Board. Defendant McClellan signed or authorized the signing of the Shelf Registration Statement for the Secondary Public Offerings.

34. Defendant James E. Bass ("Bass") served, between July 2004 and his August 26, 2020 resignation, as a director on Reata's Board. Defendant Bass signed or authorized the signing of the Shelf Registration Statement for the Secondary Public Offerings.

35. Defendants McGaughy, Nielsen, Rose, McClellan, and Bass are herein referred to as the Director Defendants. The Officer Defendants and the Director Defendants are herein referred to as the "Individual Defendants."

E. Underwriter Defendants

36. Defendant Jefferies LLC ("Jefferies") is a limited liability company incorporated under the laws of Delaware, with principal executive offices located at 520 Madison Avenue, 10th Floor, New York, New York 10022. Jefferies acted as an underwriter for the 2019 Offering, helping to draft and disseminate the 2019 Offering Documents and solicit investors to purchase the Reata shares issued and sold pursuant thereto.

37. Defendant SVB Securities LLC, f/k/a SVB Leerink LLC ("Leerink") is a limited liability company incorporated under the laws of Delaware, with principal executive offices located at 53 State Street, 40th Floor, Boston, Massachusetts 02109. Leerink is the successor to Leerink Partners LLC ("Leerink Partners"), following the November 2018 acquisition of Leerink Partners' parent holding company, Leerink Holdings LLC, by SVB Financial Group. Leerink acted as an underwriter for the 2019 Offering, helping to draft and disseminate the 2019 Offering

Documents and solicit investors to purchase the Reata shares issued and sold pursuant thereto.

38. Defendant Stifel, Nicolaus & Company, Incorporated ("Stifel") is a company incorporated under the laws of Missouri, with principal executive offices located at 501 North Broadway, Saint Louis, Missouri 63102. Stifel acted as an underwriter for the 2019 Offering, helping to draft and disseminate the 2019 Offering Documents and solicit investors to purchase the Reata shares issued and sold pursuant thereto.

39. Defendant Robert W. Baird & Co., Inc. ("Baird") is a company incorporated under the laws of Wisconsin, with principal executive offices located at 777 East Wisconsin Avenue, Milwaukee, Wisconsin 53201. Baird acted as an underwriter for the 2019 Offering, helping to draft and disseminate the 2019 Offering Documents and solicit investors to purchase the Reata shares issued and sold pursuant thereto.

40. Defendant Ladenburg Thalmann & Co., Inc. ("LT&Co") is a company incorporated under the laws of Delaware, with principal executive offices located at 640 Fifth Avenue, 4th Floor, New York, New York 10019. LT&Co acted as an underwriter for the 2019 Offering, helping to draft and disseminate the 2019 Offering Documents and solicit investors to purchase the Reata shares issued and sold pursuant thereto.

41. Defendant Cantor Fitzgerald & Co. ("Cantor") is a company incorporated under the laws of New York, with principal executive offices located at 110 East 59th Street, New York, New York 10022. Cantor acted as an underwriter for the 2019 Offering, helping to draft and disseminate the 2019 Offering Documents and solicit investors to purchase the Reata shares issued and sold pursuant thereto.

42. Defendant Citigroup Global Markets Inc. ("Citigroup") is a company incorporated under the laws of New York, with principal executive offices located at 388 Greenwich Street,

New York, New York 10013. Citigroup acted as an underwriter for the 2019 Offering, helping to draft and disseminate the 2019 Offering Documents and solicit investors to purchase the Reata shares issued and sold pursuant thereto.

43. Defendant Barclays Capital Inc. ("Barclays") is a company incorporated under the laws of Connecticut, with principal executive offices located at 745 7th Avenue, New York, New York 10019. Barclays acted as an underwriter for the 2020 Offering, helping to draft and disseminate the 2020 Offering Documents and solicit investors to purchase the Reata shares issued and sold pursuant thereto.

44. Defendant Goldman Sachs & Co. LLC ("Goldman") is a limited liability company incorporated under the laws of New York, with principal executive offices located at 200 West Street, New York, New York 10282. Goldman acted as an underwriter for the 2020 Offering, helping to draft and disseminate the 2020 Offering Documents and solicit investors to purchase the Reata shares issued and sold pursuant thereto.

45. Defendants Jeffries, Leerink, Stifel, Baird, LT&Co, Cantor, and Citigroup are referred to herein as the "2019 Offering Underwriter Defendants." Defendants Barclays and Goldman are referred to herein as the "2020 Offering Underwriter Defendants" and, together with the 2019 Offering Underwriter Defendants, are referred to herein as the "Underwriter Defendants." Defendants Reata, the Officer Defendants, the Director Defendants, and the Underwriter Defendants are referred to collectively herein as "Defendants."

F. Relevant Nonparty

46. Kyowa Kirin Co., Ltd., f/ka Kyowa Hakko Kirin Co., Ltd. ("Kyowa Kirin") is a global pharmaceutical company organized and headquartered in Japan. In 2009, Kyowa Kirin entered into an agreement with Reata in which Kyowa Kirin obtained rights to develop and commercialize Bard in certain regions of Asia in exchange for payments of up to $272 million to

Reata. Thereafter, Kyowa Kirin collaborated with Reata in Bard's development and conducted clinical studies on Bard, including TSUBAKI.

IV. FACTUAL BACKGROUND

A. The FDA's Drug Review and Approval Process

47. In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act. To approve a drug for sale in the U.S., the FDA first requires:

- Preclinical laboratory tests and animal tests conducted under good laboratory practice;
- The submission to the FDA of an investigational new drug ("IND") application for human clinical testing, which must become effective before any human clinical trial commences;
- Adequate and well-controlled human clinical trials to establish the safety and efficacy of the product, and conducted in accordance with good clinical practices;
- The submission to the FDA of an NDA for the applicable small molecule drug product;
- FDA acceptance, review, and approval of the NDA (including the product labeling and package insert); and
- Satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made to assess compliance with current good manufacturing practice.

48. Preclinical studies include laboratory evaluations and animal studies to assess the potential safety and efficacy of the drug candidate, conducted in compliance with FDA regulations regarding good laboratory practices.

49. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of the IND application. The IND includes a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the efficacy criteria. The IND becomes automatically effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the studies. In this event, the IND sponsor must resolve any FDA concerns for the IND to become effective and clinical trials to begin.

50. Clinical trials involve the administration of the drug candidate to healthy human volunteers or patients with the disease to be treated, under supervision by qualified principal investigators, and in accordance with good clinical practices and applicable pre-defined protocols (*e.g.*, detailing the objectives of the applicable phase of the trial, dosing procedures, research subject selection and exclusion criteria, and the safety and effectiveness criteria to be evaluated).

51. Clinical trials are typically conducted in three sequential phases prior to approval, but in certain cases the phases may overlap or be combined. These phases include:

A. *Phase 1.* Phase 1 clinical trials represent the initial introduction of a product candidate into human subjects, frequently healthy volunteers. In Phase 1, the product candidate is usually tested for pharmacodynamic ("PD") and pharmacokinetic ("PK") properties such as safety (including adverse events), dosage tolerability, absorption, distribution, metabolism, and excretion.

B. *Phase 2.* Phase 2 clinical trials involve a limited number of patients with the disease for which the drug candidate is being developed, to (i) preliminarily evaluate the efficacy of the drug candidate for specific indications, (ii) determine dosage tolerability and optimal dosage, and (iii) identify possible adverse effects and safety risks.

C. *Phase 3.* If a drug candidate is found to be potentially effective and to have an acceptable safety profile in Phase 2 trials, the clinical trial program may be expanded to Phase 3 clinical trials to further evaluate clinical efficacy, optimal dosage, and safety within an expanded patient population.

52. Clinical trial results, together with preclinical study results and detailed information on the manufacture, composition, and quality of the drug candidate, are submitted to the FDA in the form of an NDA requesting approval to market the drug.

53. Once the NDA submission is accepted, the FDA informs the applicant of the specific date by which the FDA intends to complete its review (the "PDUFA Date"), which is typically 10 months from the date of submission. The FDA reviews NDAs to determine, among other things, whether the proposed drug is safe and effective for its intended use, and whether a risk evaluation and mitigation strategy ("REMS") is necessary to assure safe use of the drug. The FDA can also convene an advisory committee of external experts to provide input on certain

review issues relating to risks, benefits, and the interpretation of clinical trial data. The FDA will either issue an approval of the NDA or a Complete Response Letter ("CRL") detailing the deficiencies and information required for reconsideration of the application.

54. Throughout the approval process, the FDA provides drug sponsors with particular opportunities to meet with the FDA and obtain the FDA's advice relating to the development and review of INDs and NDAs. The FDA subdivides its meeting opportunities into four types: (i) Type A Meetings; (ii) Type B Meetings; (iii) Type B – End-of-Phase ("EOP") Meetings; and (iv)Type C Meetings, as summarized below.

A. **Type A Meetings**. Type A Meetings are, in essence, emergency meetings: meetings described by the FDA as necessary for an otherwise stalled drug development. Type A Meetings are used, for example, to discuss "clinical holds," where the FDA has required suspension of clinical trials.

B. **Type B Meetings**. Type B Meetings, often referred to as "milestone" meetings, are principally used to ensure sponsor/FDA alignment **prior** to major sponsor submissions or endeavors, such as IND applications ("pre-IND meetings"), NDAs ("pre-NDA meetings"), or emergency use authorization applications. Type B Meetings also include meetings regarding REMS or other post-marketing requirements that occur outside the context of the review of a marketing application and meetings for drugs granted breakthrough therapy designation. One central subset of Type B meetings – Type B (EOP) Meetings – primarily comprises meetings scheduled to follow the end of Phase 2 trials and/or precede Phase 3 trials.

C. **Type C Meetings**. Type C Meetings include any meetings other than Type A, B, or B (EOP) Meetings. Common Type C Meetings include discussions of so-called CMC issues (issues relating to chemistry, manufacturing, and controls).

B. CKD, GFR and eGFR

55. CKD is characterized by a progressive worsening in the glomerular filtration rate ("GFR") – the rate at which the kidneys filter waste products from the blood. CKD can progress to end-stage kidney failure, which is fatal absent artificial blood filtering (*i.e.*, dialysis) or a kidney transplant.

56. Because GFR is burdensome to measure directly, clinicians have developed and

rely on a simpler measure: *estimated* GFR. eGFR can be determined from a blood test, known as a serum creatinine blood test, that measures the levels of creatinine in the bloodstream.[3] eGFR is expressed in milliliters of cleansed blood per minute per body surface area (units that read as __ mL/min/1.72m2).

57. CKD is typically broken down into five stages defined by eGFR levels:

A. Stage 1 CKD (eGFR of 90+): mild kidney damage, but kidneys are still working well.

B. Stage 2 CKD (eGFR of 60-89): still mild kidney damage, kidneys are still working well.

C. Stage 3 CKD (eGFR of 30-59): decreased kidney function; onset of symptoms.

D. Stage 4 CKD (eGFR of 15-29): poor kidney function; moderate/severe kidney damage.

E. Stage 5 CKD (eGFR below 15): kidney failure – life-threatening absent dialysis or a kidney transplant. Also referred to as end-stage kidney disease ("ESKD").

58. Alport is a rare genetic form of CKD caused by mutations in genes encoding a structural component of the kidney's glomerular base membrane. The kidneys of patients with Alport progressively lose filtering capacity (average annual eGFR declines of 3-4 mL/min/1.73 m2), which can lead to ESKD and the need for chronic dialysis or a kidney transplant. In patients with the most severe forms of Alport, approximately 50% progress to dialysis by age 25, 90% by age 40, and nearly 100% by age 60. Alport affects 30,000 to 60,000 people in the U.S.

[3] The body makes and uses creatine to provide energy to muscles. When muscles use this energy they release creatinine, a toxin, into the blood, which the kidneys then filter and excrete. Kidney function and eGFR can be determined by measured creatinine levels in conjunction with several other data points (*e.g.*, age, sex, height, weight, race/ethnicity, etc.).

C. Bard Was Reata's Most Important Product Candidate and the Largest Determinant of Reata's Value

59. Shortly after its 2003 inception, Reata acquired exclusive worldwide licenses for Bard and omaveloxolone ("Omav"). Thereafter and at all times during the Class Period, Reata's operations have focused primarily on researching, developing, and commercializing Bard and Omav, Reata's self-described "two lead product candidates."

60. At all relevant times, Bard was Reata's most important product. Reata was developing Bard for more indications and larger patient populations than Omav, and clinical trials were more advanced for Bard than Omav. In recognition of these and other relevant facts, analysts' models and valuations of Reata ascribed the single largest part of Reata's value to Bard.[4]

D. Reata's Relevant Pre-Class Period Efforts to Develop Bard

1. Bard's First Phase III Trial Was Discontinued Due to Safety Concerns

61. In June 2011, Reata launched a Phase 3 clinical trial, named BEACON, to study whether Bard slowed progression to ESKD in 2,185 patients with Stage 4 CKD (patients with eGFR between 15 and 30) and type 2 diabetes. BEACON's primary endpoint measured the time taken by patients to reach ESKD (*i.e.*, need for chronic dialysis or renal transplant) or cardiovascular death; multiple secondary endpoints included, *inter alia*, the rate of change in patients' eGFR. BEACON was originally planned to last for approximately two years, by which time it was expected that significant numbers of patients would reach the primary endpoints.

62. However, safety concerns caused BEACON to be terminated early, in October

[4] Reata did not generate any revenue from product sales during the Class Period, as no Reata products have yet received FDA approval for sale to the public. Examination of Reata's reported R&D expenses, which Reata detailed throughout the Class Period by product category, illustrates the centrality of Bard and Omav to Reata's operations and shows that Bard alone accounted for approximately 37% of Reata's total R&D expenses (with Omav at 15%).

2012, after its independent data and safety monitoring committee noticed a statistically significant increase in heart failure events and recommended that BEACON be discontinued.

2. Reata Salvaged and Repositioned Bard for Development via Re-analysis of the BEACON Data

63. Bard's development then stalled due to BEACON's safety issues. Reata, however, endeavored to restart it by: (i) re-analyzing the BEACON data to focus narrowly on the precise nature and causes of the elevated heart failure events occasioned there; and (ii) re-positioning Bard's development and indications (*i.e.*, the proposed diseases and patient populations for which Bard treatment was sought), to avoid or mitigate the risks uncovered in BEACON.

64. Between 2012 and 2014, Reata conducted a series of post hoc analyses of the BEACON data and found that a small subset of patients with effective or prior heart failure, who experienced fluid overload in the first four weeks of Bard treatment, were responsible for the entirety of the increased risk.

65. Reata thereafter sought to restart Bard's development in a manner designed to avoid and/or mitigate these risks.

66. First, Reata repositioned the indications for which it sought to develop Bard. As late-stage CKD patients (CKD Stage 4 and end-stage CKD patients) are at greater risk of fluid overload, Reata ceased targeting these indications, and instead shifted to focus primarily on earlier-stage CKD patient populations (in whom such elevated risks were absent). Throughout the Class Period, Reata focused on genetically inherited forms of CKD, like Alport,[5] that cause progressive deterioration of kidney function and can be treated *prior* to late-stage CKD.

[5] While Reata sought to develop Bard as a treatment for indications other than Alport, this case concerns only misrepresentations made by Defendants concerning Reata's efforts to obtain FDA approval for Bard for treatment of Alport.

67. Second, Reata also modified its trial protocols to avoid and/or mitigate these risks by: (i) *excluding* from new Bard trials patients at elevated risk – those with prior heart failure or biomarkers of heart failure; (ii) requiring closer monitoring of fluid levels during the first four weeks of treatment; and (iii) introducing a modified dosing schedule, where patients would start treatment with fractional doses and gradually escalate to full daily dosage.

68. After Reata presented such risk avoidance and mitigation strategies to the FDA beginning in late 2013, the FDA allowed Reata to resume IND studies of Bard. The Class Period Bard trials appeared to have avoided reproducing the kinds of serious adverse cardiac events, such as fluid overload, seen in BEACON mostly by excluding from such trials any patients at elevated risk of such events.

E. Facts and Concepts Relevant to Evaluation of Bard's Efficacy and Safety

1. Pharmacodynamic Effects versus Disease-Modifying Effects

69. Pharmacology, which studies the interaction between drugs and humans, has two broad arms: (i) PD, which studies the biochemical, physiologic, and molecular effects of drugs on the body (*i.e.*, what the drug does to the body), and (ii) PK, which studies a drug's absorption, distribution, metabolism, and excretion (*i.e.*, what the body does to the drug).

70. In Bard's case, a relevant PD effect of treatment with Bard, as clinical trials indicated, is a boost in patients' eGFR. The exact mechanism that produces this effect is complex, and, as Reata explained in its Class Period SEC filings, involves intervention in biochemical pathways that regulate gene activity. Chemically, Bard binds to a protein known as Keap1, which in turn governs the activity of another very important protein, Nrf2, which operates as a "transcription factor" (a protein that controls gene activity and turns certain genes "on" or "off") for an array of detoxifying, anti-inflammatory, and antioxidant defense genes.

71. In CKD and its associated gradual decline in kidney function, treatment efficacy is

generally viewed through the prism of slowing the decline in kidney function: *i.e.*, altering the course of the disease (a "disease-modifying" effect). A drug's disease-modifying effects are often evaluated through time-based studies that measure the time taken to progress to a relevant clinical endpoint (*e.g.*, ESKD). If patients treated with the drug take longer to progress ESKD than patients treated with a placebo, it is evident that the drug has altered the course of the disease and produces a disease-modifying effect.

72. Where the disease/decline is long-term, and the relevant clinical endpoints may require very long time periods to reach, such studies are not always feasible or practical. Alternatively, studies in certain instances can utilize alternative, "surrogate" endpoints – such as eGFR here – where traditional clinical endpoints may be sufficiently difficult or impractical.

73. However, the use of eGFR as a surrogate endpoint for a clinical outcome generates ambiguity with respect to whether a drug produces *disease-modifying* effects. While a PD effect is evident – a boost to eGFR following treatment with Bard – it provides no evidence of a disease-modifying effect. The solution to this problem adopted by the FDA and industry members is to measure and evaluate retained eGFR.

2. The Retained eGFR Test Is Designed to Distinguish PD Effects and Reveal Disease-Modifying Effects

74. Retained eGFR is the measurement of eGFR following (i) cessation of further treatment with the drug, **and (ii) an additional period of time sufficient to allow the drug and its PD effects to become effectively extinguished**. Consequently, in the first instance, a retained eGFR measure strips away the drug's PD effects on eGFR. In the second instance, this allows the determination of whether there is **any eGFR benefit that remains after PD effects have been reversed** (a "retained benefit"). If the measurement of retained eGFR reveals a retained benefit, this is an indication or evidence that the drug has some disease-modifying effect.

a. Ceasing Drug Treatment, and Measuring eGFR After "Washout" of the Drug's PD Effects

75. The concept and accurate measure of retained eGFR are premised on **removing** PD effects to render visible any additional disease-modifying effects. Removal of PD effects requires not only cessation of treatment with the drug, but an additional period of time, following drug discontinuation, for the drug to exit the body and for the drug's PD effects to cease, or "resolve." This additional period of time is termed the "washout period," and its goal – cessation of further PD effects – is referred to as "washout."

76. Washout is a function of both PK (how the body metabolizes the drug) and PD (how the drug works in and affects the body). One drug's washout can and usually does differ from another's. Likewise, longer and larger doses of a drug may require longer washout periods than shorter and smaller treatments of the same drug.

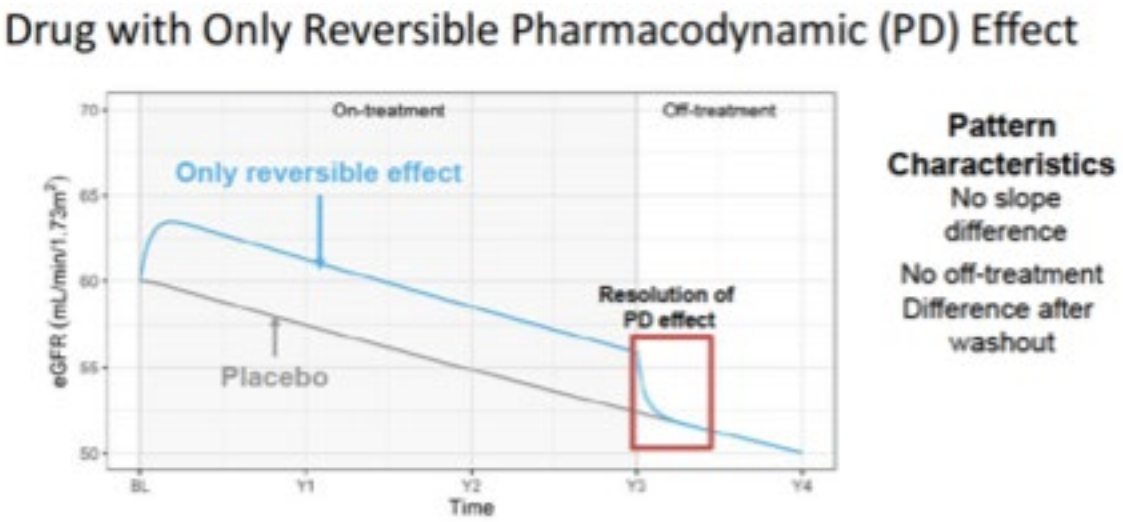
b. Relevance for Efficacy

77. The primary relevance of retained eGFR concerns **efficacy**: specifically, indication of a drug's disease-modifying effects.

78. The two charts presented on the following pages illustrate why and how. Both show illustrative eGFR measurements for two patient groups – one group treated with the drug (the "treatment group") and the other with a placebo (the "placebo group") – throughout a trial featuring (i) three years of treatment, followed by (ii) a washout period after year three.

79. The first chart illustrates a scenario where eGFR measurements following the washout period show that no retained benefit exists. Looking from bottom to top, the grey line at the bottom, showing the eGFR measures of the placebo group, illustrates, as expected in CKD, continuous kidney function decline, starting at eGFR of 60, declining to approximately 52.5 at year three, and continuing to decline thereafter. Above the grey line, the blue line, by contrast,

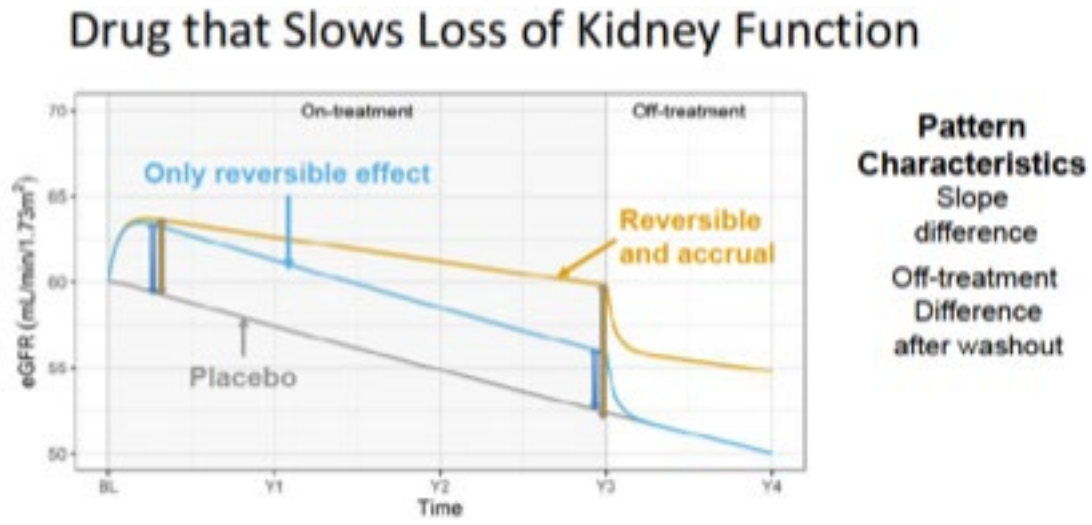
shows eGFR levels for patients in the treatment group. As the blue line shows, the treatment produces an initial boost to eGFR, which rises from 60 to approximately 63. Thereafter, during the three-year treatment period, the eGFR of patients in the treatment group (blue line) declines in parallel with the eGFR of placebo patients (grey line) but retains at all times the initial eGFR boost from treatment relative to the placebo group (three eGFR points higher than the placebo group at all on-treatment times). However, following year three, drug treatment is discontinued. During the ensuing washout period following year three (defined by the red box), eGFR levels in the treatment group fall sharply, and by the end of the washout period, to levels indistinguishable from the placebo group.



See FDA AdCom Slides at 7; *see also* FDA Briefing Book at 19.

80. In the above scenario, the drug has only a reversible PD effect, but no disease-modifying effect. The effect on eGFR disappears in the off-treatment period after the PD effect has fully reversed, after which eGFR is the same as it would have been had no drug been given.

81. The second chart below illustrates a different scenario: where post-washout eGFR measurements indicate that a retained benefit exists.



See FDA AdCom Slides at 8; *see also* FDA Briefing Book at 19.

82. In this second scenario, the treatment patient group (orange line) displays a reaction to the drug visibly different in two respects. First, following the same initial boost to eGFR at the commencement of treatment (rising three eGFR points above the placebo group), patients in the treatment group, during the three-year treatment period, do not feature **parallel** chronic eGFR loss to patients in the placebo group. Instead, during the three-year treatment course, the treatment group's eGFR declines less, or more slowly, than in the placebo group, which indicates there is a disease-modifying effect. Second, after the three-year treatment period is completed, and drug treatment ceases, eGFR levels in the treatment group fall – as the drug's PD effects "wash out" – **but post-washout eGFR levels remain higher than eGFR in the placebo group**.

83. This (illustrative) retained eGFR result indicates that the drug's effects are not limited to PD effects present only during, and because of, continuing treatment. Instead, there is an indication that the drug has produced a more enduring and fundamental benefit – one indicating that somehow, bodily functioning has improved to alter disease course/progression.

c. Relevance for Safety

84. Over and above its central, normal relevance for safety, retained eGFR, for Bard particularly, also had important safety implications.

85. Although Reata asserted that Bard improved eGFR by expanding glomerular *surface area*, thereby increasing kidney filtering capacity, the FDA was concerned that Bard's boost to eGFR was produced by increasing blood pressure within the kidney, referred to as "hyperfiltration." While hyperfiltration could boost eGFR in the short term, the increased pressure could damage the kidneys in the longer term. Retained eGFR measurement was of additional significance for Bard because it could provide further evidence as to whether Bard did, or did not, operate through hyperfiltration. If eGFR levels following long-term Bard treatment and washout were *worse* in the treatment group than in the placebo group, that could indicate that Bard caused hyperfiltration. Conversely, post-washout eGFR showing a retained benefit might indicate that Bard was not working through a mechanism that caused longer-term kidney damage.

3. Retained eGFR's Validity and Relevance Rest on and Require an Adequate Washout Period

86. Retained eGFR was a crucial metric for evaluating Bard's efficacy and safety – and for that reason, was incorporated as a "key secondary endpoint" into the CARDINAL trial that was intended to and did support the Bard NDA.

87. **For a retained eGFR measurement to be valid or relevant, it is necessary that the washout period that precedes it be long enough to allow the drug's PD effects to extinguish**. If the washout period is insufficient for their removal, the purported retained eGFR is not truly a retained eGFR at all because it includes the very thing it claims to exclude: the drug's PD effects.

88. A retained eGFR measurement taken within the washout period, while the drug's

PD effects are still active, will present two related and fundamental problems.

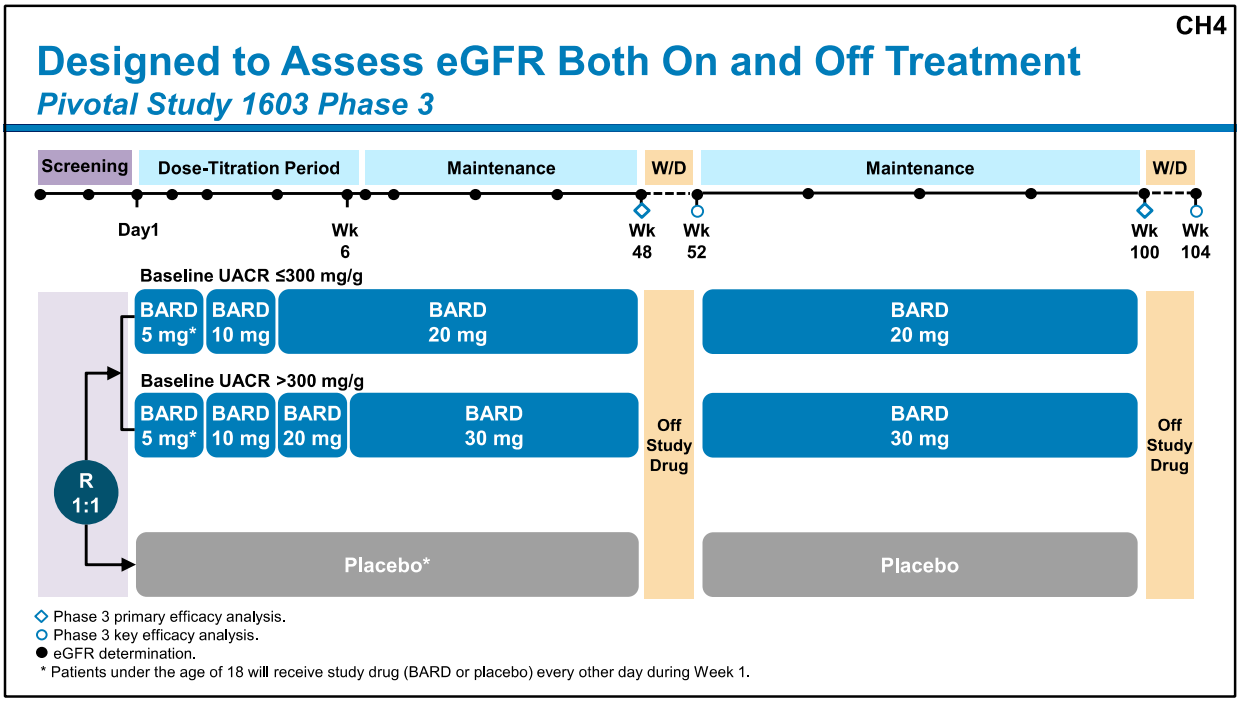
A. First, it will be materially inflated, because it will include some portion of the drug's PD effects over and above any retained benefit.

B. Second, it will not be what it claims to be: eGFR that is **retained following the extinction of PD effects**, thus erasing the measure's validity and relevance.

F. The CARDINAL Trial Used to Evidence Bard's Efficacy and Safety

89. The Class Period begins with Reata's announcement that it had a pre-IND meeting with the FDA on or about October 5, 2016, where it had obtained FDA "guidance" concerning how to design a protocol that could form the basis for FDA evaluation and possible approval of Bard as a treatment for Alport CKD and that, based on this guidance, Reata would initiate a combined, pivotal phase 2/3 trial (the CARDINAL trial).

90. The CARDINAL trial's design is displayed in the chart below:



See Reata AdCom Slides,[6] at 18.

91. With respect to the Phase 3 portion of CARDINAL, which was intended and used as the evidentiary basis for the Bard NDA, the most relevant aspects of the design included:

A. A two-year treatment course consisting of:

a) treatment with Bard for 48 weeks, at which year-one eGFR would be measured;

b) a four-week washout period, from weeks 48-52, after which year-one "retained" eGFR would be measured;

c) resumption of treatment for another 48 weeks after year one (*i.e.*, from weeks 53-100), at which year-two eGFR would be measured; and

d) a four-week washout period, from weeks 100-104, after which year-two "retained" eGFR would be measured;

B. On-treatment eGFR change, measured at weeks 48 and 100 versus baseline eGFR, as a primary endpoint (with change from baseline in the Bard treatment group to be measured against change in the placebo group);

C. Retained eGFR change, measured at weeks 52 and 104 following four-week washouts, versus baseline eGFR (with change from baseline in the Bard treatment group to be measured against change in the placebo group) as a "key secondary endpoint";

D. Purported FDA accord with the foregoing; and

E. The FDA's "guidance" to Reata that success with respect to year-one retained eGFR data could support accelerated FDA approval, and success with respect to year-two retained eGFR data could support full approval.

92. As Defendants explained, FDA approval would require a successful showing of retained eGFR: CARDINAL had to reach not just its primary endpoint **but also its "key secondary endpoint," retained eGFR**.

93. During the Class Period, Reata announced: (i) Phase 2 year-one results (and

[6] U.S. FOOD & DRUG ADMIN., REATA PHARMACEUTICALS PRESENTATIONS FOR THE DECEMBER 8, 2021 MEETING OF THE CARDIOVASCULAR AND RENAL DRUGS ADVISORY COMMITTEE (2021) (hereinafter, the "Reata AdCom Slides").

retained eGFR) on July 23, 2018; (ii) Phase 3 year-one results (and retained eGFR) on November 11-12, 2019; and (iii) Phase 2 year-two results (and retained eGFR) on November 9, 2020. On each occasion, Reata reported that Bard generated a material, statistically significant retained eGFR benefit, purportedly indicating Bard's disease-modifying effects. On or about February 25, 2021, Reata filed the Bard NDA based on this and further CARDINAL data.

G. Undisclosed Adverse Facts Known to Defendants During the Class Period

1. The FDA Spent Most of the Class Period Repeatedly and Privately Warning Reata that CARDINAL's Four-Week Washout Period Was Inadequate

94. Throughout the Class Period, Defendants consistently represented that: (i) CARDINAL's design, including, specifically, its measurement of retained eGFR following a four-week washout period, was the product of and in accord with "guidance" that the FDA provided to Reata; and (ii) per the same FDA guidance, success on CARDINAL's year-one retained eGFR key secondary endpoint, so designed, could support accelerated FDA approval, and on year-two retained eGFR, so designed, full approval. *See* Section V.A.1.a, *infra*.

95. The truth, however, was almost exactly the opposite. As the FDA revealed on December 6-8, 2021, in connection with the AdCom Meeting:

A. Reata had lost contact with, and failed to secure, FDA guidance throughout the Class Period;

B. The FDA repeatedly warned Reata that FDA concurrence with respect to CARDINAL's protocol had **not** been obtained, and repeatedly advised Reata to obtain it before proceeding with CARDINAL Phase 3; and

C. Most specifically, CARDINAL's four-week washout period had an inadequate basis, was insufficient for extinguishment of Bard's PD effects, therefore did not measure truly retained eGFR, and thus was not capable of (i) demonstrating disease-modifying

effects, or (ii) providing requisite evidence of the same necessary for FDA approval.

96. In its initial October 5, 2016 pre-IND meeting with Reata, the FDA informed Reata that CARDINAL would need to evaluate **retained** eGFR, rather than merely on-treatment eGFR, to distinguish Bard's PD effects from disease-modifying effects, if any. *See, e.g.*, FDA Briefing Book at 39 ("At a pre[-]IND 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."); *see also* FDA AdCom Slides at 9.

97. However, as the FDA would later reveal on December 6-8, 2021, it ***"repeatedly voiced concerns"*** about the evaluation of the retained eGFR:

> 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).

See FDA Briefing Book at 39; *see also* FDA AdCom Slides at 9 ("During the course of development, FDA grew concerned about the timing of the Applicant's post-treatment assessment and whether it was adequate to differentiate the pharmacodynamic effect on kidney function from its effect on disease progression and voiced this concern to the Applicant.").

98. While the FDA's "repeated[] . . . concerns" were raised **privately** with Reata, Defendants did not disclose those concerns to investors during the Class Period.

99. The FDA raised its concerns with CARDINAL in December 2016, when the FDA provided Reata with an "advice letter" containing "extensive written feedback" on CARDINAL's

design (the "December 2016 Advice Letter"). *See* FDA Briefing Book at 39 n.2. Notably, the FDA issued its December 2016 Advice Letter to Reata just a few short weeks after Reata's November 14, 2016 public announcement of CARDINAL and its design – which Defendants purported to be in accord with FDA guidance.

100. Reata did not modify CARDINAL's washout period following the FDA's December 2016 Advice Letter. The Company instead launched CARDINAL's exploratory Phase 2 trial, which measured retained eGFR at one year, after 48 weeks of treatment and a four-week washout period. Reata announced one-year retained eGFR from CARDINAL Phase 2 on July 23, 2018.

101. Following Reata's completion of Phase 2, and before the decisive Phase 3 portion of CARDINAL approached the time for its critical retained eGFR measurements, the FDA contacted Reata in September 2018 to encourage Reata to request, as is typical, an "End-of-Phase 2 meeting." *See* FDA Briefing Book at 39 n.2. End-of-Phase 2 meetings occupy an especially important role in the FDA's regulatory scheme, as they are the principal and last opportunity to ensure alignment between the FDA and a drug sponsor on Phase 3 plans, protocols, and adequacy, and to identify any additional, as-yet missing information that might be needed to support an eventual NDA, *prior to* actual initiation of Phase 3. *See* 21 C.F.R. § 312.47(b).

102. Here, in September 2018, the FDA encouraged Reata to request an End-of-Phase 2 meeting to "discuss the development program" (*i.e.*, CARDINAL Phase 3) and "ensure alignment." *See* FDA Briefing Book at 39 n.2.

103. Reata declined to request or have an End-of-Phase 2 meeting and explained to the FDA that Reata was "not seeking input from the Division on the program at this time." *Id*. Instead, Reata continued CARDINAL Phase 3, keeping the four-week washout period for the retained

eGFR measurements, and continued to issue a stream of public statements extolling CARDINAL's purported accordance with FDA guidance without ever disclosing that Reata ignored the FDA's requests for an End-of-Phase 2 meeting.

104. Remarkably, after Reata declined the FDA's suggested End-of-Phase 2 meeting and proceeded to Phase 3 without further discussion, the FDA wrote back to Reata in February 2019 with a three (3)-part message:

A. First, the FDA re-emphasized to Reata "the importance of obtaining FDA concurrence that a study intended to support a marketing application was adequate and acceptable for this purpose[,]" and "encouraged [Reata] to obtain Agency concurrence on the adequacy and acceptability of the study to support a marketing application." *See* FDA Briefing Book at 39 & 39 n.2. These reminders communicated to Reata that the FDA had **not** signed off on CARDINAL Phase 3's design or adequacy – that its "concurrence" was still yet to be obtained.

B. Second, the FDA "also encouraged [Reata] to submit a written response to the comments in the FDA's December 2016 advice letter . . . ." *Id.* at 39 n.2. This indicated that the "extensive written feedback" that the FDA originally provided to Reata in December 2016 (i) had, ever since, been effectively ignored by Reata, and (ii) was still relevant for CARDINAL Phase 3 adequacy and acceptability. *Id.*

C. Third, the FDA "reiterated its offer to meet with [Reata] to discuss the development program and a path forward." *See id.*

105. Just as with the December 2016 Advice Letter, there is no indication that Reata provided any substantive response to the FDA's February 2019 communication, or to the issues the FDA first communicated in December 2016 and reiterated in February 2019, to "obtain Agency

concurrence" on those issues and/or on CARDINAL's adequacy and acceptability. *See id.* at 39. Reata continued with the first year of CARDINAL Phase 3, without any modifications to obtain FDA concurrence, and reported year-one results from CARDINAL Phase 3, including retained eGFR figures following a four-week washout period, on November 11-12, 2019. Reata continued to publicly represent that CARDINAL operated pursuant to FDA guidance, but Defendants did not disclose that Reata had declined the FDA's invitation to meet and to obtain agency concurrence.

106. In January 2020, Reata met with the FDA concerning CARDINAL (the "January 2020 FDA Meeting"). Reata's intent in the January 2020 FDA Meeting was to propose a quick NDA filing for FDA accelerated approval, based on the CARDINAL year-one eGFR data. *See, e.g.*, *id.* at 39. However, the FDA refused to accept such an NDA filing and expressed concerns about the adequacy of the CARDINAL Phase 3 efficacy and safety data. *Id*.

107. Specifically, the FDA expressed concerns with CARDINAL's four-week washout period, which the FDA indicated was unsupported and/or inadequate. *See id.* at 39 ("concerns about the interpretability of the eGFR findings given the available information on the time course for resolution of bardoxolone's pharmacodynamic effect"). Because retained eGFR validity rests on washout period adequacy, the FDA's concerns went straight to the validity of the retained eGFR measurements based on that washout period. *Id*.; *see also* FDA AdCom Slides at 17 ("The key secondary endpoint in CARDINAL was intended to assess whether bardoxolone slows the loss of kidney function in patients with Alport syndrome. Interpretation of this endpoint depends on the adequacy of the washout period used in the trial.") .

108. The FDA also expressed concerns over the relatively high number of patients who discontinued Bard treatment in the first year ("the amount of missing data in the bardoxolone arm")

and what it deemed a "lack of clarity" with respect to "how patients with missing data" would be accounted for statistically "in key analyses intended to disentangle the drug's pharmacodynamic effect on kidney function from its effect on the irreversible loss of kidney function." *See* FDA Briefing Book at 39.

109. Additionally, the FDA expressed two safety concerns. First, whether Bard boosted eGFR in the short term by increasing blood pressure within the kidney, which could, in turn, produce long-term kidney damage – *i.e.*, the above-mentioned hyperfiltration issue. One marker of such long-term kidney damage is albuminuria (the presence of the protein albumin in the urine). A healthy kidney does not let albumin pass from the blood into the urine. A damaged kidney allows some albumin to pass into the urine. Albuminuria is, therefore, a sign of kidney disease. Bard treatment appeared to increase albuminuria. Second, due to the way CARDINAL's blood pressure data was collected, the FDA found the data insufficiently precise, making adequate safety evaluation impossible. *See id.* at 39.

110. Immediately following the January 2020 FDA Meeting, the tone and content of the Reata Defendants' public disclosures concerning FDA matters shifted notably. During their two (2) quarterly conference calls immediately following the January 2020 meeting, in February 2020 and May 2020, the Reata Defendants suddenly refused to make any comments or answer any analyst questions concerning Reata's interactions with the FDA. And in August 2020, when the Reata Defendants resumed commentary on FDA-related matters, they still omitted to disclose any of the sharp substantive differences between Reata and the FDA that had surfaced in the January 2020 FDA Meeting, and instead mischaracterized FDA-Reata debates as primarily procedural ones, concerning merely the timing rather than the substance of a Bard NDA filing. *See* Sections V.A.16-18 and V.C.6, *infra*. Moreover, Reata's February-August 2020 disclosures continued to

represent that CARDINAL, with its four-week washout period, was proceeding in accordance with FDA guidance.

111. In September 2020, when CARDINAL's year-two data was nearing release, the FDA again met with Reata and again reiterated all the concerns expressed in the January 2020 meeting. *See* FDA Briefing Book at 39. On November 9, 2020, Reata announced CARDINAL Phase 3 year-two results, including retained eGFR at two years following a four-week washout period.

112. The FDA's recommendation that Reata either "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)[]" could not have been made at the September 2020 meeting. At that time, CARDINAL Phase 3 was already over (and hence could not be "revise[d]"). *See id.* at 39. Therefore, this particular FDA communication concerning CARDINAL's design and washout period adequacy **must have been made no later than in the January 2020 FDA Meeting**. Most likely, it was made earlier still, when CARDINAL Phase 3 had either not yet begun (the FDA's December 2016 and September 2018 communications) or had only recently begun (the FDA's February 2019 communication), because these were the only times that CARDINAL Phase 3 could still be "modif[ied] . . . to obtain the information . . . ." *See id.*

113. The history of the FDA's interactions with Reata concerning CARDINAL makes it clear that Defendants' public descriptions of the same matter throughout the Class Period were materially misleading. Defendants consistently represented that CARDINAL's design, which incorporated retained eGFR as a key secondary endpoint and purported to measure it after a four-week washout period, accorded with FDA guidance and had the FDA's blessing, at all times. Yet

in fact, and for virtually that entire time, the FDA had repeatedly communicated to Reata – in December 2016, September 2018, February 2019, and January and September 2020 – that this was **not** the case, and that Reata did **not** have – and was repeatedly advised to obtain – FDA concurrence with respect to CARDINAL. A particular focus of these FDA communications to Reata was the appropriate washout period for retained eGFR measurement. No later than January 2020, the FDA informed Reata that CARDINAL's four-week washout period was insufficient, and advised Reata to either obtain a valid empirical foundation for an appropriate washout period or utilize in CARDINAL alternative washout periods longer than four weeks.

2. Bard Did Not Wash Out Within Two or Four Weeks, but Rather Required Eight Weeks for Washout

114. Throughout the Class Period, Defendants repeatedly represented that Bard washout took only 10-14 days. This indicated that CARDINAL's four-week washout period was more than adequate to allow Bard's PD effects to extinguish, and thus that CARDINAL's **retained** eGFR measurements were valid.

115. The truth, however, was far different. As the FDA explained and revealed on December 6-8, 2021, after two (2) years of Bard treatment, the Alport patients in CARDINAL required a far longer washout period of approximately eight weeks, or 60 days – **four times longer than represented by Defendants, and twice as long as the four-week period utilized in CARDINAL**. *See* FDA Briefing Book at 22-23, 59-61; FDA AdCom Slides at 10-17.

116. As the FDA also revealed on December 6-8, 2021, Reata's claims for purported Bard washout within 10-14 days, and/or for the adequacy of CARDINAL's four-week washout period, were without adequate basis and were contradicted by available data. *See* FDA Briefing Book at 44-49. Reata provided five bases for a 10-14 day washout, all of which the FDA found lacking. *Id*.

117. First, Reata had ignored the single most relevant prior study, named TSUBAKI, which was **the only prior study of Bard that included serial off-treatment collection of eGFR**. TSUBAKI took, as an exploratory endpoint, serial measures of eGFR in patients, following cessation of treatment with Bard, for up to 12 weeks. These TSUBAKI measurements indicated that Bard washout took approximately eight weeks. *See* FDA Briefing Book at 44; *see also* FDA AdCom Slides at 13.

118. Contemporaneous, published accounts of TSUBAKI did not report any of its post-treatment, retained eGFR measurements or findings, and instead focused on TSUBAKI's results relating to its primary and secondary endpoints: on-treatment effects of Bard on GFR (directly measured) and eGFR.[7] Thus, nothing in the published TSUBAKI materials could have alerted the investing public to the results indicating that Bard washout took approximately eight weeks. However, the Reata Defendants had access to that data and were very familiar with TSUBAKI, which had been conducted by Reata's Japanese partner in Bard's development, Kyowa Kirin. Reata mentioned or discussed TSUBAKI in virtually all its quarterly and annual SEC filings during the Class Period (postdating TSUBAKI's completion in late 2017) and in multiple conference calls. Indeed, on November 6, 2017, Reata had even (i) issued a press release hailing TSUBAKI's results, and (ii) held a conference call with analysts and investors "to review the Phase 2 results of TSUBAKI and CARDINAL."[8]

119. Instead of looking to TSUBAKI, Reata had scoured other Bard studies for

[7] *See e.g.*, Reata November 6, 2017 presentation titled "Program Update of Bardoxolone Methyl in CKD," at pp. 13-1; Masaomi Nangaku, Hironori Kanda *et al*., "Randomized Clinical Trial on the Effect of Bardoxolone Methyl on GFR in Diabetic Kidney Disease Patients (TSUBAKI Study)," Kidney Int Rep. 2020 Jun; 5(6): 879–890, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7271944/.

[8] *See* Press Release, Reata Pharmaceuticals, Inc., Reata Provides Update on Bardoxolone Methyl from the American Society of Nephrology Kidney Week Meeting (Nov. 6, 2017).

purportedly probative data, and had extracted, from five different studies, none of which were designed to provide for systematic or indeed any serial measurement of off-treatment eGFR, limited serial eGFR data accidentally available for 15 different patients. *See* FDA Briefing Book at 44. Each of these 15 accidental instances had eGFR measurements collected in three different periods: (i) one to six (1-6) days post-treatment cessation; (ii) seven to thirteen (7-13) days post-treatment cessation; and (iii) fourteen to forty-two (14-42) days post-treatment cessation. *Id*. Based on the observation that eGFR values, on average, in these 15 cases, did not exhibit further declines between the second and third periods – *i.e*., after 14 days – Reata purportedly concluded that Bard washed out within 14 days. However, as the FDA observed, this sample set was too small, too heterogeneous (*e.g*., drawn from studies that featured different dosing durations, daily dose amounts, and different patient populations/diseases), and too accidental "to draw any meaningful conclusion concerning the off-treatment time-course for patients with [Alport]," let alone to overrule the only study, TSUBAKI, actually designed to evaluate off-treatment time course via systematic, serial measurement. *Id*.

120. Second and similarly, Reata amalgamated retained eGFR results from seven prior Bard studies to claim that there was no association between (i) the magnitude of off-treatment changes in eGFR, and (ii) the number of days post-drug discontinuation at which the off-treatment measure of eGFR was taken, for all values fourteen (14) days or more after the last dose. *See id.* However, these seven studies pooled sharply heterogeneous data with respect to dosing (different durations and daily doses) and patient populations (at least four different diseases). Moreover, for half of the patients in this analysis, there were no serial eGFR measurements at all. *Id*. The FDA concluded that it was "unclear how the findings of the analysis based on this heterogeneous data set, with sparse sampling, supports the adequacy of four weeks for patients with [Alport]." *Id*.

121. Third, although Reata cited multiple studies demonstrating that on-treatment eGFR boosts had reversed four weeks after treatment cessation, by which time eGFR had returned to pre-study baseline levels, all these studies involved **a much shorter treatment duration** (no more than eight weeks, versus nearly two years in CARDINAL) and none involved patients with Alport. *See id.* As such, these studies did not indicate an appropriate washout period for CARDINAL, where Alport patients had been treated with Bard for approximately two years. *Id*.

122. Fourth, Reata argued that (i) in-vitro lab results showed Bard to exert effects at concentrations as low as 0.8 ng/mL, and (ii) according to Reata's PK model, Bard concentrations would fall to that threshold level 16 days after the last dose. *See* FDA Briefing Book at 45-46. However, as the FDA pointed out, this argument improperly assumed, contrary to direct evidence from CARDINAL itself and TSUBAKI, and contrary to the mechanism of action theorized for Bard **by Reata**, that changes in eGFR (i) were directly proportional to Bard concentration, and (ii) occurred **without any delay** between Bard's PK effects (the drug's metabolization by the body) and its PD effects (the drug's effects on the body). *Id*. Yet TSUBAKI and CARDINAL both directly evidenced a substantial delay between PK states (drug concentration) and PD states (eGFR). For example, TSUBAKI showed that after treatment cessation, Bard levels had subsided to zero after four weeks, **but eGFR took eight weeks to return to baseline**. *Id*. Similar delays were evident in CARDINAL. For example, maximum Bard concentrations were reached at weeks six to eight (6-8) of treatment, but maximum eGFR levels were not reached until four to six (4-6) weeks later, around week twelve (12). *Id*. Moreover, these delays are exactly what would be expected given the mechanism of action Reata described for Bard – effects on gene expression, which require extended time periods to initiate and extinguish. *Id*.

123. Fifth and relatedly, Reata proffered a similar argument that suffered from the same

flaw: the assumption that eGFR increase was directly proportional to Bard concentration. *See* FDA Briefing Book at 47-48. However, as discussed immediately above and as the FDA concluded, "[t]he assumption of the proportional increase in eGFR relative to bardoxolone concentration, without delay, is inconsistent with the observed data across multiple studies." *Id*. at 48.

124. Finally, Reata observed that other biomarkers in CARDINAL, following treatment cessation, had returned to baseline levels four weeks after discontinuation of Bard. *See id.* However, as the FDA point out, there was no reason to "expect[] that the time-course of other PD markers will be the same as eGFR." *Id*. Moreover, as the FDA also observed and as is discussed above, Bard's "mechanism of action is more consistent with a delay in the change in eGFR relative to bardoxolone concentration rather than a change in eGFR that is directly proportional to and immediately follows changes in measured bardoxolone concentration . . . ." *Id*. (emphasis added).

125. In sum, the FDA concluded that the "justification provided by [Reata] for the adequacy of the 4-week washout in patients with [Alport] is not compelling . . . ." FDA Briefing Book at 49; *see also id.* at 19 ("[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 from 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 [Alport] . . . .").

126. To determine an adequate washout period for CARDINAL, the FDA developed a model that incorporated: (i) standard PK and PD considerations (including, as discussed above, a delay in the onset/offset of eGFR relative to Bard concentration) to describe the disease

progression and drug effects of Bard in patients with Alport; and (ii) available empirical data from the TSUBAKI Bard trial ("because TSUBAKI was the only trial in the development program with serial off-treatment collection of eGFR for up to 12 weeks post-dose"). *See* FDA Briefing Book at 22-23 and 49-59; FDA AdCom Slides at 14. The FDA then validated the model against actual data observations from CARDINAL phases 2 and 3. *See* FDA Briefing Book at 49-59. The FDA's model accurately predicted the eGFR values observed in CARDINAL. *Id*. at 22-23, 58-59.

127. Using standard techniques and available data, the FDA model indicated that Bard's PD effects required a washout period of approximately 60 days, or eight weeks. *See* FDA Briefing Book at 22-23, 60-62. At the end of the four-week washout period utilized in CARDINAL, approximately 28% of Bard's PD effects were still present. *Id*. at 22-23. Therefore, CARDINAL's four-week washout period was "insufficient to resolve the reversible PD effect of [Bard]." *Id*.

3. CARDINAL's Retained eGFR Results Were Inaccurate, Invalid, and Incapable of Supporting FDA Approval

128. From July 23, 2018 onwards, Defendants reported retained eGFR results from CARDINAL that appeared to successfully meet CARDINAL's stated key secondary endpoint and to provide legitimate evidence that Bard produced significant retained eGFR benefits.

129. Given Defendants' concurrent representations that CARDINAL had been designed based on FDA guidance, and that success on CARDINAL's retained eGFR endpoints could form the basis for FDA approval, the retained eGFR results from CARDINAL that Defendants announced appeared to constitute evidence supporting FDA approval.

130. However, underneath these appearances was an opposite reality. Because CARDINAL utilized an insufficient washout period of only four weeks, CARDINAL's retained eGFR results were materially inflated. They included a significant contribution from Bard's PD effects, which were still present four weeks after Bard treatment had ceased, when retained eGFR

was measured. For this reason, CARDNAL's retained eGFR results were **not retained eGFR at all**. Consequently, even if the eGFR results appeared to meet CARDINAL's key secondary endpoint, they still **could not** serve as a basis for FDA approval.

H. Following the FDA's December 6-8, 2021 Corrective Disclosures, Reata Shares Plummet

131. The FDA's publication of the FDA Briefing Book on December 6, 2021, three days in advance of the AdCom Meeting, together with the December 8, 2021 AdCom Meeting itself, disclosed the above-detailed adverse facts. *See* Section V.B.3, *infra*. In so doing, they corrected Defendants' prior, Class Period statements, whose omission of these facts made them materially misleading. *Id*. For example, the FDA Briefing Book revealed the multiple occasions – beginning in December 2016, and including further communications in September 2018, February 2019, and January and September 2020 – when the FDA had communicated to Reata (i) that Reata had **not** secured FDA accordance with respect to CARDINAL's design, and/or (ii) the FDA's **particular** concerns with CARDINAL's four-week washout period, and hence with the validity and adequacy of any "retained" eGFR data premised on it. *Id*. Likewise, the FDA Briefing Book revealed that CARDINAL's four-week washout period was inadequate, that Bard required eight weeks to wash out, and thus that CARDINAL's purported "retained" eGFR data provided neither indication of truly retained eGFR nor support for FDA approval. *Id*. The corrective disclosures in the FDA Briefing Book caused Reata shares to plunge 37.8% on December 6, 2021, from $78.69 to $48.92 per share. *Id*. Then, three days later, after the AdCom Meeting ended with a unanimous vote against Bard approval, based on and crediting the shortcomings with CARDINAL's retained eGFR data identified in the FDA Briefing Book, Reata share price plunged another 45.1% on December 9, 2021, to $29.11 per share. *Id*.

V. DEFENDANTS' VIOLATIONS OF THE EXCHANGE ACT

A. Defendants' Material Misstatements and Omissions in Violation of the Exchange Act

1. Overview of Alleged False and/or Misleading Statements

132. Defendants made several kinds of false and/or misleading statements, summarized here, which they repeated during and throughout the Class Period, as detailed in Sections V.A.2-25, *infra*.

a. The FDA Guidance Representations

133. The Class Period begins on November 14, 2016, when the Reata Defendants first announced that the FDA had provided them with "guidance" for a study of Bard's efficacy and safety as a treatment for Alport – *i.e.*, CARDINAL.

134. According to Defendants' representations, the purported FDA "guidance" concerned (i) how CARDINAL should be designed and (ii) what CARDINAL results could serve as a basis for FDA approval. With respect to CARDINAL's design, Defendants represented that FDA guidance called for measurement of retained eGFR after one- and two-year treatment periods **followed by a four-week washout period**.[9] With respect to CARDINAL's results and FDA approval, Defendants represented that FDA guidance stated that such retained eGFR measurements, if showing a retained benefit after one year of treatment and a four-week washout period, could support accelerated FDA approval, while a retained eGFR benefit after two years of treatment and a four-week washout period could support full FDA approval.

[9] Specifically, CARDINAL's design comprised a two-year Phase 3 trial where retained eGFR would be measured at the end of year one and again at the end of year two. Per this design, patients would be treated with Bard during weeks one to forty-eight (1-48), then withdrawn for four weeks through week 52 (at which point the first such retained eGFR measure would be made), then restarted on Bard again for another 48 weeks between weeks 53 and 100, and finally withdrawn again during weeks 101-104, after which a second such retained eGFR measure would be made.

135. The above-identified representations are referred to as the "FDA Guidance Representations." Essentially, in and through the FDA Guidance Representations, Defendants represented (i) that CARDINAL, including its four-week washout period for retained eGFR, had been designed pursuant to and in accordance with FDA guidance, and (ii) that successful retained eGFR results from CARDINAL would support FDA approval. For example, as the Reata Defendants represented in Reata's March 2, 2018 Form 10-K:

> The U.S. Food and Drug Administration (FDA) has provided us with guidance that, in patients with CKD caused by Alport syndrome, an analysis of retained eGFR, which is the eGFR change after a four week withdrawal of drug, demonstrating an improvement versus placebo after one year of bardoxolone methyl treatment may support accelerated approval. In addition, data demonstrating an improvement versus placebo in retained eGFR after two years of treatment may support full approval.

See Reata 2017 Form 10-K at 3 (Mar. 2, 2018).

136. Defendants repeated the FDA Guidance Representations in nearly all subsequent Class Period statements concerning CARDINAL, as detailed in Sections V.A.2-23, *infra*.

137. The FDA Guidance Representations were materially false and/or misleading. Unbeknownst to Lead Plaintiff and the Class, the FDA **repeatedly warned** Reata between December 2016 and September 2020 that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval.

b. The CARDINAL Design Representations

138. Throughout the Class Period, Defendants represented that CARDINAL had been designed to measure and was measuring **retained** eGFR. Indeed, measurement of retained eGFR after one/two years treatment and a four-week washout period was designated as CARDINAL's "key secondary endpoint," and FDA approval was predicated on those retained eGFR results.

139. Defendants' representations that CARDINAL was designed to measure, and was

measuring, **retained** eGFR are referred to herein as the "CARDINAL Design Representations." Defendants repeated the CARDINAL Design Representations in nearly all Class Period statements concerning CARDINAL until the trial had been completed, as detailed in Sections V.A.2-14, *infra*.

140. The CARDINAL Design Representations were materially false and/or misleading. The CARDINAL measurements and data that Defendants represented to be retained eGFR were not retained eGFR. Because Bard required eight weeks to wash out, as indicated *inter alia* by the TSUBAKI study, CARDINAL's measurement of eGFR only four weeks after Bard discontinuation would and did measure a substantial portion of Bard's **PD effects that still remained after four weeks** (the FDA estimated that 23-38% of the full PD effects still remained four weeks after cessation), rather than, as Defendants represented, purported eGFR benefits retained **after Bard's PD effects had fully resolved**.

c. The 10-14 Day Washout Representations

141. During the Class Period, Defendants repeatedly asserted that after Bard treatment was discontinued, no more than 10-14 days were required for Bard to wash out.

142. These assertions are referred to as the "10-14 Day Washout Representations." Defendants repeated such 10-14 Day Washout Representations throughout the Class Period.

143. Were the 10-14 Day Washout Representations true, then: (i) eGFR measured 14 days after Bard treatment ceased would capture the benefit, if any, produced by Bard that was retained after Bard and its PD effects had washed out (*i.e.*, retained eGFR); and (ii) CARDINAL's four-week washout period was adequate for producing valid retained eGFR data.

144. The 10-14 Day Washout Representations were false. Bard did not wash out within 14 days but instead, as indicated *inter alia* by the TSUBAKI study, remained present and/or continued to exert PD effects for approximately eight weeks, or 60 days.

145. Defendants' 10-14 Day Washout Representations were a requisite predicate for the

Cardinal Design Representations, the CARDINAL Retained eGFR Representations and the Prior Study Retained eGFR Representations – and hence were material. All these misrepresentations shared a common claim: namely, that by measuring eGFR four weeks after withdrawing patients from Bard, Reata's clinical studies were measuring – and generating data concerning – **retained** eGFR. This claim, however, was not true. Because Bard did not wash out until eight weeks after treatment cessation, Reata's studies measuring eGFR after only four weeks – halfway through the eight-week period required for full washout – were **not** actually measuring retained eGFR, but were instead capturing Bard's lingering PD effects and mislabeling them as retained eGFR.

d. The CARDINAL Retained eGFR Representations

146. During the Class Period, Defendants repeatedly represented that CARDINAL's results demonstrated a sizable, statistically significant retained eGFR benefit for Bard (the "CARDINAL Retained eGFR Representations").

147. These representations were materially false and/or misleading. Bard treatment required eight weeks to wash out, as indicated *inter alia* by the TSUBAKI study, before a true, accurate, and/or valid retained eGFR measure could be made. However, CARDINAL's retained eGFR measurements were made only four weeks after cessation of treatment with Bard: *i.e.*, only halfway through, rather than following the end of, the requisite washout period. Consequently, the purported retained eGFR benefits purportedly evidenced in CARDINAL's results were no such thing, but rather were contaminated and elevated by the very thing Defendants represented them to be free of – Bard's PD effects. This contamination made CARDINAL's results not only inaccurate, but fundamentally invalid: they were not retained eGFR at all.

148. Defendants first made CARDINAL Retained eGFR Representations on July 23, 2018, when they first announced year-one results from CARDINAL Phase 2. Defendants updated such representations following (i) the announcement of year-one results from CARDINAL Phase

3 on November 11, 2019, and (ii) the announcement of year-two results from CARDINAL on November 9, 2020. CARDINAL Retained eGFR Representations featured in effectively all of Defendants' Class Period disclosures from July 23, 2018 onwards.

e. The Prior Study Retained eGFR Representations

149. During the Class Period, Defendants repeatedly represented that the results from Reata's older BEAM and BEACON studies also demonstrated sizable, statistically significant retained eGFR benefits for Bard (the "Prior Study Retained eGFR Representations").

150. These representations were materially false and/or misleading, for the same reasons that the CARDINAL Retained eGFR Representations were. BEAM's and BEACON's retained eGFR measurements, just like CARDINAL's, were made only four weeks after Bard treatment had ceased – *i.e.*, only halfway through, rather than following the end of, the requisite eight-week washout period indicated by TSUBAKI. Consequently, the retained eGFR benefits purportedly evidenced in BEAM and BEACON were no such thing, but rather were contaminated by the very thing Defendants represented them to be free of – Bard's PD effects.

151. Defendants made Prior Study Retained eGFR Representations on the first day of the Class Period and repeated them throughout the entirety of the Class Period.

f. The Bard NDA Representations

152. During the last part of the Class Period, from approximately November 9, 2020 onwards, Defendants made a series of representations concerning the intended filing, filing, and status/progress of the Bard NDA (the "Bard NDA Representations").

153. The Bard NDA Representations were materially misleading because they omitted to disclose numerous facts then known by Defendants that were highly material to evaluation of the Bard NDA, and that indicated far greater risks to its approval than publicly understood in light of Defendants' other accumulated misstatements, including:

A. that Bard's PD effects did **not** wash out quickly (per the 10-14 Day Washout Representations), but instead required eight weeks for washout;

B. that as a result, the purported retained eGFR results from CARDINAL, BEAM, and BEACON (constantly repeated via CARDINAL Retained eGFR Representations and Prior Study Retained eGFR Representations) neither measured nor evidenced truly retained eGFR, and thus could not and did not support FDA approval; and

C. that the FDA had **repeatedly warned** Reata between December 2016 and September 2020 that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval.

154. These omissions meant that the Reata Defendants, on the one hand, and Lead Plaintiff and other Class members, on the other hand, had substantially different sets of information for understanding the Bard NDA's merits and the likelihood of FDA approval. The Reata Defendants were privy to the FDA's concerns that CARDINAL's washout period was too short to measure true retained eGFR, that the purported retained eGFR data from CARDINAL might not constitute or evidence retained eGFR at all, and hence that key efficacy data supporting the Bard NDA's approvability, and purporting to indicate that Bard evidenced disease-modifying effects rather than simply PD effects, was a hollow simulacrum.

155. On the other hand, and as a result of Defendants' above-summarized material misrepresentations and omissions, Lead Plaintiff and Class members were aware of none of this. In the world created by Defendants' disclosures:

A. Bard washed out quickly (per the 10-14 Day Washout Representations), which supported the apparent validity of the retained eGFR results from CARDINAL, BEAM,

and BEACON (as constantly repeated via the CARDINAL Retained eGFR Representations and Prior Study Retained eGFR Representations), and

B. the FDA had always fully supported – rather than long questioned – the validity of retained eGFR data produced and adduced by Reata (per the FDA Guidance Representations).

156. Lead Plaintiff and Class members were thereby led to a far more sanguine – and materially incomplete and inaccurate – view of Reata's prospects and the prospects for FDA approval of the Bard NDA.

g. Other Misrepresentations

157. The six categories of misstatements and omissions summarized above account for the lion's share of the Class Period statements alleged to have been false and misleading. However, on rare occasions, Defendants made additional *sui generis* misstatements not subsumed by the above categories and whose alleged falsity is detailed below in *ad hoc* fashion.

2. The November 14, 2016 Statements

158. Before the market opened on November 14, 2016, Reata: (i) issued a press release titled "Reata Announces Plan for Global Phase 2/3 Trial in Chronic Kidney Disease Caused by Alport Syndrome," announcing what it termed a "clinical development pathway" for Bard as a treatment for Alport, purportedly based on and in accord with FDA "guidance" (the "Bard Pathway Press Release"); (ii) issued a press release announcing third-quarter 2016 results (the "Q3 2016 Results Release"); (iii) filed with the SEC a Form 10-Q, signed by Defendant Huff, for the third quarter of 2016 (the "Q3 2016 10-Q"); and (iv) at noon Eastern Standard Time ("EST"), hosted a conference call with analysts and investors to further discuss, specifically, the "clinical development pathway for [Bard] in Alport syndrome" (the "Bard Pathway Conference Call").

159. The central news in the November 14, 2016 disclosures was the development path

for Bard as a treatment for Alport, purportedly based on – and in accord with – FDA guidance. This was the sole focus of the Bard Pathway Press Release and the Bard Pathway Conference Call and a central focus in the Q3 2016 Results Release and the Q3 2016 10-Q.

160. The Bard Pathway Press Release contained FDA Guidance Representations and CARDINAL Design Representations, stating in relevant part:

> **Reata Announces Plan for Global Phase 2/3 Trial in Chronic Kidney Disease Caused by Alport Syndrome**
>
> *– Conference call and webcast November 14 at 12:00 p.m. EST –*
>
> **Received Guidance from the FDA on Key Design Aspects of a Single, Pivotal Trial in Alport Syndrome with an eGFR-Based Endpoint**
>
> ***
>
> In a Type B meeting on October 5th, 2016, the U.S. Food and Drug Administration ("FDA") provided guidance that a single, pivotal trial utilizing a retained estimated glomerular filtration rate ("eGFR") endpoint could serve as the basis for approval in this life-threatening, orphan disease.
>
> ***
>
> The Phase 3 portion will be designed to support registration . . . and the key secondary endpoints will be the change from baseline in eGFR after withdrawal of drug for four weeks (off treatment) after one and two years. After the initial withdrawal, patients will be restarted on study drug with their original treatment assignments and will continue on study drug for a second year. Based on FDA guidance, if the trial is positive, the year one off treatment data could support accelerated approval under subpart H of the Food, Drug, and Cosmetic Act, and the year two off treatment data could support full approval.
>
> ***
>
> During October 2016, Reata met with the Division to discuss submitting an Investigational New Drug application for the use of bardoxolone methyl in slowing, halting, or reversing renal decline in patients with Alport syndrome. Reata sought FDA guidance on the design of a randomized, placebo-controlled Phase 2 trial with eGFR-based endpoints in patients with Alport syndrome. Reata asked the Division to comment on eligibility criteria, age range of patients (including children as young as 12 years), risk mitigation features, proposed dose, endpoints, and other elements. The meeting was collaborative, and the Division recommended a more efficient pathway to registration utilizing a single pivotal study. They acknowledged that it would not be feasible to conduct a Phase 3 study in Alport syndrome patients with

> a primary endpoint of time to ESRD. The Division indicated that data on change in eGFR could serve as the basis for approval if increases in eGFR are at least partially retained after withdrawal of drug, which would indicate that the drug affects progression of the disease. The Division stated that it would consider accelerated approval of bardoxolone methyl for Alport syndrome based on eGFR data through one year (with a four week withdrawal period). Longer-term data could serve as the basis for full approval.

Bard Pathway Press Release.

161. The Q3 2016 Results Release offered similar FDA Guidance Representations and CARDINAL Design Representations:

> *Bardoxolone Methyl in Chronic Kidney Disease Caused by Alport Syndrome*
>
> During a meeting with the U.S. Food and Drug Administration ("the FDA") in October 2016, Reata received guidance from the FDA on key elements of a single, pivotal trial that would study the safety and efficacy of bardoxolone methyl in patients with CKD caused by Alport syndrome. . . .
>
> The Phase 3 primary efficacy endpoint will be the change from baseline in eGFR in bardoxolone methyl-treated patients relative to placebo after one year. The eGFR change after one year will be measured while the patients are on treatment, and the key secondary endpoints will be the change from baseline in eGFR after withdrawal of drug for four weeks (off treatment) after one and two years. After the initial withdrawal, patients will be restarted on study drug with their original treatment assignments and will continue on study drug for a second year. Based on FDA guidance, if the trial is positive, the year one off treatment data could support accelerated approval under subpart H of the Federal Food, Drug, and Cosmetic Act, and the year two off treatment data could support full approval.

162. The Bard Pathway Press Release also contained (i) 10-14 Day Washout Representations ("Sub-therapeutic concentrations of drug are achieved within approximately 10 days after drug withdrawal"), and (ii) Prior Study Retained eGFR representations (data/findings from BEAM and BEACON purportedly demonstrating retained eGFR benefits, based on four-week washout periods, and purportedly indicating Bard's potential disease-modifying effect):

> Most importantly, in both BEAM and BEACON, bardoxolone methyl treatment increased eGFR relative to both baseline and placebo after cessation of drug for four weeks (Table 4). Sub-therapeutic concentrations of drug are achieved within approximately 10 days after drug withdrawal. The sustained increase in eGFR through one year of treatment and the presence of a sustained eGFR improvement

after withdrawal of drug suggest that the maladaptive structural deficits that contribute to declining kidney function may be improved over the course of longer-term treatment with bardoxolone methyl.

163. The Q3 2016 10-Q contained FDA Guidance Representations, CARDINAL Design Representations, and Prior Study Retained eGFR Representations:

> In addition, we recently met with the FDA and received guidance on endpoints and general design characteristics of a single, pivotal Phase 2/3 trial in CKD caused by Alport syndrome and are in the process of designing that trial.
>
> ***
>
> *Regulatory Interaction on Alport Syndrome*
>
> During a meeting with the FDA in October 2016, the FDA provided us with guidance on key elements of a single, pivotal clinical trial that would study the safety and efficacy of bardoxolone methyl in patients with CKD caused by Alport syndrome. We initially proposed a Phase 2 trial in Alport patients; however, the FDA suggested a potentially more efficient path to registration utilizing a single trial with estimated GFR, or eGFR, based endpoints.
>
> We are in the process of designing the Phase 2/3 pivotal trial. Based on the guidance from the FDA . . . [t]he eGFR change at one year will be measured after 48 weeks while the patient is on treatment, and after withdrawal of drug for four weeks (retained eGFR). After withdrawal, patients will be restarted on study drug with their original treatment assignments and will continue on study drug for a second year. The change from baseline in eGFR in bardoxolone methyl-treated patients relative to placebo will be measured again after two years. The eGFR change at two years will also be measured after 100 weeks while the patient is on treatment and after withdrawal of drug for four weeks (retained eGFR). If the trial is successful, the year one retained eGFR data could support accelerated approval under subpart H of the Federal Food, Drug, and Cosmetic Act, or the FD&C Act, and the year two retained eGFR data could support full approval under the FD&C Act.
>
> *Clinical Experience with Bardoxolone Methyl in CKD caused by Type 2 Diabetes*
>
> In addition to preclinical models of chronic renal disease, bardoxolone methyl has been studied in seven studies of patients with CKD from type 2 diabetes that enrolled approximately 2,600 patients. Reata conducted six Phase 2 studies that demonstrated significant improvements in renal function evidenced by increases in eGFR. . . . These studies included the BEAM study . . . . BEAM enrolled primarily moderate or Stage 3 CKD patients and demonstrated that eGFR improvements were sustained for 52 weeks on treatment and that eGFR at week 56, four weeks after withdrawal of drug, was greater than both baseline and placebo eGFR values. The BEAM data demonstrated that a portion of the on treatment eGFR improvement

> was retained after withdrawal of drug and suggested that bardoxolone methyl had disease-modifying activity in CKD from type 2 diabetes.

2016 Q3 10-Q at 7, 13, 14, 19-20.

164. During the Bard Pathway Conference Call, Defendants Huff and Meyer reiterated the (i) FDA Guidance Representations, (ii) CARDINAL Design Representations, (iii) 10-14 Day Washout Representations, and (iv) Prior Study Retained eGFR Representations:

> HUFF: Today, we announced that we're initiating a development program in a rare form of severe chronic kidney disease that's caused by Alport Syndrome. . . .
>
> We initially approached the FDA in August of this year seeking guidance on the design of a Phase 2 program in Alport Syndrome. We had a very collaborative interaction with the agency, and during our Type B meeting, the FDA suggested that a single pivotal Phase 2/3 trial that demonstrates that bardoxolone methyl produces a retained estimated GFR treatment benefit versus placebo could be sufficient to register the drug for approval in Alport Syndrome.
>
> The agency stated that a significant retained improvement in estimated GFR after 48 weeks of treatment and four weeks off-drug could support accelerated approval. They added that full approval could be supported by similar data at the end of two years of treatment.
>
> Based on the guidance from the FDA, we decided to initiate a Phase 2/3 study in Alport Syndrome . . . .
>
> ***
>
> MEYER: We have investigated bardoxolone methyl's potential to demonstrate disease-modifying activity in both BEAM and BEACON. Sub-therapeutic concentrations of drug are achieved within approximately 10 days after drug withdrawal and there are no active metabolites.
>
> In these studies, we assess kidney function four weeks after drug withdrawal, which was approximately three weeks after all pharmacologic activity of bardoxolone methyl was gone. We observed a significant improvement relative to placebo at the mid and high dose in BEAM as well as in BEACON. The sustained increase in kidney function through one year of treatment and the presence of a sustained kidney function improvement after withdrawal of drug suggests that remodeling and fibrosis that contribute to decline in kidney function may be improved over the course of longer-term treatment with bardoxolone methyl.
>
> As Warren mentioned earlier, we have received clear guidance from FDA about requirements for approval of bardoxolone methyl in Alport Syndrome, which will require only a single pivotal trial. . . .

> The estimated GFR change will be measured while the patients are on treatment, and the key secondary endpoint will be the change from baseline in estimated GFR after withdrawal of drugs for four weeks later, at week 52. After the initial withdrawal, patients will be restarted on study drug with their original treatment assignments and will continue on study drug for a second year. Based on FDA guidance, if the trial is positive, the year one off-treatment data could support accelerated approval and the year two off-treatment data could support full approval. . . .
>
> We have designed the Alport Syndrome trial to be able to replicate the findings of the BEAM trial, which showed a clinically meaningful and statistically significant placebo-corrected improvement in kidney function four weeks after withdrawal after one year of treatment. . . .
>
> Based on bardoxolone's extensive development history that has shown improvements in renal function across many studies in a range of patients including diabetic CKD, the similarity of the pathophysiology of Alport Syndrome to diabetic CKD and the retained treatment benefit demonstrated by bardoxolone in two independent studies, we have confidence in the design of our study and that bardoxolone may be the first therapy approved for patients with Alport Syndrome.

Bard Pathway Conference Call, Bloomberg transcript at 2, 6-7.

165. The FDA Guidance Representations contained in the November 14, 2016 Bard Pathway Press Release, Q3 2016 Results Release, Q3 2016 Form 10-Q, and Bard Pathway Conference Call were materially false and misleading. Specifically, the claims of acting in accord with FDA "guidance" purportedly supporting (i) use of a four-week washout period and (ii) the resulting retained eGFR as a basis for FDA approval, were misleading for failure to disclose that Reata had not obtained FDA concurrence on these matters. *See* Section IV.G.1, *supra*.

166. The CARDINAL Design Representations contained in the November 14, 2016 Bard Pathway Press Release, Q3 2016 Results Release, Q3 2016 Form 10-Q, and Bard Pathway Conference Call were materially false and misleading. Because PD effects remained for eight weeks after extended Bard treatment, utilization of an inadequate four-week washout period for retained eGFR measurement meant that CARDINAL would not actually measure what was claimed (*i.e.*, retained eGFR) at all – and hence, that any ensuing retained eGFR results would

provide neither evidence of any truly retained eGFR benefit nor basis for FDA approval. *See* Sections IV.G.2-3, *supra*.

167. The 10-14 Day Washout Representations contained in the November 14, 2016 Bard Pathway Press Release and Bard Pathway Conference Call were materially false and misleading. In truth, extended Bard treatment, such as in CARDINAL, BEAM, and BEACON, required eight weeks to wash out: a period at least four times longer than the represented 10-14 days. *See* Section IV.G.2, *supra*.

168. The Prior Study Retained eGFR Representations contained in the November 14, 2016 Bard Pathway Press Release, Q3 2016 Form 10-Q, and Bard Pathway Conference Call were materially false and misleading. In truth, because BEAM and BEACON measured retained eGFR after an inadequate four-week washout period, they neither measured nor evidenced any retained eGFR benefit or disease-modifying effects for Bard. *See* Sections IV.G.2-3, *supra*.

3. The March 3, 2017 Statements

169. Shortly following Reata's November 14, 2016 statements, the FDA provided Reata with its December 2016 Advice Letter, containing "extensive written feedback" on CARDINAL's design, including the basis and adequacy of the four-week washout period upon which the validity of CARDINAL's purported retained eGFR data and results would be based. *See* Section IV.G.1, *supra*; *see also* FDA Briefing Book at 39 n.2

170. On March 3, 2017, Reata: (i) issued a press release announcing results for the fourth quarter and year of 2016 (the "Q4 2016 Results Release"); and (ii) filed with the SEC a Form 10-K, signed by Defendant Huff and the Director Defendants, for 2016 (the "2016 10-K").

171. The Q4 2016 Results Release contained FDA Guidance Representations and CARDINAL Design Representations:

Bardoxolone Methyl in Chronic Kidney Disease Caused by Alport Syndrome

Bardoxolone methyl is also currently being studied in a single, pivotal Phase 2/3 trial, known as CARDINAL, for the treatment of chronic kidney disease, or CKD, caused by Alport syndrome. . . . [B]ased on the guidance from the FDA, we have designed the trial as an international, multi-center, double-blind, randomized, placebo-controlled trial that studies the safety, tolerability, and efficacy of bardoxolone methyl in qualified patients with Alport syndrome . . . . The Phase 3 portion is designed to support registration and patients will be randomized 1:1 to either bardoxolone methyl or placebo. The eGFR change at one year will be measured after 48 weeks while the patient is on treatment, and after withdrawal of drug for four weeks (retained eGFR). . . . The eGFR change at two years will also be measured after 100 weeks while the patient is on treatment and after withdrawal of drug for four weeks (retained eGFR). If the trial is successful, the year one retained eGFR data could support accelerated approval under subpart H of the Federal Food, Drug, and Cosmetic Act, or the FD&C Act, and the year two retained eGFR data could support full approval under the FD&C Act. Reata expects to have Phase 2 data by the end of 2017 and to have the one year withdrawal data that could support accelerated approval in the first half of 2019.

172. The 2016 10-K repeated FDA Guidance Representations and CARDINAL Design Representations:

Clinical Development for Bardoxolone Methyl in Chronic Kidney Disease Caused by Alport Syndrome

During a meeting with the FDA in October 2016, the FDA provided us with guidance on key elements of a single, pivotal clinical trial that would study the safety and efficacy of bardoxolone methyl in patients with CKD caused by Alport syndrome. We initially proposed a Phase 2 trial in Alport syndrome patients; however, the FDA provided guidance that a single pivotal trial with an eGFR endpoint could support both accelerated and full approval.

We have initiated the Phase 2 portion of CARDINAL, a single, pivotal Phase 2/3 clinical trial and dosed the first patient on March 2, 2017. With the aid of international key opinion leaders and the Alport Syndrome Foundation and based on the guidance from the FDA, we have designed the trial as an international, multi-center, double-blind, randomized, placebo-controlled trial that studies the safety, tolerability, and efficacy of bardoxolone methyl in qualified patients with Alport syndrome . . . .

. . . The Phase 3 portion is designed to support registration . . . . The eGFR change at one year will be measured after 48 weeks while the patient is on treatment, and after withdrawal of drug for four weeks (retained eGFR). . . . The eGFR change at two years will also be measured after 100 weeks while the patient is on treatment and after withdrawal of drug for four weeks (retained eGFR). If the trial is

> successful, the year one retained eGFR data could support accelerated approval under subpart H of the Federal Food, Drug, and Cosmetic Act, or the FD&C Act, and the year two retained eGFR data could support full approval under the FD&C Act.

2016 10-K at 3-4, 19-20.

173. In a subsection titled "Previous Renal Findings in Clinical Trials of Bardoxolone Methyl," the 2016 10-K asserted Prior Study Retained eGFR Representations:

> *Previous Renal Findings in Clinical Trials of Bardoxolone Methyl*
>
> Prior to initiating the current clinical development programs in PH and CKD caused by Alport syndrome, bardoxolone methyl was evaluated in multiple trials . . . .
>
> We conducted six Phase 1 and 2 studies that demonstrated significant improvements in renal function evidenced by increases in eGFR . . . . These trials included the BEAM trial, [which] . . . demonstrated that eGFR improvements were sustained for 52 weeks on treatment and that eGFR at week 56, four weeks after withdrawal of drug, was greater than both baseline and placebo eGFR values. The BEAM data demonstrated that a portion of the on treatment eGFR improvement was retained after withdrawal of drug and suggested that bardoxolone methyl had disease-modifying activity in CKD caused by diabetes.
>
> ***
>
> [In BEAM and BEACON,] [a]fter one year of treatment, a residual eGFR increase from baseline was observed in bardoxolone methyl patients after cessation of drug for four weeks, while an eGFR decline from baseline was observed in placebo patients. These data suggest that the maladaptive structural deficits that contribute to declining kidney function may be improved over the course of longer-term treatment with bardoxolone methyl.

2016 10-K at 16-19.

174. The FDA Guidance Representations in the Q4 2016 Results Release and 2016 10-K were materially false and misleading. Specifically, the claims of acting in accord with FDA "guidance" purportedly supporting (i) use of a four-week washout period and (ii) the resulting retained eGFR as a basis for FDA approval, were misleading for failure to disclose that Reata had not obtained FDA concurrence on these matters. *See* Section IV.G.1, *supra*. Defendants failed to disclose that the FDA had **repeatedly warned** Reata, beginning with the FDA's December 2016

Advice Letter, that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval. *Id*.

175. The CARDINAL Design Representations in the Q4 2016 Results Release and 2016 10-K were materially false and misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR measurement meant that CARDINAL would not actually measure what was claimed (*i.e.*, retained eGFR) at all – and hence, that any ensuing retained eGFR results would provide neither evidence of any truly retained eGFR benefit nor basis for FDA approval. *See* Sections IV.G.2-3, *supra*.

176. The Prior Study Retained eGFR Representations in the 2016 10-K were materially false and misleading. In truth, because BEAM and BEACON measured retained eGFR after an inadequate four-week washout period, they neither measured nor evidenced any retained eGFR benefit or disease-modifying effects for Bard. *See* Sections IV.G.2-3, *supra*.

177. Additionally, the 2016 10-K contained various "risk factors" purporting to disclose the material risks Reata faced (the "Risk Factor Disclosures"). *See* 2016 10-K at 44-74. In relevant part – risks relating to Reata's development and commercialization of product candidates, and to government regulation – the Risk Factor Disclosures stated:

> *The clinical and commercial success of bardoxolone methyl and omaveloxolone will depend on a number of factors, many of which are beyond our control*.
>
> The clinical and commercial success of bardoxolone methyl and omaveloxolone will depend on a number of factors, including the following, many of which are beyond our control:
>
> - the timely initiation, continuation, and completion of our Phase 2 and Phase 3 clinical trials for bardoxolone methyl and omaveloxolone, which will depend substantially upon requirements for such trials imposed by the U.S. Food and Drug Administration, or FDA, and other regulatory agencies and bodies;

- our ability to demonstrate the safety and efficacy of our product candidates to the satisfaction of the relevant regulatory authorities; [and]

- 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[.] . . .

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.

***

The regulatory approval process is highly uncertain, and we may not obtain regulatory approval for the commercialization of our product candidates. . . .

We have not obtained regulatory approval for any product candidate, and it is possible that none of bardoxolone methyl, omaveloxolone, or any future product candidates we may discover, in-license, or acquire and seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or other regulatory authorities for many reasons, including:

- inadequate design or implementation of our clinical trials;

- failure to demonstrate to the satisfaction of regulatory authorities that a product candidate is safe and effective for its proposed indication;

- failure of clinical trials to meet the level of statistical or clinical significance required for approval;

- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

- FDA refusal to accept efficacy results from clinical trial sites outside the United States where the standard of care is potentially different from that in the United States; [and]

- the insufficiency of data collected from preclinical studies and clinical trials of our present or future product candidates to support the submission and filing of an NDA or other submission or to obtain regulatory approval[.] . . .

The FDA or other regulatory authorities may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans . . . .

> . . . Even if we believe our current or planned clinical trials are successful, regulatory authorities may not agree that our completed clinical trials provide adequate data on safety or efficacy.

2016 10-K at 45-46, 63-64.

178. The above-identified Risk Factor Disclosures were inadequate and were themselves materially misleading. They inaccurately described certain risks – specifically, that the FDA might not approve Bard due to "inadequate design or implementation of our clinical trials[,]" failure to demonstrate Bard's "safety and efficacy . . .[] to the satisfaction of the relevant regulatory authorities," and FDA disagreement "that our completed clinical trials provide adequate data on safety or efficacy[]" – as **potential** risks, stated in a generalized and hypothetical manner, while omitting to disclose material, then-existing facts – such as the FDA's December 2016 Advice Letter – indicating that these risks were actually materializing.

4. The July 24, 2017 Statements

179. On July 24, 2017, Reata: (i) issued a press release presenting initial data from CARDINAL Phase 2 indicating that Bard had improved patient eGFR and announcing that in light of such positive data, CARDINAL Phase 3 was commencing (the "CARDINAL Phase 2 Initial Results Release"); and (ii) at 8:30 a.m. EST, hosted a conference call with analysts and investors to discuss further the CARDINAL Phase 2 initial data and the plans and design for CARDINAL Phase 3 (the "CARDINAL Phase 2 Initial Results Conference Call").

180. The CARDINAL Phase 2 Initial Results Release repeated FDA Guidance Representations and CARDINAL Design Representations:

> **About the CARDINAL Clinical Study Design** . . .
>
> The Phase 3 portion of CARDINAL is designed to support regulatory approval of bardoxolone for the treatment of Alport syndrome. It will be double-blind, placebo-controlled, and will randomize approximately 150 patients on a 1:1 basis to once-daily, oral bardoxolone or placebo. The eGFR change will be measured after 48 weeks while the patient is on treatment ("on-treatment eGFR") and again after 52

> weeks after the patient has stopped taking the study drug for a four-week withdrawal period ("retained eGFR"). Based on guidance from the United States Food and Drug Administration (the "FDA"), the year one retained eGFR benefit data may support accelerated approval under subpart H. . . . The second year on-treatment eGFR change will be measured after 100 weeks and the retained eGFR benefit will be measured after withdrawal of drug for four weeks at week 104. Based upon guidance from the FDA, the year two retained eGFR benefit data may support full approval. . . .
>
> The key secondary endpoint of the Phase 3 portion of the trial is the change from baseline in retained eGFR benefit after one year of treatment. The retained eGFR analysis is designed to demonstrate that bardoxolone has disease-modifying activity in Alport syndrome patients.

181. During the CARDINAL Phase 2 Initial Results Conference Call, Defendants Huff and Meyer, in responding to analysts' questions, emphasized the sufficiency of the four-week washout period for removal of Bard's PD effects, the purported ability of retained eGFR following a four-week washout period to demonstrate efficacy and disease-modifying effects, and the FDA's purported accord with the foregoing. In so doing, they repeated FDA Guidance Representations, CARDINAL Design Representations, 10-14 Day Washout Representations, and Prior Study Retained eGFR Representations:

> A - Warren Huff
>
> With respect to your comment about the two years, this was the request of the FDA -- was they stated specifically that the retained eGFR benefit at week 52, after one year, could potentially support accelerated approval if it's statistically separated from placebo. And to come back -- bring that data back to them.
>
> ***
>
> A - Colin Meyer
>
> . . . And as far as the clinical meaningfulness, we think the on treatment effect is the full renal benefit of the drug. Importantly, FDA wants us to show the off treatment retained benefit, which would be evidence of the disease modifying activity. It also rules out harm. And so, that's why we're measuring those two end points, the primary endpoint we've (Inaudible; microphone inaccessible) the on treatment effect. And the key secondary is retained benefit.

CARDINAL Phase 2 Initial Results Conference Call, Bloomberg transcript at 7-9.

> Q – [Nina] [Robert W. Baird analyst]
>
> This actually (Nina) on for Brian. So regarding proteinuria, how do you think about that as a marker of renal damage and a potential benefit from treatment in contrast to measuring eGFR?
>
> ***
>
> A - Warren Huff
>
> I'd just add too that it's the actual endocytosis of the protein in the proximal tubules is one of the main drivers of the chronic inflammation fibrosis and remodeling in the renal interstitium. And we actually -- the key secondary endpoint of the study is -- we put the patients on drug or placebo for 48 weeks and then we remove the drug for four weeks. And we know that there is no active drug or metabolites present. Then we compare the estimated GFR back to both baseline and placebo.
>
> And in our two longer term diabetic CKD studies, we showed unequivocally that after patients had been on for a year. And then they were taken off drug, their kidney -- their estimated GFR, which we now know is real GFR, was significantly higher than their baseline value, leading strongly to the conclusion that there's been a structural improvement in the kidney. And I think that would trump any secondary marker like protein status.

CARDINAL Phase 2 Initial Results Conference Call, Bloomberg transcript at 15-16.

182. The FDA Guidance Representations in the CARDINAL Phase 2 Initial Results Release, and Defendants Huff's and Meyer's assertions of FDA Guidance Representations during the CARDINAL Phase 2 Initial Results Conference Call, were materially false and/or misleading. Specifically, the claims of acting in accord with FDA "guidance" purportedly supporting (i) use of a four-week washout period and (ii) the resulting retained eGFR as a basis for FDA approval, were misleading for failure to disclose that Reata had not obtained FDA concurrence on these matters. *See* Section IV.G.1, *supra*. Defendants failed to disclose that the FDA had **repeatedly warned** Reata, beginning with the FDA's December 2016 Advice Letter, that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout would be invalid and incapable of supporting FDA approval. *Id*.

183. The CARDINAL Design Representations in the CARDINAL Phase 2 Initial Results Release, and Defendants Huff's and Meyer's assertions of CARDINAL Design Representations during the CARDINAL Phase 2 Initial Results Conference Call, were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, use of an inadequate four-week washout period for retained eGFR measurement meant that CARDINAL would not actually measure what was claimed (*i.e.*, retained eGFR) – and hence, that any ensuing retained eGFR results would provide neither evidence of any truly retained eGFR benefit nor basis for FDA approval. *See* Sections IV.G.2-3, *supra*.

184. Defendant Huff's assertion of Prior Study Retained eGFR Representations in the CARDINAL Phase 2 Initial Results Conference Call was materially false and/or misleading. In truth, because BEAM and BEACON measured retained eGFR after an inadequate four-week washout period, they neither measured nor evidenced any retained eGFR benefit or disease-modifying effects for Bard. *See* Sections IV.G.2-3, *supra*.

185. Defendant Huff's assertion of 10-14 Day Washout Representations in the CARDINAL Phase 2 Initial Results Conference Call ("we remove the drug for four weeks. And we know that there is no active drug or metabolites present[]") was materially false and/or misleading. In truth, extended Bard treatment, such as in CARDINAL, BEAM, and BEACON, required eight weeks to wash out: a period at least four times longer than the represented 10-14 days. *See* Section IV.G.2, *supra*.

186. The market reacted favorably to the Reata Defendants' July 24, 2017 disclosures of CARDINAL's progress. Reata's share price rose $4.37 per share on July 24, 2017 (from the prior closing price of $31.10 per share) to close trading at $35.47 per share, a one-day increase of 14.1%. More than 1.1 million Reata shares traded that day – the first time daily trading exceeded

1 million shares since Reata's May 26, 2016 initial public offering.

5. Statements Made in Connection with Reata's July 26, 2017 Secondary Public Offering

187. On July 26, 2017, taking advantage of the jump in Reata's share price occasioned by Reata's July 24, 2017 disclosures, Reata issued and sold 3,737,500 shares of Class A common stock at $31.00 per share through a secondary stock offering underwritten by Defendants Jefferies, Leerink, Stifel, Baird, and LT&Co. (the "July 2017 Offering"). Gross proceeds to Reata from the July 2017 Offering totaled $115.9 million; net proceeds, after payment of $7.0 million to the July 2017 Offering underwriters, totaled $108.9 million.

188. The July 2017 Offering Documents[10] contained disclosures concerning Reata's "Clinical Pipeline" that gave pride of place and first mention to the development of Bard for Alport and included FDA Guidance Representations and CARDINAL Design Representations:

> ***Bardoxolone Methyl for the Treatment of Chronic Kidney Disease Caused by Alport Syndrome*** . . .
>
> The Phase 3 portion of CARDINAL . . . eGFR change will be measured after 48 weeks while the patient is on treatment, or on-treatment eGFR, and again after 52 weeks after the patient has stopped taking the study drug for a four-week withdrawal period, or retained eGFR. Based on guidance from the United States Food and Drug Administration, or the FDA, the year one retained eGFR benefit data may support accelerated approval under subpart H. . . . The second year on-treatment eGFR change will be measured after 100 weeks and the retained eGFR benefit will be measured after withdrawal of drug for four weeks at week 104. Based upon guidance from the FDA, the year two retained eGFR benefit data may support full approval.

July 2017 Offering Prospectus at S-2 – S-3.

[10] The shares sold in the July 2017 Offering were registered, issued, and sold pursuant to (i) a registration statement on Form S-3 filed by Reata with the SEC on June 23, 2017, as amended on July 10, 2017, declared effective on July 14, 2017, and signed by Defendants Huff, Bass, McClellan, McGaughy, Nielsen, and Rose (the "July 2017 Offering Registration Statement"); and (ii) a prospectus supplement, which formed part of the July 2017 Offering Registration Statement, dated July 26, 2017 (the "July 2017 Offering Prospectus," and together with the July 2017 Offering Registration Statement, the "July 2017 Offering Documents").

189. The FDA Guidance Representations in the July 2017 Offering Prospectus were materially false and misleading. Specifically, the claims of acting in accord with FDA "guidance" purportedly supporting (i) use of a four-week washout period and (ii) the resulting retained eGFR as a basis for FDA approval, were misleading for failure to disclose that Reata had not obtained FDA concurrence on these matters. *See* Section IV.G.1, *supra*. Defendants failed to disclose that the FDA had **repeatedly warned** Reata, beginning with the FDA's December 2016 Advice Letter, that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout would be invalid and incapable of supporting FDA approval. *Id*.

190. The CARDINAL Design Representations in the July 2017 Offering Prospectus were materially false and misleading. Because PD effects remained for eight weeks after extended Bard treatment, use of an inadequate four-week washout period for retained eGFR measurement meant that CARDINAL would not actually measure what was claimed (*i.e.*, retained eGFR), and hence, that any ensuing retained eGFR results would provide neither evidence of any truly retained eGFR benefit nor basis for FDA approval. *See* Sections IV.G.2-3, *supra*.

6. The November 13, 2017 Statements

191. The first patient for CARDINAL Phase 3 was enrolled on August 7, 2017.

192. On November 13, 2017, Reata: (i) issued a press release announcing third quarter 2017 results (the "Q3 2017 Results Release"); and (ii) filed with the SEC a Form 10-Q, signed by Defendant Huff, for the third-quarter of 2017 (the "Q3 2017 10-Q").

193. The Q3 2017 Results Release repeated FDA Guidance Representations and CARDINAL Design Representations:

> In August, 2017, Reata began enrolling patients in the Phase 3 portion of CARDINAL . . . .

> . . . The primary endpoint of the trial will be the change from baseline in estimated glomerular filtration rate (eGFR) at 48 weeks while the patient is on treatment, or on-treatment eGFR, and again at 52 weeks after the patient has stopped taking the study drug for a four-week withdrawal period, or retained eGFR. Based upon guidance from the United States Food and Drug Administration (FDA), the year one retained eGFR benefit data may support accelerated approval under subpart H. After withdrawal, patients will be restarted on study drug with their original treatment assignments and will continue on study for a second year, with on-treatment eGFR change measured at 100 weeks, and the retained eGFR benefit after withdrawal of drug for four weeks at week 104. Based upon guidance from the FDA, the year two retained eGFR benefit data may support full approval.

194. The Q3 2017 10-Q likewise contained FDA Guidance Representations and CARDINAL Design Representations:

> In August 2017, after having announced preliminary results from the CARDINAL Phase 2 trial, we began enrolling patients in the Phase 3 portion of CARDINAL . . . .
>
> . . . The eGFR change will be measured after 48 weeks while the patient is on treatment, or on-treatment eGFR, and again after 52 weeks after the patient has stopped taking study drug for a four-week withdrawal period, or retained eGFR. Based on guidance from the FDA, the year one retained eGFR benefit data may support accelerated approval under subpart H. Data from year one of CARDINAL are expected to be available in the second half of 2019. . . . The second year on-treatment eGFR change will be measured after 100 weeks and the retained eGFR benefit will be measured after withdrawal of drug for four weeks at week 104. Based upon guidance from the FDA, the year two retained eGFR benefit data may support full approval. In July 2017, we received orphan drug designation for bardoxolone methyl for the treatment of Alport syndrome.

Q3 2017 10-Q at 16-19.

195. The FDA Guidance Representations in the Q3 2017 Results Release and the Q3 2017 10-Q were materially false and/or misleading. Specifically, the claims of acting in accord with FDA "guidance" purportedly supporting (i) use of a four-week washout period and (ii) the resulting retained eGFR as a basis for FDA approval, were misleading for failure to disclose that Reata had not obtained FDA concurrence on these matters. *See* Section IV.G.1, *supra*. Defendants failed to disclose that the FDA had **repeatedly warned** Reata, beginning with the FDA's December 2016 Advice Letter, that it did **not** concur with CARDINAL's design, that the four-

week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval. *Id*.

196. The CARDINAL Design Representations in the Q3 2017 Results Release and Q3 2017 10-Q were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, use of an inadequate four-week washout period for retained eGFR measurement meant that CARDINAL would not actually measure what was claimed (*i.e.*, retained eGFR) – and hence, that any ensuing retained eGFR results would provide neither evidence of any truly retained eGFR benefit nor basis for FDA approval. *See* Sections IV.G.2-3, *supra*.

7. The Reata Defendants' November 2017 Statements Concerning TSUBAKI

197. On November 6, 2017, Reata: (i) issued a press release reporting in near real-time the release of TSUBAKI results on November 4, 2017; (ii) hosted a November 6, 2017 conference call to discuss TSUBAKI and CARDINAL with analysts and investors; and (iii) published to its website a presentation titled "Program Update of Bardoxolone Methyl in CKD,"[11] used by Defendant Meyer during the November 6, 2017 conference call, which reviewed TSUBAKI's findings (slides 13-19) and noted that TSUBAKI included serial eGFR measurements during a 12-week period following cessation of Bard treatment for measurement of retained eGFR (slide 14).

198. The Q3 2017 Results Release and Q3 2017 10-Q both hailed the TSUBAKI study:

> On November 4, 2017, Reata's partner, Kyowa Hakko Kirin, presented results of the TSUBAKI study at ASN. In TSUBAKI, bardoxolone demonstrated statistically significant and clinically meaningful increases in directly-measured glomerular filtration rate (GFR) in patients with type 2 diabetes and CKD using the "gold standard" inulin clearance method. The observed increase in GFR demonstrates that historical increases in eGFR produced by bardoxolone in various forms of

[11] *See* Events & Presentations Archive, *Program Update of Bardoxolone Methyl in CKD*, REATA PHARMACEUTICALS, INC. (Nov. 6, 2017), available at: https://www.reatapharma.com/investors/events-and-presentations/event-details/2017/Program-Update-of-Bardoxolone-Methyl-in-CKD/default.aspx.

> CKD, including Alport syndrome, reflect a true increase in kidney function. Bardoxolone demonstrated a favorable safety profile with no effect on blood pressure, urinary volume or sodium retention, and no evidence of overt fluid overload or cardiac toxicity.

Q3 2017 Results Release; Q3 2017 10-Q at 19.

199. Thus, the Reata Defendants were clearly familiar with the TSUBAKI study, which indicated that Bard's washout took approximately eight weeks. Yet Defendants continued to misleadingly maintain that CARDINAL's four-week washout period was adequate and appropriate in all their subsequent CARDINAL Design Representations, 10-14 Day Washout Representations, and CARDINAL Retained eGFR Representations.

8. The March 2, 2018 Statements

200. On March 2, 2018, Reata: (i) issued a press release announcing fourth-quarter and full-year 2017 results (the "Q4 2017 Results Release"); and (ii) filed with the SEC a Form 10-K, signed by Defendant Huff and the Director Defendants, for 2017 (the "2017 10-K").

201. The Q4 2017 Results Release contained FDA Guidance Representations and CARDINAL Design Representations:

> **Pipeline Highlights** . . .
>
> In the Phase 2 clinical trial, bardoxolone methyl demonstrated a statistically significant, mean increase from baseline in kidney function, as assessed by eGFR, at the 12 week endpoint. On the basis of the Phase 2 results, we initiated the Phase 3 portion of the CARDINAL trial, which will enroll approximately 150 patients with Alport syndrome. The United States Food and Drug Administration (FDA) has provided guidance that one year data from the ongoing Phase 3 portion of the trial demonstrating an improvement in retained eGFR, which is the increase in eGFR versus placebo after the patients have been taken off drug for four weeks, may support accelerated approval for bardoxolone methyl.

202. The 2017 10-K likewise contained FDA Guidance Representations and CARDINAL Design Representations:

> We are conducting a Phase 2/3 trial called CARDINAL . . . that studies the safety and efficacy of bardoxolone methyl in patients with CKD caused by Alport

> syndrome. . . .
>
> [W]e began enrolling the Phase 3 portion of CARDINAL last year. . . . The U.S. Food and Drug Administration (FDA) has provided us with guidance that, in patients with CKD caused by Alport syndrome, an analysis of retained eGFR, which is the eGFR change after a four week withdrawal of drug, demonstrating an improvement versus placebo after one year of bardoxolone methyl treatment may support accelerated approval. In addition, data demonstrating an improvement versus placebo in retained eGFR after two years of treatment may support full approval.
>
> ***
>
> The FDA has provided us with guidance that, in patients with CKD caused by Alport syndrome, data demonstrating an improvement versus placebo in retained eGFR after one year of bardoxolone methyl treatment may support accelerated approval, and data demonstrating an improvement versus placebo in retained eGFR after two years of treatment may support full approval. Based on this guidance, we are conducting a Phase 2/3 trial called CARDINAL in patients with a severe, genetic form of CKD caused by Alport syndrome, and we expect data from the study to be available during the second half of 2019.

2017 10-K at 3, 6-7.

203. The FDA Guidance Representations in the Q4 2017 Results Release and 2017 10-K were materially false and/or misleading. Specifically, the claims of acting in accord with FDA "guidance" purportedly supporting (i) use of a four-week washout period and (ii) the resulting retained eGFR as a basis for FDA approval, were misleading for failure to disclose that Reata had not obtained FDA concurrence on these matters. *See* Section IV.G.1, *supra*. Defendants failed to disclose that the FDA had **repeatedly warned** Reata, beginning with the FDA's December 2016 Advice Letter, that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval. *Id*.

204. The CARDINAL Design Representations in the Q4 2017 Results Release and 2017 10-K were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR

measurement meant that CARDINAL would not actually measure what was claimed (*i.e.*, retained eGFR) – and hence, that any ensuing retained eGFR results would provide neither evidence of any truly retained eGFR benefit nor basis for FDA approval. *See* Sections IV.G.2-3, *supra*.

205. The 2017 10-K also contained forceful and extended assertions of Prior Study Retained eGFR Representations and 10-14 Day Washout Representations:

> **Bardoxolone Methyl for the Treatment of Rare Chronic Kidney Diseases**
>
> *Overview*
>
> We are developing bardoxolone methyl for the treatment of patients with CKD caused by Alport syndrome . . . .
>
> . . . Importantly, in BEAM and BEACON, bardoxolone methyl treatment for one year produced a retained eGFR benefit after the drug was withdrawn. This retained eGFR benefit provides additional evidence that bardoxolone methyl treatment may protect the structure of the kidney and may prevent or delay the need for dialysis or a transplant.
>
> ***
>
> *Bardoxolone Methyl Produces a Retained eGFR Benefit after Withdrawal of Drug*
>
> To further assess whether increases in eGFR from bardoxolone methyl treatment have the potential to delay or prevent ESRD and the need for dialysis or a transplant over the long term, we conducted a retained benefit analysis in the BEAM and BEACON clinical trials. In those trials, after patients had been treated with bardoxolone methyl or placebo for approximately one year, the drug was withdrawn for four weeks, and the post-withdrawal eGFR was compared to the patient's baseline eGFR. Bardoxolone methyl and any active metabolites are eliminated from the body within approximately 10 days after withdrawal, so we believe the post-withdrawal eGFR change is a measure of the effect of long term bardoxolone methyl treatment on the structure of the kidney and its disease-modifying potential.
>
> **Bardoxolone Methyl Produced Post-Withdrawal eGFR Benefit in BEAM and BEACON**
>
	Baseline eGFR	Placebo-corrected Post-week 48 Withdrawal Δ eGFR	WK 12/Post-Withdrawal Correlation
BEAM (Mid/High Dose)	32	4.8 ($p<0.05$)	$r=0.53$ ($p<0.001$)
BEACON	23	1.8 ($p<0.001$)	$r=0.43$ ($p<0.001$)
>
> Importantly, in both BEAM and BEACON, bardoxolone methyl treatment

> produced a statistically significant improvement in retained eGFR versus placebo after withdrawal of drug. Also, the acute increase in eGFR from bardoxolone methyl treatment observed at 12 weeks was predictive of both the on-treatment and retained eGFR benefit after one year of treatment. This finding is important because it indicates that increases in eGFR from a relatively short, 12 week, treatment periods with bardoxolone methyl may be predictive of a long term clinical benefit.

2017 10-K at 6-7, 8-11.

206. The Prior Study Retained eGFR Representations in the 2017 10-K were materially false and/or misleading. In truth, because BEAM and BEACON measured retained eGFR after an inadequate four-week washout period, they neither measured nor evidenced any retained eGFR benefit or disease-modifying effects for Bard. *See* Sections IV.G.2-3, *supra*.

207. The 10-14 Day Washout Representations in the 2017 10-K ("Bardoxolone methyl and any active metabolites are eliminated from the body within approximately 10 days after withdrawal, so we believe the post-withdrawal eGFR change is a measure of the effect of long term bardoxolone methyl treatment on the structure of the kidney and its disease-modifying potential.") were materially false and/or misleading. In truth, extended Bard treatment, such as in CARDINAL, BEAM, and BEACON, required eight weeks to wash out: a period at least four times longer than the represented 10-14 days. *See* Section IV.G.2, *supra*.

208. The 2017 10-K contained Risk Factor Disclosures that were: (i) substantively identical, in relevant part, to those in the 2016 10-K (*see* ¶177, *supra*), and (ii) inadequate and materially misleading. *See* 2017 10-K at 39-40, 56-67. They inaccurately described certain risks – specifically, that the FDA might not approve Bard due to "inadequate design or implementation of our clinical trials[,]" failure to demonstrate Bard's "safety and efficacy . . .[] to the satisfaction of the relevant regulatory authorities[,]" and FDA disagreement "that our completed clinical trials provide adequate data on safety or efficacy[]" – as **potential** risks, stated in a generalized and hypothetical manner, while omitting to disclose material, then-existing facts – such as the FDA's

December 2016 Advice Letter – indicating that these risks were actually materializing.

9. The May 25, 2018 Statements

209. On May 25, 2018, Reata hosted a conference call to discuss Bard's clinical study results. In response to analyst questions that sought clarification between Bard's PD effects and its potential disease-modifying effects, Defendant Meyer emphasized the importance of retained eGFR results and reiterated Prior Study Retained eGFR Representations to claim that evidence indicated that Bard was indeed disease-modifying:

> A - Colin Meyer
>
> . . . And so, we believe that that would obviously be disease modifying. Mechanistically, I think the off-treatment data are the most relevant clinical data we have to date that suggests that the drug does have disease-modifying activity because in the BEAM and BEACON trials, when we withdrew patients from the drug, let the drug wash out, let the acute effect wash out, and there was no more drug present, kidney function was improved relative to placebo in both trials. Not only was it improved, it was actually above baseline and this is an important distinction amongst other trials with other agents that have been recently reported, where there may have been an increase versus placebo. The kidney function was still below baseline.
>
> And so, we think that is the best evidence of disease-modifying activity. We're obviously generating those data in our Alport syndrome patients.

May 25, 2018 Conference Call, Bloomberg transcript at 11-12.

210. Defendant Meyer's above-identified statements, repeating Prior Study Retained eGFR Representations and asserting that Bard had fully washed out within four weeks, were materially false and/or misleading. In truth, because BEAM and BEACON measured retained eGFR after an inadequate four-week washout period (*i.e.*, when PD effects were still present), they neither measured nor evidenced any retained eGFR benefit or disease-modifying effects for Bard. *See* Sections IV.G.2-3, *supra*.

10. The July 23, 2018 Statements

211. On July 23, 2018, Reata: (i) issued a press release titled "Reata Announces Positive Phase 2 Data for Bardoxolone Methyl in CKD Caused by Alport Syndrome and Autosomal Dominant Polycystic Kidney Disease," announcing *inter alia* "positive one-year results for the Phase 2 portion of CARDINAL" that demonstrated a "[s]ignificant [r]etained [b]enefit" (the "CARDINAL Phase 2 Results Release"); and (ii) held a conference call at 8:00 a.m. EST with analysts and investors (the "CARDINAL Phase 2 Results Conference Call").

212. The CARDINAL Phase 2 Results Release featured the first Class Period assertion of CARDINAL Retained eGFR Representations (*i.e.*, that CARDINAL data demonstrated a retained eGFR benefit after treatment and a four-week washout period), and contained FDA Guidance Representations and CARDINAL Design Representations (to pointedly represent that under purported FDA guidance, such results could serve as a basis for FDA approval):

> *Statistically Significant Retained Benefit of 4.1 mL/min in Alport Syndrome Patients Following 48 Weeks of Treatment and 4 Weeks of Drug Withdrawal* . . .
>
> In the Phase 2 portion of CARDINAL, significantly increased estimated glomerular filtration rate (eGFR) at Week 48 from baseline (n=25) of 10.4 mL/min/1.73 m2 ($p<0.0001$) was observed in patients treated with bardoxolone. . . .
>
> Significantly increased eGFR from baseline at Week 52 after withdrawal of active drug for four weeks (the retained eGFR benefit) by a mean of 4.1 mL/min/1.73 m2 ($p<0.05$) was also observed with bardoxolone treated patients. These results provide evidence that bardoxolone may delay or prevent kidney failure. The U.S. Food and Drug Administration (FDA) has provided Reata with guidance that, in Alport syndrome patients, a significant improvement in placebo-corrected retained eGFR after one year of bardoxolone treatment may support accelerated approval and, after two years of bardoxolone treatment, may support full approval.
>
> With respect to safety in the Phase 2 portion of CARDINAL, no treatment-related serious adverse events have been reported, and the reported adverse events have generally been mild to moderate in intensity. Twenty-five patients were available for the analysis, and no discontinuations were due to bardoxolone treatment.
>
> ***

> "The results announced today add to the large body of clinical evidence that bardoxolone treatment has the potential to prevent or delay kidney failure in rare forms of chronic kidney disease" said Warren Huff, Reata's President and Chief Executive Officer. . . . "[T]he magnitude of the observed retained eGFR benefit after withdrawal of drug versus the historical rate of eGFR loss suggests that the Phase 3 portion of CARDINAL is conservatively powered with respect to the key secondary endpoint of retained eGFR benefit.
>
> ***
>
> **About the CARDINAL Clinical Study** . . .
>
> The key secondary endpoint of the Phase 3 portion of the trial is the change from baseline in retained eGFR benefit after 48 weeks on-treatment and four weeks off-treatment relative to placebo and is designed to demonstrate that bardoxolone has disease-modifying activity in Alport syndrome patients. Based upon guidance from the FDA, the 52-week retained eGFR benefit data may support accelerated approval under subpart H. . . . The second-year on-treatment eGFR change will be measured after 100 weeks and the retained eGFR benefit will be measured after withdrawal of drug for four weeks at Week 104. Based upon guidance from the FDA, the year-two retained eGFR benefit data may support full approval.

213. During the CARDINAL Phase 2 Results Conference Call, Defendants Huff and Meyer focused their introductory remarks on extended assertion of the CARDINAL Retained eGFR Representations, and also repeated FDA Guidance Representations and CARDINAL Design Representations:

> J. Warren Huff . . .
>
> In November of last year, we reported data on the primary endpoint of the Phase 2 open-label portion of CARDINAL demonstrating that bardoxolone produced large significant improvements in estimated GFR after 12 weeks of treatment in Alport syndrome patients. Based on those results, we initiated a Phase 3 study, that if (00:03:58) successful, we believe will support registration in Alport syndrome. . . . Today, we'll provide a detailed update on the full one-year data from the Phase 2 portion of CARDINAL . . . .
>
> . . . Next slide. With respect to the CARDINAL Phase 2 study, the key data being discussed today are the effect on estimated GFR of bardoxolone after one year of treatment for (00:04:44) the on-treatment effect, as well as the retained eGFR of bardoxolone after one year of treatment and withdrawal of drug for four weeks. What we call the retained eGFR benefit.
>
> Of course, the on-treatment effect on eGFR is important because it represents the

full clinical benefit to the patient while taking active drug. The retained eGFR benefit is important because it provides data on the long-term effect of the drug on the risk of kidney failure and the need for dialysis or transplant. If you treat patients for a long-term and then completely withdraw the drug so that no active drug is present and then compare the post-treatment kidney function to placebo, you can assess whether the treatment protected or harmed the kidney. If the post withdrawal eGFR is greater than placebo, it's evidence that the drug may delay kidney failure.

It also demonstrates that the on-treatment kidney function increase was not due to a damaging mechanism. If the treatment temporarily increased GFR through a mechanism that damaged the kidney such as pressure-mediated hyperfiltration. When the drug was removed, the eGFR of the damaged kidney would be lower than both baseline and placebo. If kidney function is functioning better than placebo after withdrawal, it showed that the treatment benefited the organ.

We believe this is why the FDA has accepted the placebo-corrected retained eGFR benefit is the standard registrational endpoint in rare forms of CKD. FDA provided us with guidance in 2016 that they would take this endpoint for approval in Alport syndrome. And it's the key secondary endpoint in the Phase 3 study. . . .

Colin Meyer:

Thanks Warren. . . .

The FDA has provided written guidance that is statistically significant placebo-corrected retained benefit at one year may support accelerated approval in Alport syndrome and that full approval may be granted based on retained benefit after two years. We expect to announce one-year data from the pivotal portion of CARDINAL in the second half of 2019.

***

The eGFR data at Week 52 after a four weeks withdrawal, also known as retained eGFR benefit analysis, are shown on this slide. The mean improvement in eGFR at Week 52 was 4.1 mL per minute, which was statistically significant.

To our knowledge, bardoxolone is the first therapy to produce a retained eGFR benefit that is above baseline in a long-term CKD trial. Since we observed that bardoxolone treatment produce a positive retained eGFR benefit after withdrawal of drug, these data suggest that bardoxolone protected kidney function during treatment and may delay or prevent end-stage kidney disease.

***

Next slide. In summary, we observed a large statistically and clinically significant improvement in kidney function at Week 48 that translated to a statistically significant retained eGFR benefit after drug withdrawal that was substantially above baseline in patients who are progressing on average 4.2 mL per minute prior

> to study entry. These efficacy results are consistent with the results from our studies of bardoxolone in diabetic CKD and are indicative of structural improvements in the kidney that may result in a delay in patients progressing to end-stage kidney disease.
>
> ***
>
> J. Warren Huff:
>
> Thanks, Colin. Next slide. As I mentioned earlier, in 11 clinical trials involving more than 2,800 patients, bardoxolone treated patients experienced increased estimated GFR versus both baseline and placebo. The data presented today add meaningfully to this body of work. The on-treatment improvement in estimated GFR observed in Alport syndrome patients represents the recovery of approximately two years of kidney function loss in these patients.
>
> Further, bardoxolone produced a retained eGFR benefit that is significantly above baseline and one of the most challenging forms of CKD to treat. The positive retained eGFR benefit shows that bardoxolone treatment for one year benefited the organ and suggests that long-term treatment with bardoxolone may delay or prevent kidney failure in these patients who respond to treatment.
>
> It also demonstrates that the increases in kidney function were not due to a damaging mechanism. If bardoxolone treatment temporarily increased GFR through a mechanism that damage the kidney, when the drug was removed the eGFR of treated patients would have been lower than both baseline and their expected annual decline rate of approximately 4 mL per minute to 5 mL per minute.

CARDINAL Phase 2 Results Conference Call, Bloomberg transcript at 2-8.

214. In response to analyst questions in the CARDINAL Phase 2 Results Conference Call concerning retained eGFR, the FDA's views on retained eGFR, and Bard's safety, Defendants Huff and Meyer again repeated FDA Guidance Representations, CARDINAL Retained eGFR Representations, and CARDINAL Design Representations, stating that (i) CARDINAL produced a significant retained eGFR benefit, (ii) the FDA supported the retained eGFR standard for approval, and (iii) the purported retained eGFR results were a further indication that Bard produced its eGFR benefit without damaging the kidneys:

> Q - Yigal Dov Nochomovitz [Citigroup analyst]
>
> Thank you for taking the question and congrats on a very, very nice result.

> Regarding the retained eGFR at two years to get the full approval, what are your expectations there and what has the FDA said about that? Is that something where you sort of need to show something similar to what you've shown here assuming this is reproduced in the first year of the Phase 3 CARDINAL?
>
> A - Colin Meyer
>
> Hi, Yigal. Yes. So FDA has provided guidance that once again for accelerated approval, they would take a statistically significant separation at one year and they would take for full approval statistically significant separation at two years. . . .
>
> And as you know, we've powered our Alport syndrome trial to show a difference of at least 2.2 mL per minute (00:25:08). And so, for the trial to be successful and show significant difference, it has to be above that threshold. And so, we feel very comfortable with that.
>
> ***
>
> A - J. Warren Huff
>
> I actually would just add one thing and that is that there's a very good reason why the FDA accepts the retained GFR (00:37:33) benefit for approval and it is very strong evidence that the drug treatment benefited the organ directly. I mean, just think about it. It's a brute force, very tough endpoint to hit. These patients were on the drug for a year. If the drug was increasing pressure and damaging the kidney when the drug was completely removed after a year, the damaged organ would certainly be functioning worse than placebo and of course worse than baseline.
>
> But what do we observe? There's no drug present, but their kidney is functioning 4 mL per minute better than it was prior to (00:38:16) entry into the study. And this is actually in patients that were declining 4 mL per minute annually from treatment. How could the drug be damaging with that clinical data?

CARDINAL Phase 2 Results Conference Call, Bloomberg transcript at 8-9, 12-13.

215. The CARDINAL Retained eGFR Representations in the CARDINAL Phase 2 Results Release, and Defendants Huff's and Meyer's extended assertions of the CARDINAL Retained eGFR Representations during the CARDINAL Phase 2 Results Conference Call, were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR measurement meant that: (i) CARDINAL had not actually measured what was claimed (*i.e.*, retained eGFR), and instead had measured PD effects; (ii) CARDINAL's purported retained eGFR

results neither constituted nor measured truly retained eGFR and thus provided no indication of disease-modifying effects; and (iii) CARDINAL's retained eGFR results therefore would not and could not provide a basis for FDA approval. *See* Section IV.G.3, *supra*.

216. The FDA Guidance Representations in the CARDINAL Phase 2 Results Release, and Defendants Huff's and Meyer's assertions of the FDA Guidance Representations during the CARDINAL Phase 2 Results Conference Call, were materially false and/or misleading. Specifically, the claims of acting in accord with FDA "guidance" purportedly supporting (i) use of a four-week washout period and (ii) the resulting retained eGFR as a basis for FDA approval, were misleading for failure to disclose that Reata had not obtained FDA concurrence on these matters. *See* Section IV.G.1, *supra*. Defendants failed to disclose that the FDA had **repeatedly warned** Reata, beginning with the FDA's December 2016 Advice Letter, that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval. *Id*.

217. The CARDINAL Design Representations in the CARDINAL Phase 2 Results Release, and Defendants Huff's and Meyer's assertions of the CARDINAL Design Representations during the CARDINAL Phase 2 Results Conference Call, were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR measurement meant that CARDINAL would not actually measure what was claimed (*i.e.*, retained eGFR) – and hence, that any ensuing retained eGFR results would provide neither evidence of any truly retained eGFR benefit nor basis for FDA approval. *See* Sections IV.G.2-3, *supra*.

218. Reata's July 23, 2018 disclosures – essentially, that CARDINAL Phase 2 results

showed a significant retained eGFR benefit from Bard at one year of treatment – provided the market with indication of two critical matters: (i) that Bard had a disease-modifying effect; and (ii) that Bard was likely to surpass the FDA's retained eGFR approval threshold in CARDINAL Phase 3. Analysts following Reata took away exactly these messages from the July 23, 2018 disclosures, sharing the conclusion that the Phase 2 results disclosed on July 23, 2018 had "de-risked" the pivotal CARDINAL Phase 3 results – *i.e.*, the results indicated that CARDINAL Phase 3 endpoints would be successfully met. For example, in July 23, 2018 analyst reports, Leerink analyst Joseph Schwartz and Jefferies analyst Maury Raycroft wrote:

> • **Bottom Line: This morning RETA reported positive 'retained benefit' data from the Alport syndrome patients enrolled in the Ph.2 portion of the CARDINAL study, which was better than we expected . . . , and which we believe derisks Ph.3 results expected in 2H19**. . . .
>
> • **Bardoxolone retained much more benefit (4.1 ml/min) after 4 weeks of discontinuation in the Ph.2 portion of the study reported today than the 2.2 ml/min threshold which the Ph.3 is powered for and the FDA will require for accelerated approval based on the patients enrolled in the Ph.3. portion of the study**. Importantly, the Phase 2 portion of the study does not include a placebo arm whereas the Ph.3 does. Since estimated glomerular filtration rate (eGFR) is expected to decline by around 4.2 ml/min per year for patients in the placebo arm, we believe these results are highly derisking since the implied placebo- corrected difference of 8.3 is almost four times the threshold for success.

Joseph P. Schwartz, *Better than Exp Retained Benefit and PKD Data Derisks Ph3 & Expands Opportunity*, SVB SECURITIES LLC, F/K/A SVB LEERINK LLC, 1 (July 23, 2018).

> **RETA succeeded in the unconventional ph.II retained benefit analysis in Alport syndrome -- after drug withdrawal for four wks, pts maintained +4.1 ml/ min eGFR improvement, implying a +8.3 mL/min benefit vs expected decline of ~-4.2. . . . We believe the new data de-risked the ph.III's potential for success** . . . .
>
> **RETA succeeded in the retained benefit analysis for ph.II CARDINAL in Alport syndrome**. After 48 wks of treatment eGFR was +10.4mL/min; pts were withdrawn from bard for 4 wks and retained a stat sig benefit of +4.1mL/min -- this type of analysis is risky, particularly in a disease like Alport caused by mutations that impair the structure of kidney glomeruli. . . .

> **Based on the collective efficacy and safety de-risking, we increased our probability of success for . . . Alport (now 65% vs 40% prior)** . . . . Importantly, we believe the new results de-risked the ongoing Alport ph.III, given that the ph.III retained benefit analysis (also at 1 yr) is powered to detect placebo-corrected benefit of 2.2 mL/min (n=150) vs today's update showing 8.3mL/min. We assume RETA succeeds at the 1-yr analysis and gets approved for Alport by 2020.
>
> **For safety, the retained benefit demonstrated that bard is not damaging the kidne**y . . . .

Maury Raycroft, *Retained Benefit Analysis De-Risked Ongoing Alport Ph.III And ADPKD Opportunity*, JEFFERIES LLC, 1 (July 23, 2018).

219. For these reasons, the July 23, 2018 disclosures caused investors to immediately and significantly re-value Reata. On July 23, 2018, as more than 4.1 million Reata shares traded, **Reata's share price rose 65% in a single day**, gaining $30.15 per share from its prior closing price ($46.40 per share on July 20, 2018) to close July 23, 2018 trading at $76.55 per share.

11. Statements Made in Connection with Reata's July 25, 2018 Secondary Public Offering

220. Taking advantage of the dramatic appreciation in Reata's share price occasioned by Reata's July 23, 2018 disclosures that CARDINAL Phase 2 demonstrated a significant retained eGFR benefit after one year of treatment, Reata announced, the same day, a proposed secondary stock offering of 3.0 million shares (with an overallotment option of an additional 450,000 shares).

221. On July 25, 2018, Reata issued and sold 3.45 million shares of Class A common stock at $72.00 per share through a secondary stock offering underwritten by Defendants Jefferies, Leerink, Stifel, Cantor, and LT&Co. (the "July 2018 Offering"). Gross proceeds to Reata from the July 2018 Offering totaled $248.4 million, and net proceeds, after payment of $14.9 million to the July 2018 Offering underwriters, totaled $233.5 million.

222. The July 2018 Offering Documents[12] contained FDA Guidance Representations, CARDINAL Design Representations, CARDINAL Retained eGFR Representations, and 10-14 Day Washout Representations:

> ***CARDINAL, a Study in Patients with CKD Caused by Alport Syndrome*** . . .
>
> In July 2018, we announced positive interim safety and efficacy data for the ongoing open-label Phase 2 portion of CARDINAL. . . . Data demonstrate that bardoxolone methyl significantly improved kidney function in Alport syndrome patients as measured by eGFR. In the Phase 2 portion of CARDINAL, we observed the following: . . .
>
> - A statistically significant mean increase from baseline in retained eGFR, which is the eGFR change after a four-week withdrawal of drug, at Week 52 of 4.1 mL/min/1.73 m 2 ($p<0.05$) in 25 patients was observed.
>
> - Bardoxolone methyl and any active metabolites are eliminated from the body within approximately 10 days after withdrawal, so we believe this retained eGFR benefit is a measure of the effect of long term treatment on the structure of the kidney and its disease-modifying potential. . . .
>
> - We believe this retained eGFR benefit provides evidence that increases in eGFR observed with bardoxolone methyl therapy may be durable and may prevent or delay kidney failure.
>
> ***
>
> In the second half of 2017, we began enrolling the Phase 3 portion of CARDINAL . . . . The FDA has provided us with guidance that an analysis of retained eGFR, demonstrating an improvement versus placebo after one year of bardoxolone methyl treatment, may support a New Drug Application (NDA) submission for accelerated approval of bardoxolone methyl for the treatment of CKD caused by Alport syndrome, and data demonstrating an improvement versus placebo in retained eGFR after two years of treatment may support full approval. Enrollment in the Phase 3 portion of CARDINAL is proceeding as planned, and we expect to have one year top-line results available in the second half of 2019. Based on retained eGFR benefit observed in CARDINAL Phase 2 patients at Week 52, we

[12] The shares sold in the July 2018 Offering were registered, issued, and sold pursuant to (i) a shelf registration statement on Form S-3 filed by Reata with the SEC on July 23, 2018, signed by Defendants Huff, Bass, McClellan, McGaughy, Nielsen, and Rose (the "Shelf Registration Statement"); and (ii) a prospectus supplement, which formed part of the Shelf Registration Statement, dated July 23, 2018 (the "July 2018 Offering Prospectus," and together with the Shelf Registration Statement, the "July 2018 Offering Documents").

> believe the Phase 3 portion of CARDINAL is conservatively powered. No safety concerns have been reported by the DMC.

July 2018 Offering Prospectus at S-1 – S-2.

223. The FDA Guidance Representations contained in the July 2018 Offering Prospectus were materially false and/or misleading. Specifically, the claims of acting in accord with FDA "guidance" purportedly supporting (i) use of a four-week washout period, and (ii) the resulting retained eGFR as a basis for FDA approval, were misleading for failure to disclose that Reata had not obtained FDA concurrence on these matters. *See* Section IV.G.1, *supra*. Defendants failed to disclose that the FDA had **repeatedly warned** Reata, beginning with the FDA's December 2016 Advice Letter, that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval. *Id*.

224. The CARDINAL Design Representations contained in the July 2018 Offering Prospectus were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR measurement meant that CARDINAL would not actually measure what was claimed (*i.e.*, retained eGFR) – and hence, that any ensuing retained eGFR results would provide neither evidence of any truly retained eGFR benefit nor basis for FDA approval. *See* Sections IV.G.2-3, *supra*.

225. The CARDINAL Retained eGFR Representations in the July 2018 Offering Prospectus (*i.e*., the one-year retained eGFR benefit from CARDINAL Phase 2) were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR measurement meant that: (i) CARDINAL had not actually measured what was claimed (*i.e.*, retained eGFR) and

instead had measured PD effects; (ii) CARDINAL's purported retained eGFR results neither constituted nor measured truly retained eGFR and thus provided no indication of disease-modifying effects; and (iii) CARDINAL's retained eGFR results therefore would not and could not provide basis for FDA approval. *See* Section IV.G.3, *supra.*

226. The 10-14 Day Washout Representations in the July 2018 Offering Prospectus were materially false and/or misleading. In truth, extended Bard treatment, such as in CARDINAL, BEAM, and BEACON, required eight weeks to wash out: a period at least four times longer than the represented 10-14 days. *See* Section IV.G.2, *supra*.

12. The November 7, 2018 Statements

227. In September 2018, the FDA reached out to Reata, following the completion of CARDINAL Phase 2, to encourage Reata to request an End-of-Phase 2 meeting intended to "ensure alignment" between the FDA and Reata with respect to CARDINAL's adequacy *prior* to commencing the CARDINAL Phase 3 trial – *i.e.*, *before* it would be too late to modify CARDINAL's design to respond to FDA concerns (for example, by including additional off-treatment eGFR measurements more than four weeks after treatment end). *See* Section IV.G.1, *supra*. Reata declined the FDA's invitation and did not have an End-of-Phase-2 meeting with the FDA.

228. On November 7, 2018, Reata: (i) issued a press release announcing third-quarter 2018 results (the "Q3 2018 Results Release"); (ii) filed with the SEC a Form 10-Q, signed by Defendant Huff, for the third quarter of 2018 (the "Q3 2018 10-Q"); and (iii) at 8:00 a.m. EST, hosted a conference call with analysts and investors (the "Q3 2018 Conference Call").

229. The Q3 2018 Results Release contained CARDINAL Retained eGFR Representations:

Product Development Updates

Phase 2/3 CARDINAL Trial of Bardoxolone Methyl in Alport Syndrome

In July, we reported positive data from the Phase 2 portion of the CARDINAL study, which demonstrated a significant improvement in estimated glomerular filtration rate (eGFR) after 48 weeks of treatment with bardoxolone methyl (bardoxolone), and a statistically significant retained eGFR benefit following 4 weeks of drug withdrawal. To our knowledge, bardoxolone is the first therapy to produce a retained eGFR benefit that is above baseline in a long-term chronic kidney disease (CKD) trial, and we believe this retained eGFR benefit provides evidence that increases in eGFR observed with bardoxolone therapy may prevent or delay kidney failure. Enrollment in the pivotal Phase 3 portion of the CARDINAL trial of bardoxolone in Alport syndrome is complete at 157 patients, and top-line data are expected in the second half of 2019.

230. The Q3 2018 10-Q contained (i) CARDINAL Retained eGFR Representations, (ii) Prior Study Retained eGFR Representations, (iii) FDA Guidance Representations, and (iv) 10-14 Day Washout Representations:

Bardoxolone Methyl in CKD Caused by Alport Syndrome and Additional Rare Forms of CKD

The clinical trial data for bardoxolone methyl demonstrate consistent, clinically meaningful improvement in kidney function . . . . Specifically, we have observed . . . increases in retained eGFR, which is the eGFR change after a four-week withdrawal of drug, that was evaluated following 48 weeks of treatment in two patient populations. We believe these data support the potential for bardoxolone methyl to delay or prevent dialysis, kidney transplant, and death in patients with Alport syndrome and other rare forms of CKD. Further details on the clinical trials of bardoxolone methyl include the following: . . .

- In BEAM and BEACON, bardoxolone methyl treatment for one year showed statistically significant, mean increases in retained eGFR that potentially indicates disease modifying benefits.

***

In July 2018, we announced positive interim safety and efficacy data for the ongoing open-label Phase 2 portion of CARDINAL. . . . Data demonstrate that bardoxolone methyl significantly improved kidney function in Alport syndrome patients as measured by eGFR. In the Phase 2 portion of CARDINAL, we achieved the following: . . .

- A statistically significant, mean increase from baseline in retained eGFR at Week 52 of 4.1 mL/min/1.73 m2 ($p<0.05$) in 25 patients was

observed.

- Bardoxolone methyl and any active metabolites are eliminated from the body within approximately 10 days after withdrawal, so we believe this retained eGFR benefit is a measure of the effect of long-term treatment on the structure of the kidney and its disease-modifying potential.

- To our knowledge, bardoxolone methyl is the first therapy to produce a retained eGFR benefit that is above baseline in a long-term CKD trial.

- We believe this retained eGFR benefit provides evidence that increases in eGFR observed with bardoxolone methyl therapy may prevent or delay kidney failure.

***

The Phase 3 portion of CARDINAL is an international, multi-center, randomized, double-blind, placebo-controlled trial that is studying the safety and efficacy of bardoxolone methyl in patients with CKD caused by Alport syndrome. We are currently conducting the Phase 3 portion of CARDINAL. . . . The FDA has provided us with guidance that an analysis of retained eGFR, demonstrating an improvement versus placebo after one year of bardoxolone methyl treatment, may support a New Drug Application (NDA) submission for accelerated approval of bardoxolone methyl for the treatment of CKD caused by Alport syndrome, and data demonstrating an improvement versus placebo in retained eGFR after two years of treatment may support full approval. We expect to have one year top-line results available in the second half of 2019. Based on retained eGFR benefit observed in CARDINAL Phase 2 patients at Week 52, we believe the Phase 3 portion of CARDINAL is conservatively powered. No safety concerns have been reported by the DMC.

Q3 2018 10-Q at 13-15.

231. During the Q3 2018 Conference Call, in response to analyst questions regarding whether Bard operated through hyperfiltration, Defendant Meyer asserted that the retained eGFR results seen in CARDINAL, BEAM, and BEACON (*i.e.*, the CARDINAL Retained eGFR Representations and the Prior Study Retained eGFR Representations) indicated no long-term kidney function damage consistent with hyperfiltration, and instead indicated disease-modifying activity:

> A - Colin Meyer . . .
>
> As far as some of your specific questions about proteinuria, and then eGFR, there has been a question if the increase in GFR is due to something called hyperfiltration which importantly is a very specific effect of increased pressure in the kidney that may transiently increase GFR that it ultimately within the period of just a few months cause injury and loss of GFR.
>
> We've shown very carefully in animal models that does not occur. The drug restores surface area that's constricted in the setting of inflammation, basically restoring increasing GFR to a non-damaging pattern. We're now shown in several trials, including Alport syndrome and CARDINAL and diabetic CKD in the BEAM and BEACON trials that the effect is durable for at least one year and so, and the magnitude is quite large. This is very distinct once again from a pattern of hyperfiltration. And importantly, we've shown retained benefit now in three different trials, including the CARDINAL Phase 2 trial. That rules out harm to kidney and demonstrates disease modifying activity.

Q3 2018 Conference Call, Bloomberg transcript at 7-8.

232. The November 7, 2018 assertions of CARDINAL Retained eGFR Representations in the Q3 2018 Results Release, Q3 2018 10-Q, and the Q3 2018 Conference Call were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR measurement meant that: (i) CARDINAL had not actually measured what was claimed (*i.e.*, retained eGFR), and instead had measured PD effects; (ii) CARDINAL's purported retained eGFR results neither constituted nor measured truly retained eGFR and thus provided no indication of disease-modifying effects; and (iii) CARDINAL's retained eGFR results therefore would not and could not provide basis for FDA approval. *See* Section IV.G.3, *supra*.

233. The November 7, 2018 assertions of Prior Study Retained eGFR Representations in the Q3 2018 10-Q and in the Q3 2018 Conference Call were materially false and/or misleading. In truth, because BEAM and BEACON measured retained eGFR after an inadequate four-week washout period, they neither measured nor evidenced any retained eGFR benefit or disease-modifying effects for Bard. *See* Sections IV.G.2-3, *supra*.

234. The FDA Guidance Representations contained in the Q3 2018 10-Q were materially false and/or misleading. Specifically, the claims of acting in accord with FDA "guidance" purportedly supporting (i) use of a four-week washout period and (ii) the resulting retained eGFR as a basis for FDA approval, were misleading for failure to disclose that Reata had not obtained FDA concurrence on these matters. *See* Section IV.G.1, *supra*. Defendants failed to disclose that the FDA had **repeatedly warned** Reata, beginning with the FDA's December 2016 Advice Letter, that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval. *Id*. Additionally, these representations failed to disclose that in September 2018, the FDA asked Reata for an End-of-Phase 2 meeting, and stressed the importance of such a meeting, and Reata declined.

235. The 10-14 Day Washout Representations contained in the Q3 2018 10-Q were materially false and/or misleading. In truth, extended Bard treatment, such as in CARDINAL, BEAM, and BEACON, required eight weeks to wash out: a period at least four times longer than the represented 10-14 days. *See* Section IV.G.2, *supra*.

13. The February 28, 2019 Statements

236. In February 2019, the FDA: (i) again reached out to Reata; (ii) once again communicated to Reata its previously-expressed concerns with the adequacy of CARDINAL's washout period, and hence with the validity of CARDINAL's retained eGFR data; and (iii) once again urged Reata to meet with the FDA and obtain FDA concurrence on these matters, and respond to the issues raised by the FDA in its December 2016 Advice Letter, before proceeding with CARDINAL Phase 3 and before it would be too late to modify CARDINAL's design (for example, by including additional off-treatment eGFR measurements more than four weeks after treatment had ended). *See* Section IV.G.1, *supra*. Reata effectively ignored the FDA's February

2019 communication and proceeded with CARDINAL Phase 3.

237. On February 28, 2019, Reata: (i) issued a press release announcing fourth-quarter and full-year 2018 results (the "Q4 2018 Results Release"); (ii) filed with the SEC a Form 10-K, signed by Defendant Huff and the Director Defendants, for 2018 (the "2018 10-K"); and (iii) at 8:00 a.m. EST, hosted a conference call with analysts and investors (the "Q4 2018 Conference Call").

238. The Q4 2018 Results Release contained FDA Guidance Representations and CARDINAL Retained eGFR Representations:

> **Pipeline Highlights**
>
> **Phase 3 Portion of the CARDINAL Trial of Bardoxolone in Alport Syndrome**
>
> In the second half of 2018, we completed enrollment in the pivotal Phase 3 CARDINAL study of bardoxolone in patients with CKD caused by Alport syndrome. A total of 157 patients were enrolled. The FDA has provided us with written guidance that, in patients with CKD caused by Alport syndrome, an analysis of retained eGFR demonstrating an improvement versus placebo after one year of bardoxolone treatment may support accelerated approval. In July, we reported one-year retained eGFR data from the open-label Phase 2 portion of CARDINAL, which demonstrated a statistically significant increase from baseline in mean eGFR of 4.1 mL/min/1.73 m^2 ($p<0.05$) after 48 weeks of treatment and four weeks off-treatment in 25 patients. . . . We expect to report top-line, one-year data from the pivotal Phase 3 portion of CARDINAL in the second half of this year.

239. The 2018 10-K contained repeated assertions of FDA Guidance Representations and CARDINAL Retained eGFR Representations:

> **Overview** . . .
>
> We have fully enrolled two registrational clinical trials: CARDINAL, studying Bard in chronic kidney disease (CKD) caused by Alport syndrome, and MOXIe, studying Omav in Friedreich's ataxia (FA). . . . We designed CARDINAL and MOXIe based on the results of earlier clinical studies and guidance from the FDA on a potential path to approval.
>
> ***
>
> We are conducting a Phase 2/3 clinical trial studying Bard in patients with CKD

> caused by Alport syndrome called CARDINAL. . . . In the Phase 2 portion of CARDINAL, Bard demonstrated . . . a statistically significant increase from baseline in mean eGFR at Week 52 after withdrawal of drug for four weeks. This retained eGFR benefit is important because it provides compelling evidence that drug treatment may delay or prevent the need for dialysis or transplant. The FDA has provided us with written guidance that, in patients with CKD caused by Alport syndrome, an analysis of retained eGFR demonstrating an improvement versus placebo after one year of Bard treatment may support accelerated approval, and an improvement versus placebo after two years of treatment may support full approval. . . . If the trial results are positive, we believe the results, together with other data from our development program, will be sufficient to form the basis of an NDA submission to the FDA seeking approval of Bard for the treatment of CKD caused by Alport syndrome.
>
> ***
>
> [W]e believe measuring eGFR after withdrawal of active drug isolates, and allows the measure of, the functional improvement associated with the effect of the drug on the underlying structure of the kidney. We believe the retained eGFR benefit observed in the Phase 2 portion of CARDINAL provides evidence that Bard treatment improved the structure of the kidney, modified the course of the disease, and may prevent or delay kidney failure and the need for dialysis or a kidney transplant. . . .
>
> The FDA has provided us with written guidance that, in patients with CKD caused by Alport syndrome, an analysis of retained eGFR demonstrating an improvement versus placebo after one year of Bard treatment may support accelerated approval and an improvement versus placebo after two years of treatment may support full approval. If the results of the Phase 3 portion of CARDINAL are positive, we believe the results, together with other data from our development program, will be sufficient to form the basis of an NDA submission to the FDA seeking approval of Bard for the treatment of CKD caused by Alport syndrome. We have received orphan drug designation from the FDA for Bard for the treatment of Alport syndrome.

2018 10-K at 5, 9-10, 14-15, 94-95.

240. The 2018 10-K subsection titled "Overview of Clinical Trials of Bard in CKD" contained FDA Guidance Representations, Prior Study Retained eGFR Representations, CARDINAL Retained eGFR Representations, and 10-14 Day Washout Representations:

> *Overview of Clinical Trials of Bard in CKD*
>
> Bard has been evaluated in multiple clinical trials enrolling over 2,000 patients exposed to active drug . . . . . .Key findings from clinical trials of Bard's effects

on kidney function are summarized below.

***

Bard Treatment Produced a Retained eGFR Benefit after Withdrawal of Drug Suggesting Bard Modified the Course of CKD

The FDA has provided guidance to us and other sponsors that clinical trials with a retained eGFR benefit analysis may support approval in certain rare forms of CKD. The retained eGFR benefit is the patient's eGFR change compared to baseline after long-term treatment of approximately one year and withdrawal of active drug. We believe measuring eGFR after withdrawal of active drug isolates, and allows the measurement of, the functional improvement associated with the effect of the drug on the underlying structure of the kidney. If the drug produces an improvement in retained eGFR versus placebo, it is strong evidence that the drug has modified the course of the disease and may delay or prevent the need for dialysis or a transplant.

The duration of withdrawal varies by drug and is based on the drug's pharmacokinetic (PK)/pharmacodynamics (PD) profile, including the time it takes for a drug to reach sub-therapeutic concentrations and the reversal of PD markers. Bard is eliminated from the system within 10 days after cessation of drug treatment, and the FDA has indicated that a four-week withdrawal period, which represents approximately 17 half-lives of the drug, is appropriate for Bard in the Phase 3 CARDINAL and FALCON studies.

We assessed retained eGFR benefit in three clinical trials: BEAM, BEACON, and the Phase 2 portion of CARDINAL. In each of those trials, after patients had been treated with Bard for approximately one year, the drug was withdrawn for four weeks, and the post-withdrawal eGFR was compared to the patient's baseline eGFR. In each of these trials, Bard treatment produced a statistically significant improvement in retained eGFR versus baseline after withdrawal of drug. To our knowledge, Bard is the first therapy to produce a retained eGFR benefit that is above baseline in a long-term CKD trial. We believe the retained eGFR benefit observed in these clinical trials demonstrates that Bard treatment improved the structure of the kidney, modified the course of the disease, and may prevent or delay kidney failure and the need for dialysis or a kidney transplant. The FDA has provided us with written guidance that, in patients with CKD caused by Alport syndrome or ADPKD, an analysis of retained eGFR demonstrating an improvement versus placebo after one year of Bard treatment may support accelerated approval and an improvement versus placebo after two years of treatment may support full approval.

2018 10-K at 11, 13.

241. During the Q4 2018 Conference Call, Defendant Huff's introductory remarks asserted CARDINAL Retained eGFR Representations and FDA Guidance Representations:

> Regarding our Alport syndrome program in 2018, we reported long-term results from the phase 2 portion of CARDINAL demonstrating that patients treated with bardoxolone experienced a significant improvement in eGFR after 48 weeks of treatment, and a significant retained eGFR benefit, following four weeks of drug withdrawal. The retained eGFR benefit suggested long-term treatment with bardoxolone may safely delay or prevent kidney failure in patients with Alport syndrome.
>
> The FDA has provided us with written guidance that a statistically significant placebo-corrected retained eGFR benefit after one year of treatment may support accelerated approval and a retained eGFR benefit after two years of treatment may support full approval . . . .

Q4 2018 Conference Call, Bloomberg transcript at 2.

242. The February 28, 2019 assertions of FDA Guidance Representations in the Q4 2018 Results Release, 2018 10-K, and Q4 2018 Conference Call were materially false and/or misleading. Specifically, the claims of acting in accord with FDA "guidance" purportedly supporting (i) use of a four-week washout period, and (ii) the resulting retained eGFR as a basis for FDA approval were misleading for failure to disclose that Reata had not obtained FDA concurrence on these matters. *See* Section IV.G.1, *supra*. Defendants failed to disclose that the FDA had **repeatedly warned** Reata, beginning with the FDA's December 2016 Advice Letter and again in February 2019, that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval. *Id*. The representations were further misleading for failing to disclose that in September 2018 and February 2019, the FDA had requested an End-of-Phase 2 meeting, stressed the importance of such a meeting and of obtaining FDA concurrence on CARDINAL, but Reata ignored those requests.

243. The February 28, 2019 assertions of CARDINAL Retained eGFR Representations in the Q4 2018 Results Release, 2018 10-K, and Q4 2018 Conference Call were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment,

the use of an inadequate four-week washout period for retained eGFR measurement meant that: (i) CARDINAL had not actually measured what was claimed (*i.e.*, retained eGFR), and instead had measured PD effects; (ii) CARDINAL's purported retained eGFR results neither constituted nor measured truly retained eGFR and thus provided no indication of disease-modifying effects; and (iii) CARDINAL's retained eGFR results therefore would not and could not provide basis for FDA approval. *See* Sections IV.G.3, *supra*.

244. The Prior Study Retained eGFR Representations contained in the 2018 10-K were materially false and/or misleading. In truth, because BEAM and BEACON measured retained eGFR after an inadequate four-week washout period, they neither measured nor evidenced any retained eGFR benefit or disease-modifying effects for Bard. *See* Sections IV.G.2-3, *supra*.

245. The 10-14 Day Washout Representations contained in the 2018 10-K were materially false and/or misleading. In truth, extended Bard treatment, such as in CARDINAL, BEAM, and BEACON, required eight weeks to wash out: a period at least four times longer than the represented 10-14 days. *See* Section IV.G.2, *supra*.

246. The 2018 10-K contained Risk Factor Disclosures that were: (i) substantively identical, in relevant part, to those in the 2016 10-K (*see* ¶ 177, *supra*), and (ii) inadequate and materially misleading. *See* 2018 10-K at 52-53, 73-74. They inaccurately described certain risks – specifically, that the FDA might not approve Bard due to "inadequate design or implementation of our clinical trials[,]" failure to demonstrate Bard's "safety and efficacy . . .[] to the satisfaction of the relevant regulatory authorities[,]" and FDA disagreement "that our completed clinical trials provide adequate data on safety or efficacy[]" – as **potential** risks, stated in a generalized and hypothetical manner while omitting to disclose material, then-existing facts – such as the FDA's December 2016 Advice Letter, and the FDA's September 2018 and February 2019

communications – indicating that these risks were actually materializing.

14. The November 11-12, 2019 Statements

247. On November 11, 2019, Reata issued a press release announcing positive one-year data from CARDINAL Phase 3, including a statistically significant retained eGFR benefit at one year (48 weeks treatment and a four-week washout period) (the "CARDINAL Phase 3 Results Release").

248. On November 12, 2019, Reata: (i) issued a press release announcing third-quarter 2019 results (the "Q3 2019 Results Release"); (ii) filed with the SEC a Form 10-Q, signed by Defendants Huff and Soni, for the third quarter of 2019 (the "Q3 2019 10-Q"); and (iii) at 8:00 a.m. EST, hosted a conference call with analysts and investors to discuss further the CARDINAL Phase 3 year-one results (the "CARDINAL Phase 3 Results Conference Call").

249. The CARDINAL Phase 3 Results Release asserted FDA Guidance Representations, CARDINAL Retained eGFR Representations, and CARDINAL Design Representations:

> **Reata Announces Positive Topline Year One Results From Pivotal Phase 3 Cardinal Study of Bardoxolone Methyl in Patients With Alport Syndrome**
>
> *ACHIEVED PRIMARY ENDPOINT OF STATISTICALLY SIGNIFICANT IMPROVEMENT IN EGFR COMPARED TO PLACEBO AFTER 48 WEEKS OF TREATMENT*
>
> *ACHIEVED KEY SECONDARY ENDPOINT OF STATISTICALLY SIGNIFICANT IMPROVEMENT IN RETAINED EGFR COMPARED TO PLACEBO AFTER 48 WEEKS OF TREATMENT AND WITHDRAWAL OF DRUG FOR 4 WEEKS*
>
> Reata Pharmaceuticals, Inc. (Nasdaq:RETA) ("Reata" or the "Company"), a clinical-stage biopharmaceutical company, announced today that the Phase 3 portion of the CARDINAL study of bardoxolone methyl (bardoxolone) in patients with chronic kidney disease (CKD) caused by Alport syndrome met its primary and key secondary endpoints. . . . After 48 weeks of treatment and a four-week withdrawal period, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean retained eGFR of 5.14 mL/min/1.73 m2 (p=0.0012).
>
> ***

Trial Overview and Results . . .

The primary endpoint for the study was the change in eGFR, an important measure of the ability of the kidney to filter waste products out of the blood, after 48 weeks of treatment. The key secondary endpoint for the study was the change in the retained eGFR after 48 weeks of treatment and four weeks of drug withdrawal. . . . The second-year on-treatment eGFR will be measured after 100 weeks of treatment and the retained eGFR will be measured at Week 104 after withdrawal of drug for four weeks. The FDA has provided the Company with written guidance that, in patients with CKD caused by Alport syndrome, an analysis of retained eGFR demonstrating an improvement versus placebo after one year of bardoxolone treatment may support accelerated approval and an improvement versus placebo after two years of treatment may support full approval. . . .

At Week 52, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean retained eGFR of 5.14 mL/min/1.73 m2 (p=0.0012).

***

About the Retained eGFR Analysis . . .

The FDA has accepted for approval in rare forms of CKD the placebo-corrected "retained eGFR" after withdrawal of drug. Withdrawal of drug after long-term treatment provides evidence whether a drug either protected or harmed the kidney during treatment. If retained eGFR is higher than placebo, this is evidence that the drug protected the kidney during treatment, and, if retained eGFR is lower than placebo, this is evidence that the drug harmed the kidney during treatment. A positive retained eGFR benefit provides evidence that drug treatment may delay kidney failure.

250. The Q3 2019 10-Q likewise featured the CARDINAL Phase 3 results and contained FDA Guidance Representations and CARDINAL Retained eGFR Representations:

Overview . . .

On November 11, 2019, we announced that the Phase 3 portion of the CARDINAL study of bardoxolone in patients with CKD caused by Alport syndrome met its primary and key secondary Year 1 endpoints. . . . After 48 weeks of treatment and a four-week withdrawal period, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean retained eGFR of 5.14 mL/min/1.73 m2 (p=0.0012).

***

> ***Bardoxolone in CKD Caused by Alport Syndrome*** . . .
>
> On November 11, 2019, we announced the topline, Year 1 results from the Phase 3 portion of CARDINAL studying bardoxolone in Alport syndrome patients. . . . The FDA has provided us with written guidance that, in patients with CKD caused by Alport syndrome, an analysis of retained eGFR demonstrating an improvement versus placebo after one year of bardoxolone treatment may support a NDA submission for accelerated approval and an improvement versus placebo after two years of treatment may support full approval. . . .
>
> At Week 52, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean retained eGFR of 5.14 mL/min/1.73 m2 (p=0.0012).

Q3 2019 10-Q at 16-18.

251. Additionally, a discrete subsection of the Q3 2019 10-Q titled "Historical Development of Bardoxolone" contained Prior Study Retained eGFR Representations, as well as CARDINAL Retained eGFR Representations and FDA Guidance Representations:

> ***Historical Development of Bardoxolone***
>
> Prior to our CARDINAL Phase 3 trial, bardoxolone has been evaluated in multiple clinical trials enrolling over 2,000 patients exposed to active drug and has demonstrated consistent, clinically meaningful improvement in kidney function . . . .
>
> . . . We believe these data, in addition to the CARDINAL Phase 3 data, support the potential for bardoxolone to delay or prevent dialysis, kidney transplant, and death in patients with Alport syndrome and other rare forms of CKD. Additional observations from the prior clinical trials of bardoxolone include the following:
>
> - . . . Statistically significant improvement in retained eGFR, which is the eGFR change after a four-week withdrawal of drug, above baseline in BEAM, BEACON, and the Phase 2 portion of CARDINAL. To our knowledge, bardoxolone is the first therapy to produce a retained eGFR benefit that is above baseline in a long-term CKD trial.
>
>   - The FDA has provided guidance to us and other sponsors that clinical trials with a retained eGFR benefit versus placebo may support approval in certain rare forms of CKD. The FDA has provided guidance to us that, in patients with CKD caused by Alport syndrome or ADPKD, a retained eGFR benefit versus placebo after one year of bardoxolone treatment may support accelerated approval and after two years of bardoxolone

treatment may support full approval.

- We believe the retained eGFR benefit observed in these clinical trials demonstrates that bardoxolone treatment improved the structure of the kidney, modified the course of the disease, and may prevent or delay kidney failure and the need for dialysis or a kidney transplant.

Q3 2019 10-Q at 19-20.

252. In the CARDINAL Phase 3 Results Conference Call, Defendant Huff reiterated FDA Guidance Representations and CARDINAL Retained eGFR Representations:

> Warren Huff . . .
>
> The FDA has provided us with written guidance that in patients with CKD caused by Alport syndrome, an analysis of off-treatment eGFR demonstrating an improvement versus placebo after one year of treatment may support accelerated approval and an improvement versus placebo after two years of treatment may support full approval. . . .
>
> Following the FDA guidance, the primary endpoint for the Phase III CARDINAL Study is the change in estimated GFR from baseline and compared to placebo, after 48 weeks of treatment in the key secondary endpoint is the change in estimated GFR from baseline and compared to placebo after 48 weeks of treatment and four weeks of drug withdrawal. . . . Measuring estimated GFR after withdrawal of active drug isolates the effect of the drug on the underlying structure of the kidney. If the effect of the drug were harmful due to any mechanism known or unknown, after one year of treatment in a four-week withdrawal, kidney function would be worsened relative to placebo. However, an improvement in retained eGFR versus placebo was strong evidence that the drug has been official has the potential to modify the course of the disease and may delay or prevent the need for dialysis or a kidney transplant.

CARDINAL Phase 3 Results Conference Call, Bloomberg transcript at 2, 4.

253. After Defendant Huff's remarks, Defendant Meyer then presented the CARDINAL Phase 3 one-year results, reiterating CARDINAL Retained eGFR Representations:

> Colin Meyer . . .
>
> Bardoxolone also met its key secondary endpoint of off-treatment change in eGFR compared to placebo.
>
> In the off-treatment analysis, patients treated with bardoxolone demonstrated a

> statistically significant placebo-corrected 5.1 mL per minute improvement in mean retained eGFR compared to placebo with a p-value of 0.0012. These results suggest that disease progression for patients on bardoxolone was essentially halted during the study even when measured after four weeks of drug withdrawal.

CARDINAL Phase 3 Results Conference Call, Bloomberg transcript at 4, 6-7.

254. The November 11-12, 2019 assertions of FDA Guidance Representations in the CARDINAL Phase 3 Results Release, CARDINAL Phase 3 Results Conference Call, and Q3 2019 10-Q were materially false and/or misleading. Specifically, the claims of acting in accord with FDA "guidance" purportedly supporting (i) use of a four-week washout period and (ii) the resulting retained eGFR as a basis for FDA approval, were misleading for failure to disclose that Reata had not obtained FDA concurrence on these matters. *See* Section IV.G.1, *supra*. Defendants failed to disclose that the FDA had **repeatedly warned** Reata, beginning with the FDA's December 2016 Advice Letter and again in February 2019, that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval. *Id*. The representations were further misleading for failing to disclose that in September 2018 and February 2019, the FDA had requested an End-of-Phase 2 meeting and stressed the importance of such a meeting, but Reata ignored those requests.

255. The November 11-12, 2019 assertions of CARDINAL Retained eGFR Representations in the CARDINAL Phase 3 Results Release, CARDINAL Phase 3 Results Conference Call, and Q3 2019 10-Q were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR measurement meant that: (i) CARDINAL had not actually measured what was claimed (*i.e.*, retained eGFR) and instead had measured PD effects; (ii) CARDINAL's purported retained eGFR results neither constituted nor measured truly retained

eGFR and thus provided no indication of disease-modifying effects; and (iii) CARDINAL's retained eGFR results therefore would not and could not provide basis for FDA approval. *See* Section IV.G.3, *supra*.

256. The Prior Study Retained eGFR Representations in the Q3 2019 10-Q were materially false and/or misleading. In truth, because BEAM and BEACON measured retained eGFR after an inadequate four-week washout period, they neither measured nor evidenced any retained eGFR benefit or disease-modifying effects for Bard. *See* Sections IV.G.2-3, *supra*.

257. The CARDINAL Design Representations in the CARDINAL Phase 3 Results Release were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR measurement meant that CARDINAL would not actually measure what was claimed (*i.e.*, retained eGFR) – and hence, that any ensuing retained eGFR results would provide neither evidence of any truly retained eGFR benefit nor basis for FDA approval. *See* Sections IV.G.2-3, *supra*.

258. Analysts following Reata viewed the November 11-12, 2019 disclosures of CARDINAL Phase 3 results as extremely positive news and issued uniformly glowing reports. For example, in his November 12, 2019 report, Leerink analyst Joseph Schwartz wrote:

> **Strong Retained Benefit Brings Bard One Step Closer to [Accelerated Approval]; PT to $328**
>
> • **Bottom Line**: We see the positive Ph.3 CARDINAL data as paving the way to a substantial opp'ty in Alport syndrome . . . . Recall, bardoxolone (bard) hit on both its primary and key secondary endpoint of the CARDINAL trial, which combined with a favorable safety profile, has a high chance of receiving regulatory approval, in our view. . . .
>
> • **CARDINAL hit on primary and secondary endpoints; de-risking from a regulatory standpoint**. . . . [T]he FDA has provided RETA with written guidance that the analysis of retained eGFR demonstrating an improvement vs. pbo. after 1 yr. of treatment may support accelerated approval (AA) while similar data after 2

> yrs. may support full approval. Since the topline results capture the first yr., the robust data suggests to us that bard is one step closer to gaining regulatory approval ahead of the 2nd yr. data. . . .
>
> • **Retained benefit profile appears more robust than Jynarque (Otsuka); hyperfiltration issue is also not a concern.** In the REPRISE trial (ADPKD), tolvaptan/Jynarque demonstrated a pbo.-adjusted eGFR benefit of 1.27 mL/min . . . . In contrast, CARDINAL showed a robust pbo.-adjusted retained eGFR benefit of 5.14 mL/min . . . . With a magnitude of benefit >4x higher than tolvaptan, we think bard has a very compelling efficacy profile in Alport syndrome. Additionally, off-treatment eGFR being higher in the bard arm (vs. pbo. arm) once again disputes the notion of bard driving hyperfiltration.

Joseph P. Schwartz, *Strong Retained Benefit Brings Bard One Step Closer to AA; PT to $328*, SVB SECURITIES LLC, F/K/A SVB LEERINK LLC, 1-2 (Nov. 12, 2019).

15. Statements Made in Connection with Reata's November 14, 2019 Secondary Public Offering

259. Taking advantage of the recent substantial appreciation in Reata's share price, Reata announced, on November 12, 2019 – *i.e.*, immediately following disclosure of the CARDINAL Phase 3 one-year results – a proposed secondary stock offering of 2.0 million shares (with an overallotment option of an additional 300,000 shares). On November 14, 2019, Reata announced (i) that it had upsized the proposed offering by 20%, from 2.0 million to 2.4 million shares (along with a proportional 20% increase to the overallotment option, from 300,000 to 360,000 shares), and (ii) that the shares would be sold for $183.00 per share.

260. On November 14, 2019, following the full exercise of the overallotment option, Reata issued and sold 2.76 million shares of Class A common stock at $183.00 per share through a secondary stock offering underwritten by Defendants Citigroup, Jefferies, Leerink, Stifel, Baird, Cantor, and LT&Co. (the "2019 Offering"). After payment of $12.6 million to the 2019 Offering Underwriter Defendants, Reata's net proceeds totaled $492.5 million.

261. The shares sold in the 2019 Offering were registered, issued, and sold pursuant to: (i) Reata's July 23, 2018 Shelf Registration Statement on Form S-3, signed by Defendant Huff and

the Director Defendants; and (ii) a prospectus supplement, which formed part of the Shelf Registration Statement, dated November 13, 2019 (the "2019 Offering ProSupp").

262. The 2019 Offering ProSupp contained FDA Guidance Representations and CARDINAL Retained eGFR Representations:

> **Company Overview** . . .
>
> On November 11, 2019, we announced that the Phase 3 portion of the CARDINAL study of bardoxolone in patients with CKD caused by Alport syndrome met its primary and key secondary Year 1 endpoints. . . . After 48 weeks of treatment and a four-week withdrawal period, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean retained eGFR of 5.14 mL/min/1.73 m2 (p=0.0012). Bardoxolone treatment was generally reported to be well-tolerated and showed a similar safety profile to the Phase 2 portion of the CARDINAL study. Based on these positive results, and subject to discussions with regulatory authorities, we plan to proceed with the submission of regulatory filings for marketing approval in the United States and internationally.
>
> ***
>
> ***Bardoxolone in CKD Caused by Alport Syndrome*** . . .
>
> On November 11, 2019, we announced the topline, Year 1 results from the Phase 3 portion of CARDINAL studying bardoxolone in Alport syndrome patients. . . . The FDA has provided us with written guidance that, in patients with CKD caused by Alport syndrome, an analysis of retained eGFR demonstrating an improvement versus placebo after one year of bardoxolone treatment may support a New Drug Application (NDA) submission for accelerated approval and an improvement versus placebo after two years of treatment may support full approval. . . .
>
> At Week 52, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean retained eGFR of 5.14 mL/min/1.73 m2 (p=0.0012). Patients treated with bardoxolone experienced a nonsignificant decline from baseline in mean retained eGFR of -0.96 mL/min/1.73 m2 (p=0.45), while patients treated with placebo experienced a statistically significant decline from baseline in mean retained eGFR of -6.11 mL/min/1.73 m2 (p<0.0001).

2019 Offering ProSupp at S-1 – S-3.

263. The FDA Guidance Representations in the 2019 Offering ProSupp were materially false and misleading. Specifically, the claims of acting in accord with FDA "guidance" purportedly supporting (i) use of a four-week washout period and (ii) the resulting retained eGFR as a basis

for FDA approval, were misleading for failure to disclose that Reata had not obtained FDA concurrence on these matters. *See* Section IV.G.1, *supra*. Defendants failed to disclose that the FDA had **repeatedly warned** Reata, beginning with the FDA's December 2016 Advice Letter and again in February 2019, that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval. *Id*. The representations were further misleading for failing to disclose that in September 2018 and February 2019, the FDA had requested an End-of-Phase 2 meeting and stressed the importance of such a meeting and that Reata obtain FDA concurrence on CARDINAL, but Reata ignored those requests.

264. The CARDINAL Retained eGFR Representations in the 2019 Offering ProSupp were materially false and misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR measurement meant that: (i) CARDINAL had not actually measured what was claimed (*i.e.*, retained eGFR), and instead had measured PD effects; (ii) CARDINAL's purported retained eGFR results neither constituted nor measured truly retained eGFR and thus provided no indication of disease-modifying effects; and (iii) CARDINAL's retained eGFR results therefore would not and could not provide a basis for FDA approval. *See* Section IV.G.3, *supra*.

16. The February 19, 2020 Statements

265. In January 2020, Reata met with the FDA, and the FDA once again communicated to Reata its previously expressed concerns with the adequacy of CARDINAL's washout period, and hence with the validity of CARDINAL's retained eGFR data. *See* ¶¶ 106-09, *supra*. Additionally, the FDA expressed further concern with the high level of Bard-treated patients in CARDINAL who discontinued treatment within the first year and with Bard's effects on blood pressure and albuminuria. *Id*.

266. The January 2020 FDA Meeting was sufficiently troubling to the Reata Defendants that, as detailed in Section V.C.6, *infra*, it led Defendants Huff and Meyer to refuse to make any public comments during Reata's quarterly conference calls regarding Reata's interactions with the FDA, or to answer any analyst questions on those calls concerning Reata's FDA interactions, for the ensuing six months. However, even as Defendants Huff and Meyer refrained from all such commentary during February 2020 and May 2020 conference calls (*i.e.*, the Q4 2019 Conference Call and Q1 2020 Conference Call), the Reata Defendants' misstatements continued unabated in Reata's press releases and SEC filings.

267. On February 19, 2020, Reata: (i) issued a press release announcing fourth-quarter and full-year 2019 Results (the "Q4 2019 Results Release"); (ii) filed with the SEC a Form 10-K, signed by Defendants Huff, Soni, and the Director Defendants, for 2019 (the "2019 10-K"); and (iii) at 4:30 p.m. EST, hosted a conference call with analysts and investors (the "Q4 2019 Conference Call").

268. The 2019 10-K contained FDA Guidance Representations, CARDINAL Retained eGFR Presentations, and Prior Study Retained eGFR Representations:

> In November 2019, we announced that the Phase 3 portion of the CARDINAL study of bardoxolone in patients with CKD caused by Alport syndrome met its primary and key secondary Year 1 endpoints. . . . At Week 52, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean retained eGFR, which is the eGFR change after a four-week withdrawal of drug, of 5.14 mL/min/1.73 m2 (p=0.0012). After 52 weeks, patients in the placebo arm of CARDINAL lost an average of 6.1 mL/min/1.73 m2. Based on these positive results, and subject to discussions with regulatory authorities, we plan to proceed with the submission of regulatory filings this year for marketing approval in the United States.
>
> ***
>
> ***Overview of Clinical Evidence of Bardoxolone's Effect on Kidney Function in CKD***
>
> Prior to our CARDINAL Phase 3 trial, clinical trials enrolling over 2,000 patients

exposed to bardoxolone have demonstrated consistent, clinically meaningful improvement in kidney function . . . .

. . . We believe these data, in addition to the CARDINAL Phase 3 data, support the potential for bardoxolone to delay or prevent dialysis, kidney transplant, and death in patients with Alport syndrome and other forms of CKD.

Additional observations from the prior clinical trials of bardoxolone include the following: . . .

- Statistically significant improvement in retained eGFR above baseline in BEAM, BEACON, the Phase 2 portion of CARDINAL at one year, and the Phase 3 portion of CARDINAL at one year.
    - The FDA has provided guidance to us and other sponsors that clinical trials with a retained eGFR benefit versus placebo may support approval in certain rare forms of CKD. The FDA has provided guidance to us that, in patients with CKD caused by Alport syndrome or ADPKD, a retained eGFR benefit versus placebo after one year of bardoxolone treatment may support accelerated approval and after two years of bardoxolone treatment may support full approval.
    - We believe the retained eGFR benefit observed in these clinical trials demonstrates that bardoxolone treatment improved the structure of the kidney, modified the course of the disease, and may prevent or delay kidney failure and the need for dialysis or a kidney transplant.

Bardoxolone Development Program for the Treatment of CKD Caused by Alport Syndrome . . .

In November 2019, we announced positive topline, Year 1 results from the Phase 3 portion of CARDINAL studying bardoxolone in patients with Alport syndrome.

***

The key secondary endpoint for the study was the change in retained eGFR at 52 weeks. At Week 52, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean retained eGFR of 5.14 mL/min/1.73 m2 (p=0.0012). . . .

The FDA has provided us with written guidance that, in patients with CKD caused by Alport syndrome, an analysis of retained eGFR demonstrating an improvement versus placebo after one year of bardoxolone treatment may support an NDA submission for accelerated approval and an improvement versus placebo after two years of treatment may support full approval.

2019 10-K at 5, 13-15, 93.

269. The FDA Guidance Representations in the 2019 10-K were materially false and/or misleading. Specifically, the claims of acting in accord with FDA "guidance" purportedly supporting (i) use of a four-week washout period, and (ii) the resulting retained eGFR as a basis for FDA approval, were misleading for failure to disclose that Reata had not obtained FDA concurrence on these matters. *See* Section IV.G.1, *supra*. Defendants failed to disclose that the FDA had **repeatedly warned** Reata – beginning with the FDA's December 2016 Advice Letter, again in February 2019, and yet again in the January 2020 FDA Meeting – that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval. *Id*. The representations were further misleading for failing to disclose that: (i) in September 2018 and February 2019, the FDA had requested an End-of-Phase 2 meeting and stressed the importance of such a meeting and of obtaining FDA concurrence on CARDINAL, but Reata ignored those requests; and (ii) in the January 2020 FDA Meeting, the FDA expressed additional concerns with the high level of Bard-treated patients in CARDINAL who discontinued treatment within the first year, and with Bard's effects on blood pressure and albuminuria.

270. The CARDINAL Retained eGFR Representations in the 2019 10-K were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR measurement meant that: (i) CARDINAL had not actually measured what was claimed (*i.e.*, retained eGFR), and instead had measured PD effects; (ii) CARDINAL's purported retained eGFR results neither constituted nor measured truly retained eGFR and thus provided no indication of disease-

modifying effects; and (iii) CARDINAL's retained eGFR results therefore would not and could not provide basis for FDA approval. *See* Section IV.G.3, *supra*.

271. The Prior Study Retained eGFR Representations in the 2019 10-K were materially false and/or misleading. In truth, because BEAM and BEACON measured retained eGFR after an inadequate four-week washout period, they neither measured nor evidenced any retained eGFR benefit or disease-modifying effects for Bard at all. *See* Sections IV.G.2-3, *supra*.

272. The 2019 10-K contained Risk Factor Disclosures that were: (i) substantively identical, in relevant part, to those in the 2016 10-K (*see* ¶ 177, *supra*); and (ii) inadequate and materially misleading. *See* 2019 10-K at 51-52, 73-74. They inaccurately described certain risks – specifically, that the FDA might not approve Bard due to "inadequate design or implementation of our clinical trials[,]" failure to demonstrate Bard's "safety and efficacy . . .[] to the satisfaction of the relevant regulatory authorities[,]" and FDA disagreement "that our completed clinical trials provide adequate data on safety or efficacy[]" – as **potential** risks, stated in a generalized and hypothetical manner, while omitting to disclose material, then-existing facts – such as the FDA's December 2016 Advice Letter, the FDA's September 2018 and February 2019 communications, and the January 2020 FDA Meeting – indicating that these risks were actually materializing.

17. The May 11, 2020 Statements

273. On May 11, 2020, Reata: (i) issued a press release announcing first-quarter 2020 results (the "Q1 2020 Results Release"); (ii) filed with the SEC a Form 10-Q, signed by Defendants Huff and Soni, for the first quarter of 2020 (the "Q1 2020 10-Q"); and (iii) at 4:30 p.m. EST, hosted a conference call with analysts and investors (the "Q1 2020 Conference Call").

274. While Defendants Huff and Meyer continued to refrain from making any commentary during the Q1 2020 Conference Call regarding Reata's interactions with the FDA (just as they had during the February 2020 Q4 2019 Conference Call), the Reata Defendants'

misstatements continued unabated in Reata's press releases and SEC filings.

275. The Q1 2020 10-Q contained FDA Guidance Representations, CARDINAL Retained eGFR Representations, and Prior Study Retained eGFR Representations, *see* Q1 2020 10-Q at 16-18, that were effectively identical to those contained in the 2019 10-K and materially misleading for the same reasons, set forth at ¶¶ 268-71, *supra*.

18. The August 10, 2020 Statements

276. On August 10, 2020, Reata: (i) issued a press release announcing second-quarter 2020 results (the "Q2 2020 Results Release"); (ii) filed with the SEC a Form 10-Q, signed by Defendants Huff and Soni, for the second quarter of 2020 (the "Q2 2020 10-Q"); and (iii) at 4:30 p.m. EST, hosted a conference call with analysts and investors (the "Q2 2020 Conference Call").

277. In the latter two of the August 10, 2020 disclosures – the Q2 2020 10-Q and the Q2 2020 Conference Call – Reata and its executives exhibited yet another change in disclosure content and tone. Specifically, they abandoned the refusal to comment on FDA-related matters that they had adopted for their two prior rounds of quarterly disclosures following the January 2020 FDA Meeting, and once again started speaking about their interactions with the FDA concerning CARDINAL, Bard for treatment of Alport, and a possible Bard NDA.

278. However, while Reata and its executives resumed speaking about the FDA beginning August 10, 2020, their statements were neither accurate nor complete. While the August 10, 2020 disclosures revealed that there was some dispute between Reata and the FDA concerning an NDA for Bard for Alport, these disclosures were materially misleading because: (i) they characterized the disputes as *procedural*, concerning merely the *timing* of an NDA (specifically, whether Reata should file an NDA immediately, for accelerated approval, based on the one-year retained eGFR data from CARDINAL, or whether the FDA would recommend waiting for the second-year CARDINAL data and then filing an NDA for full approval); when (ii) in fact, the

FDA-Reata disputes were fundamentally *substantive*, and cast substantial doubt on FDA approval of any NDA, no matter its timing, based on CARDINAL data.

279. The Q2 2020 10-Q literally marked the change in disclosure strategy up front, in a new first subsection, titled "Regulatory Update," which stated, in relevant part:

> **Regulatory Update**
>
> ***Bardoxolone for CKD Caused by Alport Syndrome***
>
> Following the announcement of positive, year one data from the Phase 3 CARDINAL study of bardoxolone in patients with CKD caused by Alport syndrome in November 2019, we have been engaged in discussions with the U.S. Food and Drug Administration (FDA) regarding the Year 1 efficacy and safety results. We have had a Type C meeting where the FDA expressed concerns with basing an NDA for accelerated approval on the Year 1 data and recommended that we consider submitting the NDA with Year 2 data based, in part, on the assumption that there would not be much delay in NDA submission. Following the Type C meeting, we provided written responses, and engaged in follow up informal meetings, that we believe addressed the FDA comments regarding the Year 1 results. Accordingly, we recently requested and were granted a pre-NDA meeting by the FDA to discuss the NDA submission content and plans.
>
> Our plan has been, and continues to be, to submit the NDA for bardoxolone in Alport syndrome during fourth quarter of 2020 for accelerated approval based on the one-year data from the Phase 3 portion of CARDINAL. If the second-year results are available during an acceptable time frame, we may be able to submit the second-year data to the NDA during the review process and before the FDA makes a determination about accelerated approval. This may extend the PDUFA date, but could also result in consideration of full approval, rather than accelerated approval. Alternatively, the FDA could recommend that we wait for the second-year data from CARDINAL to file the NDA. This would permit us to file for full approval but would delay the filing until the first quarter of 2021 compared to our current guidance of filing by the end of this year.

Q2 2020 10-Q at 16.

280. Likewise, during the Q2 2020 Conference Call, Defendant Huff's introductory remarks centered, from his first words, on the same regulatory update disclosed in the Q2 2020 10-Q. Again, in Defendant Huff's telling, the differences of opinion between the FDA and Reata were merely timing matters concerning when exactly the NDA should be filed:

J. Warren Huff . . .

On today's call, I'll provide an update on our regulatory path for our lead products bardoxolone . . . .

. . . I'll begin with an update on the status of our regulatory interactions with the FDA, with respect to the potential approval of bardoxolone for the treatment of patients with Alport syndrome on Slide 5.

So following the announcement of year one data from the Phase III CARDINAL study in November of 2019, we've been engaged with the FDA to discuss the year one efficacy and safety results. We've had a Type C meeting where the FDA expressed concern with basing an NDA for accelerated approval on the year one data alone and recommended that we consider submitting the NDA with the year two data. We believe that their recommendation was based in part on their assumption that there would not be much delay in NDA submission by waiting for the year two data. The FDA invited us to address their questions and has provided suggestions for additional analyses of the year one data.

Following the Type C meeting, we've had a series of interactions including informal meetings and written submissions to the IND to address the FDA's questions and requested analyses raised at the meeting. We delayed requesting a pre-NDA meeting while we address the FDA's review questions. We recently requested and were granted a pre-NDA meeting by the FDA to discuss the NDA submission, content and plans. One of the key questions to be resolved in the pre-NDA meeting is how the year two data should be handled during the NDA review process. Our plan has been and continues to be to submit the NDA for bardoxolone in Alport syndrome during the fourth quarter of this year for accelerated approval based on the one year data from the Phase III portion of CARDINAL.

If the second year results are available during an acceptable time frame, we may be able to submit the second year data during the review process and before the FDA makes a determination about accelerated approval. This may extend the PDUFA date, but could also result in consideration of full approval rather than accelerated approval.

The FDA could recommend that we wait for the second year data from CARDINAL to file the NDA. This would permit us to file for full approval but would delay the filing until the first quarter of 2021 compared to our current guidance of filing by the end of this year.

Q2 2020 Conference Call at 2-3.

281. The above-stated representations in the Q2 2020 10-Q and Q2 2020 Conference

Call were materially misleading because: (i) they characterized the matters discussed with the FDA during the January 2020 FDA Meeting (the "Type C meeting" referenced in the Q2 2020 10-Q and Q2 2020 Conference Call) as *procedural*, concerning merely the *timing* of an NDA (specifically, whether Reata should file an NDA immediately, for accelerated approval, based on the one-year retained eGFR data from CARDINAL, or whether the FDA would recommend waiting for the second-year CARDINAL data and then filing an NDA for full approval); when (ii) in fact, the matters discussed with the FDA during the January 2020 FDA Meeting were also *substantive*, and cast substantial doubt on FDA approval of any NDA, no matter its timing, based on CARDINAL data. The "concerns" expressed by the FDA in the January 2020 FDA Meeting included fundamentally substantive concerns with the adequacy of CARDINAL's four-week washout period and the validity of the retained eGFR data predicated on that washout period – indicating that NDA approval was at mortal risk no matter the timing.

282. The Q2 2020 10-Q also contained FDA Guidance Representations, CARDINAL Retained eGFR Representations, and Prior Study Retained eGFR Representations that were virtually identical to those contained in the 2019 10-K and Q1 2020 10-Q:

> ***Bardoxolone in CKD Caused by Alport Syndrome***
>
> We are developing bardoxolone for the treatment of patients with CKD caused by Alport syndrome . . . .
>
> . . . In November 2019, we announced that the Phase 3 portion of the CARDINAL study of bardoxolone in patients with CKD caused by Alport syndrome met its primary and key secondary Year 1 endpoints. . . . At Week 52, after 48 weeks of treatment and four weeks of off-treatment period, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean eGFR of 5.14 mL/min/1.73 m2 (p=0.0012) . . . . . Based on these positive results, and subject to discussions with regulatory authorities, we plan to proceed with the submission of regulatory filings this year for marketing approval in the United States.

***

Historical Development of Bardoxolone

Prior to our CARDINAL Phase 3 trial, clinical trials enrolling over 2,000 patients exposed to bardoxolone have demonstrated consistent, clinically meaningful improvement in kidney function . . . .

. . . We believe these data, in addition to the CARDINAL Phase 3 one-year data, support the potential for bardoxolone to delay or prevent dialysis, kidney transplant, and death in patients with Alport syndrome and other forms of CKD.

Additional observations from the prior clinical trials of bardoxolone include the following: . . .

- Statistically significant improvement in eGFR during the off-treatment period in BEAM, BEACON, the Phase 2 portion of CARDINAL at one year, and the Phase 3 portion of CARDINAL at one year.
    - The FDA has provided guidance to us and other sponsors that clinical trials with an eGFR benefit versus placebo during the off-treatment period may support approval in certain rare forms of CKD. The FDA has provided guidance to us that, in patients with CKD caused by Alport syndrome or ADPKD, an eGFR benefit versus placebo during the off-treatment period after one year of bardoxolone treatment may support accelerated approval and after two years of bardoxolone treatment may support full approval.
    - We believe the eGFR benefit during the off-treatment period observed in these clinical trials demonstrates that bardoxolone treatment improved the structure of the kidney, modified the course of the disease, and may prevent or delay kidney failure and the need for dialysis or a kidney transplant.

Q2 2020 10-Q at 20-21.

283. The FDA Guidance Representations, CARDINAL Retained eGFR Representations, and Prior Study Retained eGFR Representations contained in the Q2 2020 10-Q were materially false and/or misleading for the same reasons that the nearly identical representations in the 2019 10-K and Q1 2020 10-Q were false and/or misleading, set forth in ¶¶ 268-71, *supra*.

284. However, because Defendants also disclosed a modicum of negative information

from the Company's January 2020 FDA Meeting (which had occurred seven months earlier), namely a possible delay in filing a Bard NDA, Reata's stock price declined 33.2% on August 10, 2020, from $156.20 per share to $104.41 per share. *See* Section V.B.2, *infra*.

285. The Q2 2020 10-Q also included one small disclosure change that, though all but imperceptible at the time, now appears striking (and is further discussed in Section V.C.7, *infra* concerning scienter). In the Q2 2020 10-Q, all references to the term "retained eGFR" – heretofore an absolutely critical and oft-used term in Reata's SEC filings and other public disclosures – were **removed**, and replaced instead with the alternative terminology of "eGFR during the off-treatment period" or "eGFR benefit during the off-treatment period." At the time, these alternative terminologies appeared effectively synonymous: "eGFR during the off-treatment period" was, simply, and for all the public knew, retained eGFR. However, no later than the January 2020 FDA Meeting, the Reata Defendants knew that a meaningful gap had opened between the two terminologies: eGFR at the end of CARDINAL's four-week off-treatment period was not actually retained eGFR, because CARDINAL's four-week off-treatment period was not long enough to allow Bard's PD effects to fully wash out – the necessary precondition for retained eGFR.

286. Defendants' terminological switch in the Q2 2020 10-Q did not provide any corrective disclosure. It was so subtle as to remain practically invisible, and neither analysts nor the financial press noticed the change at the time. Reata continued to make materially false and/or misleading statements and omit material information. The significance of the Reata Defendants' turn of phrase relates only to their scienter, which it further indicates.

19. The November 9, 2020 Statements

287. In September 2020, Reata and the FDA met again to discuss CARDINAL and a potential NDA filing for Bard. The FDA again reiterated to Reata its previously-expressed concerns with the adequacy of CARDINAL's washout period and hence with the validity of

CARDINAL's retained eGFR data. *See* ¶ 111, *supra*. Additionally, and as in the January 2020 FDA Meeting, the FDA expressed further concern with the high level of Bard-treated patients in CARDINAL who discontinued treatment within the first year and with Bard's effects on blood pressure and albuminuria. *Id*.

288. On November 9, 2020, Reata: (i) issued a press release announcing third-quarter 2020 results (the "Q3 2020 Results Release"); (ii) issued a separate press release titled "Reata Announces Positive Results From Year 2 of the Pivotal Phase 3 CARDINAL Study of Bardoxolone Methyl in Patients with Alport Syndrome," specifically focused on presenting the year-two results from CARDINAL (the "CARDINAL Year 2 Results Release"); (iii) filed with the SEC a Form 10-Q, signed by Defendants Huff and Soni, for the third quarter of 2020 (the "Q3 2020 10-Q"); and (iv) at 8:00 a.m. EST, hosted a conference call with analysts and investors (the "Q3 2020 Conference Call").

289. The CARDINAL Year 2 Results Release reported that CARDINAL year-two results successfully met their primary and key secondary endpoints (respectively, on-treatment benefit to eGFR at week 100, and off-treatment retained eGFR benefit at week 104, four weeks after treatment ceased) and that in light of these successes, Reata would file an NDA for Bard for Alport. In presenting these matters, the CARDINAL Year 2 Results Release asserted CARDINAL Retained eGFR Representations and Bard NDA Representations:

> **Reata Announces Positive Results From Year 2 of the Pivotal Phase 3 CARDINAL Study of Bardoxolone Methyl in Patients with Alport Syndrome**
>
> *BARDOXOLONE ACHIEVED THE YEAR 2 PRIMARY AND KEY SECONDARY ENDPOINTS WITH STATISTICALLY SIGNIFICANT IMPROVEMENTS IN EGFR AS COMPARED TO PLACEBO AT WEEK 100 AND WEEK 104* . . .
>
> 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 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.
>
> ***
>
> "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. . . . " said Warren Huff, Reata's President and Chief Executive Officer.

290. The Q3 2020 Results Release contained similar CARDINAL Retained eGFR Representations and Bard NDA Representations:

> **Clinical and Regulatory Update**
>
> *Bardoxolone Methyl ("Bardoxolone") for Alport Syndrome*
>
> In a separate press release issued today, we announced that the Phase 3 CARDINAL study of 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 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-New Drug Application ("NDA") meeting with the U.S. Food and Drug Administration ("FDA"), the Company plans to proceed with the submission of an NDA for full marketing approval in the United States in the first quarter of 2021. We will also continue preparations to file for marketing approval in Europe.

291. The Q3 2020 10-Q also contained similar CARDINAL Retained eGFR Representations and Bard NDA Representations, as well as Prior Study Retained eGFR

Representations:

Recent Key Developments

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 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.

***

Bardoxolone in 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 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).

***

We recently completed the previously announced pre-NDA meeting with the FDA to discuss the NDA submission content and plans. Based on that meeting and the FDA's responses and the subsequently announced positive results of the Year 2 data of the CARDINAL Phase 3 study, we plan to proceed with an NDA filing for full marketing approval of bardoxolone in patients with CKD caused by Alport syndrome in the first quarter of 2021. We will also continue preparations to file for marketing approval in Europe.

***

Historical Development of Bardoxolone

Clinical trials enrolling over 2,000 patients exposed to bardoxolone have demonstrated consistent, clinically meaningful improvement in kidney function . . . .

. . . We believe these data, in addition to the CARDINAL Phase 3 Year 2 data, support the potential for bardoxolone to delay or prevent dialysis, kidney transplant, and death in patients with Alport syndrome and other forms of CKD.

Additional observations from the prior clinical trials of bardoxolone include the following:

- . . . Statistically significant improvement in eGFR during the off-treatment period in BEAM, BEACON, the Phase 2 portion of CARDINAL at Year 1, and the Phase 3 portion of CARDINAL at Year 2. We believe the eGFR benefit during the off-treatment period observed in these clinical trials demonstrates that bardoxolone treatment improved the structure of the kidney, modified the course of the disease, and may prevent or delay kidney failure and the need for dialysis or a kidney transplant.

Q3 2020 10-Q at 17, 19-20, 21-22.

292. During the Q3 2020 Conference Call, Defendants Meyer and Huff both asserted CARDINAL Retained eGFR Representations:

Colin Meyer . . .

CARDINAL also successfully met its year-two key secondary endpoint of improvement in eGFR at Week- 104 after approximately two years of treatment, followed by a 4-week off treatment period. The ITT analysis demonstrates that patients treated with bardoxolone experienced a statistically significant improvement in eGFR of 4.3 mL per minute, compared to placebo, the p-value equal to 0.02. This difference is over three times as large as the treatment effect observed with tolvaptan in the REPRISE trial in patients with ADPKD, which is a more slowly progressive disease. . . .

In summary, we believe these on-treatment results demonstrate a very clinically meaningful treatment effect in a population that is rapidly progressing to kidney failure. The maintenance of the off treatment effect at year two from year one provides evidence of potential disease modifying activity, which could result in a substantially slower loss of kidney function that leaves the need for dialysis or a kidney transplant.

***

A - Warren Huff: . . .

[R]ecall that the mechanism of action of bardoxolone is to acutely increase GFR by improving the surface area in the filtration apparatus of the kidney that effect is reversible. And the purpose of the off-treatment effect is to understand if the drug

> has a beneficial or harmful effect on the underlying structure. And so for that analysis, we require that the acute reversible effect is washed out and so the change from Week-100 to 104 or 48 to 52 is simply due to the reversal of these acute improvements in surface area that are not permanent.
>
> And so in both the Week-52 and 104 analyses, we demonstrated twice in the trial significant placebo-corrected separation in the off-treatment analysis, both were statistically significant, both were similar magnitude. They were not significantly different from each other and importantly that magnitude is three times larger than what supported approval of tolvaptan in ADPKD, which is a more slowly progressive disease. You obviously don't see a similar change from Week-48 to 52 and 100 to 104 in placebo patients because they were receiving (inaudible) placebo. There is no acute effect of placebo. And so we believe this persistence of the off-treatment effect shows twice and confirms that the drug is having a disease modifying effect and therefore, it would be beneficial over the long term and that's consistent with the durability of the on-treatment effect just placebo in CARDINAL and the continued increase above baseline in the extension trial.

Q3 2020 Conference Call, Bloomberg transcript at 5, 18.

293. The November 9, 2020 assertions of CARDINAL Retained eGFR Representations in the CARDINAL Year 2 Results Release, Q3 2020 Results Release, Q3 2020 10-Q, and Q3 2020 Conference Call were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR measurement meant that: (i) CARDINAL had not actually measured what was claimed (*i.e.*, retained eGFR), and instead had measured PD effects; (ii) CARDINAL's purported retained eGFR results neither constituted nor measured truly retained eGFR and thus provided no indication of disease-modifying effects; and (iii) CARDINAL's retained eGFR results therefore would not and could not provide a basis for FDA approval. *See* Section IV.G.3, *supra*.

294. The Prior Study Retained eGFR Representations in the Q3 2020 10-Q were materially false and/or misleading. In truth, because BEAM and BEACON measured retained eGFR after an inadequate four-week washout period, they neither measured nor evidenced any retained eGFR benefit or disease-modifying effects for Bard. *See* Sections IV.G.2-3, *supra*.

295. The November 9, 2020 assertions of Bard NDA Representations in the

CARDINAL Year 2 Results Release, Q3 2020 Results Release, and Q3 2020 10-Q, though accurate in and of themselves, were still materially misleading because they omitted to disclose numerous facts then known by Defendants that were highly material to evaluation of the Bard NDA and that indicated far greater risks to its approval than publicly understood in light of Defendants' other accumulated misstatements, including:

A. that Bard's PD effects did **not** wash out quickly (per the 10-14 Day Washout Representations) but instead required eight weeks for washout;

B. that as a result, the purported retained eGFR results from CARDINAL, BEAM, and BEACON (constantly repeated via CARDINAL Retained eGFR Representations and Prior Study Retained eGFR Representations) neither measured nor evidenced truly retained eGFR, and thus could not and did not support FDA approval; and

C. that the FDA had **repeatedly warned** Reata between December 2016 and September 2020 that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval.

296. Additionally, as the capstone to his remarks in the Q3 2020 Conference Call, Defendant Meyer provided a forceful and extended assertion of the 10-14 Day Washout Representations, and the data purportedly serving as a basis for those representations, to conclude that CARDINAL's retained eGFR measurements, predicated on a four-week washout period, were "appropriate to assess persisting effect of bardoxolone after resolution the acute increase in eGFR[]":

> Colin Meyer . . .
>
> Lastly, we have evaluated the time to resolution of the acute increases in eGFR using our integrated summary of safety data set, which contains data from over 3,000 patients and has off-treatment values that range from one day to many weeks

> post discontinuation. It demonstrates gradual loss of eGFR within their first two weeks post discontinuation that plateaus beyond day 14. In our protocol, the target day to collect the off-treatment eGFR value was 28 days after the last dose. Due to operational considerations, some of these visits happened before. Now those occurred after day-28. Almost all early values occurred within a few days of day-28 and only one bardoxolone value was collected before day-21.
>
> Overall, the mean and median days off drug were 35 and 28 days, respectively. Therefore, the off-treatment data collected during CARDINAL are appropriate to assess persisting effect of bardoxolone after resolution the acute increase in eGFR. The overall conclusions of the trial are shown on the next slide. . . . All year one and year two primary and key secondary efficacy endpoints were met and demonstrated clinically meaningful improvements in eGFR.

Q3 2020 Conference Call, Bloomberg transcript at 9.

297. Defendant Meyer's assertion and defense of the 10-14 Day Washout Representations during the Q3 2020 Conference Call were materially false and/or misleading. In truth, extended Bard treatment, such as in CARDINAL, BEAM, and BEACON, required eight weeks to wash out: a period at least four times longer than the represented 14 days. *See* Section IV.G.2, *supra*. Furthermore, the data Defendant Meyer marshalled to support the 10-14 Day Washout Representations was, as the FDA later explained, an unconvincing mishmash of mostly irrelevant data that ignored the contrary findings of the most relevant data. *Id*.

298. Finally, at the end of the Q3 2020 Conference Call, Leerink analyst Joseph Schwartz directly queried Defendants Huff and Meyer as to whether the FDA still maintained the purported guidance that the Reata Defendants had ceaselessly proclaimed throughout the Class Period: that retained eGFR measured "after 4 weeks of withdrawal . . . could serve as the basis for approval[.]" Defendant Huff, in answering "Yes, that's our impression[]" and "yes, there has been no indication that they are changing their approach to the endpoints[,]" affirmatively reiterated FDA Guidance Representations:

> Q - Joseph Schwartz [Leerink analyst]
>
> Great, thanks very much and congratulations as well. I was wondering, if you could

> expound on the feedback you received from the FDA in your pre-NDA meeting, when you ask them questions regarding your submission plan for clinical data. And based on this feedback, do you have a sense of how much the new review team shares, the same crew [ph] as the prior one, which provided you with the written guidance same as the (technical difficulty) after 4 weeks of withdrawal that's greater than 2.5 mL per min could serve as the basis for approval?
>
> A - Warren Huff . . .
>
> I didn't -- I don't think I understood the second part of the question about the review teams. Could you repeat that Joe?
>
> Q - Joseph Schwartz
>
> Yeah, well, sure. I guess, the prior update on the second quarter call, I think you alluded to a new review team or change in review team and I know that in the past, you had received written guidance from the FDA with the retained benefit construct essentially agreed to, so I was wondering if that still seems to be the case now that they view that construct as sufficient for approval essentially?
>
> A - Warren Huff
>
> Yes, that's our impression. We had a new review team and that of course meant that the initial review team really didn't have familiarity with the development background, the pharmacology of the drug and items of that type. But yes, there has been no indication that they are changing their approach to the endpoints.

Q3 2020 Conference Call, Bloomberg transcript at 19.

299. Defendant Huff's affirmation of the FDA Guidance Representations during the Q3 2020 Conference Call was materially false and/or misleading. As Defendant Huff well knew, the FDA had spent the last four years repeatedly communicating to Reata – in the December 2016 Advice Letter, again in September 2018 and February 2019 communications to Reata, and yet again in January 2020 and September 2020 meetings with Reata – that a four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would not provide adequate or acceptable evidence for FDA approval. *See* Section IV.G.1, *supra*. Defendant Huff's representations were further misleading for failing to disclose that: (i) in September 2018 and February 2019, the FDA had requested an End-of-Phase 2 meeting, and

stressed the importance of such a meeting and of obtaining FDA concurrence on CARDINAL, but Reata ignored those requests; and (ii) in the January 2020 FDA Meeting and the September 2020 FDA meeting, the FDA expressed additional concerns with the high level of Bard-treated patients in CARDINAL who discontinued treatment within the first year, and with Bard's effects on blood pressure and albuminuria.

300. Analysts and the market viewed the November 9, 2020 disclosures very positively, given (i) their reaffirmation of the purported FDA guidance concerning CARDINAL's design and success threshold, and (ii) their indication that year-two CARDINAL data had met that stated threshold. For example, in his November 9, 2020 report, Leerink analyst Joseph Schwartz wrote:

> **3Q20 Recap: Pos. Two-Year CARDINAL Data, Potential for Two NDAs Next Year**
>
> • **Bottom Line**: This morning RETA announced 3Q20 financial results and provided investors with a clinical update for bardoxolone methyl in Alport syndrome (AS) and omaveloxolone in Friedreich's ataxia (FA). . . .
>
> • **Two-year CARDINAL data demonstrates bardoxolone's long-term benefit to patients, hitting both the primary and key secondary endpoints.** . . .
>
> • **RETA appears to have had a productive pre-NDA meeting for bardoxolone with the FDA, and the next major hurdle to clear will be an advisory committee meeting**. Based on management's response to our question on the conference call, we are encouraged that the new review team seems to share the same general views as the prior review team, which provided RETA with written guidance that a retained eGFR benefit greater than 2.5 mL/min could support approval. This is reassuring in the context of the positive two-year data reported today and one-year data reported last year, in our view.

Joseph P. Schwartz, *3Q20 Recap: Pos. Two-Year CARDINAL Data, Potential for Two NDAs Next Year*, SVB SECURITIES LLC, F/K/A SVB LEERINK LLC, 1, 2 (Nov. 9, 2020).

301. Reata's November 9, 2020 disclosures caused an immediate and dramatic market re-evaluation of Reata's worth. Reata shares rocketed up by $42.77 per share on November 9, 2020, to close at $174.66 per share, a one-day increase of 32.4% from the prior trading day's

closing price of $131.89 per share. November 9, 2020 trading volume of 1.33 million shares more than quadrupled Reata's average daily trading volume (285,461 shares per day) during the Class Period.

20. Statements Made in Connection with Reata's December 1, 2020 Secondary Public Offering

302. On December 1, 2020, taking advantage of the substantial appreciation in Reata's share price following the November 9, 2020 disclosure of the CARDINAL Phase 3 year-two results, Reata announced a secondary stock offering of 2.0 million shares. That same day, Reata priced, issued, and sold 2.0 million Reata shares at $140.85 per share through a secondary stock offering underwritten by Barclays and Goldman (the "2020 Offering"). Net proceeds to Reata totaled $277.8 million, after payment of $3.82 million to the 2020 Offering Underwriter Defendants.

303. The 2020 Offering shares were registered, issued, and sold pursuant to: (i) the Shelf Registration Statement; and (ii) a December 1, 2020 prospectus supplement (the "2020 Offering ProSupp" and together with the Shelf Registration Statement and documents incorporated by reference, the "2020 Offering Documents").

304. The 2020 Offering ProSupp contained CARDINAL Retained eGFR Representations, Prior Study Retained eGFR Representations, and Bard NDA Representations:

> **Recent Key Developments**
>
> ***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 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-New Drug Application

(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.

***

Bardoxolone in 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 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). . . .

We recently completed the previously announced pre-NDA meeting with the FDA to discuss the NDA submission content and plans. Based on that meeting and the FDA's responses and the subsequently announced positive results of the Year 2 data of the CARDINAL Phase 3 study, we plan to proceed with an NDA filing for full marketing approval of bardoxolone in patients with CKD caused by Alport syndrome in the first quarter of 2021. We will also continue preparations to file for marketing approval in Europe.

***

Historical Development of Bardoxolone

Clinical trials enrolling over 2,000 patients exposed to bardoxolone have demonstrated consistent, clinically meaningful improvement in kidney function . . . .

. . . We believe these data, in addition to the CARDINAL Phase 3 Year 2 data, support the potential for bardoxolone to delay or prevent dialysis, kidney transplant, and death in patients with Alport syndrome and other forms of CKD.

Additional observations from the prior clinical trials of bardoxolone include the following: . . .

- Statistically significant improvement in eGFR during the off-treatment period in BEAM, BEACON, the Phase 2 portion of CARDINAL at Year 1, and the Phase 3 portion of CARDINAL at Year 2. We believe the eGFR benefit during the off-treatment period observed in these clinical trials demonstrates that bardoxolone treatment improved the structure of the kidney, modified the course of the disease, and may prevent or delay kidney failure and the need for dialysis or a kidney transplant.

2020 Offering ProSupp at S-1, S-4 – S-5, S-6 – S-7.

305. The CARDINAL Retained eGFR Representations in the 2020 Offering ProSupp were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR measurement meant that: (i) CARDINAL had not actually measured what was claimed (*i.e.*, retained eGFR), and instead had measured PD effects; (ii) CARDINAL's purported retained eGFR results neither constituted nor measured truly retained eGFR and thus provided no indication of disease-modifying effects; and (iii) CARDINAL's retained eGFR results therefore would not and could not provide a basis for FDA approval. *See* Section IV.G.3, *supra*.

306. The Bard NDA Representations in the 2020 Offering ProSupp, though accurate in and of themselves, were still materially misleading because they omitted to disclose numerous facts then known by Defendants that were highly material to evaluation of the Bard NDA and that indicated far greater risks to its approval than publicly understood in light of Defendants' other accumulated misstatements, including:

A. that Bard's PD effects did **not** wash out quickly (per the 10-14 Day Washout Representations) but instead required eight weeks for washout;

B. that as a result, the purported retained eGFR results from CARDINAL, BEAM, and BEACON (constantly repeated via CARDINAL Retained eGFR Representations and Prior Study Retained eGFR Representations) neither measured nor evidenced truly retained eGFR, and thus could not and did not support FDA approval; and

C. that the FDA had **repeatedly warned** Reata between December 2016 and September 2020 that it did **not** concur with CARDINAL's design, that the four (4)-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on

such a washout period would be invalid and incapable of supporting FDA approval.

21. The March 1, 2021 Statements

307. On or about February 25, 2021, Reata submitted the Bard NDA to the FDA.

308. On March 1, 2021, Reata: (i) issued a press release announcing fourth-quarter and full-year 2020 results (the "Q4 2020 Results Release"); (ii) issued another press release, titled "Reata Pharmaceuticals, Inc. Submits NDA for Company's Lead Program: Bardoxolone in Alport Syndrome," reporting that Reata had filed the Bard NDA (the "Bard NDA Release"); (iii) filed with the SEC a Form 10-K, signed by Defendants Huff, Soni, McClellan, McGaughy, Nielsen, and Rose for 2020 (the "2020 10-K"); and (iv) at 8:30 a.m. EST, hosted a conference call with analysts and investors (the "Q4 2020 Conference Call").

309. The Q4 2020 Results Release, as its first topic, and the Bard NDA Release, as its entire focus, announced that Reata had filed the Bard NDA, purportedly supported by the CARDINAL Phase 3 data – *i.e.*, made Bard NDA Representations:

> Recent Company Highlights
>
> Chronic Kidney Disease
>
> *Bardoxolone Methyl ("Bardoxolone") in Alport Syndrome*
>
> Reata has submitted a New Drug Application ("NDA") for bardoxolone in Alport syndrome to the U.S. Food and Drug Administration ("FDA"). This NDA submission is based on the efficacy and safety data from the CARDINAL Phase 3 clinical trial . . . .

Q4 2020 Results Release.

> **Reata Pharmaceuticals, Inc. Submits NDA for Company's Lead Program: Bardoxolone in Alport Syndrome**
>
> Reata . . . 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").
>
> This NDA submission is based on the efficacy and safety data from the

CARDINAL Phase 3 clinical trial.

Bard NDA Release.

310. The 2020 10-K contained Bard NDA Representations, FDA Guidance Representations, CARDINAL Retained eGFR Representations, and Prior Study Retained eGFR Representations:

> *Bardoxolone for CKD Caused by Alport Syndrome . . .*
>
> On November 9, 2020, we announced the results of Year 2 of the Phase 3 CARDINAL study of bardoxolone in patients with CKD caused by Alport syndrome. The study met its primary and key secondary endpoints at the end of the study following two years of treatment (referred to as Year 2). . . . Together, these data suggest that bardoxolone treatment has beneficial long-term effects on kidney function in patients with Alport syndrome.
>
> Based on these positive results, and following a pre-NDA meeting with the FDA, we submitted a New Drug Application (NDA) with the FDA for full marketing approval in the United States. 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. We plan to submit a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) in the fourth quarter of 2021 for marketing approval of bardoxolone for the treatment of CKD caused by Alport syndrome in Europe.
>
> ***
>
> Prior to our CARDINAL Phase 3 trial, clinical trials enrolling over 2,000 patients exposed to bardoxolone have demonstrated consistent, clinically meaningful improvement in kidney function . . . .
>
> . . . We believe these data, in addition to the CARDINAL Phase 3 data, support the potential for bardoxolone to delay or prevent GFR declines that cause the need for dialysis or kidney transplant, and eventually death in patients with Alport syndrome and other forms of CKD.
>
> Additional observations from the prior clinical trials of bardoxolone include the following: . . .
>
> - Statistically significant improvement in eGFR above baseline or versus placebo during the off-treatment period in BEAM, BEACON, the Phase 2 portion of CARDINAL at one year, and the Phase 3 portion of CARDINAL at one and two years.
>
> - The FDA has provided guidance to us and other sponsors that

clinical trials with an eGFR benefit versus placebo during the off-treatment period may support approval in certain rare forms of CKD.

- We believe that the increase in off-treatment eGFR relative to placebo shows that increases in eGFR due to bardoxolone over longer durations do not have detrimental effects on kidney function. Most importantly, the observed eGFR benefit versus placebo during the off-treatment periods in these clinical trials demonstrates that bardoxolone treatment may have resulted in structural improvement, modifying the course of the disease, and delaying the need for dialysis or kidney transplant.

Bardoxolone in Patients with CKD Caused by Alport Syndrome . . .

On November 9, 2020, we announced that the Phase 3 CARDINAL study met its primary and key secondary endpoints at the end of Year 2. . . .

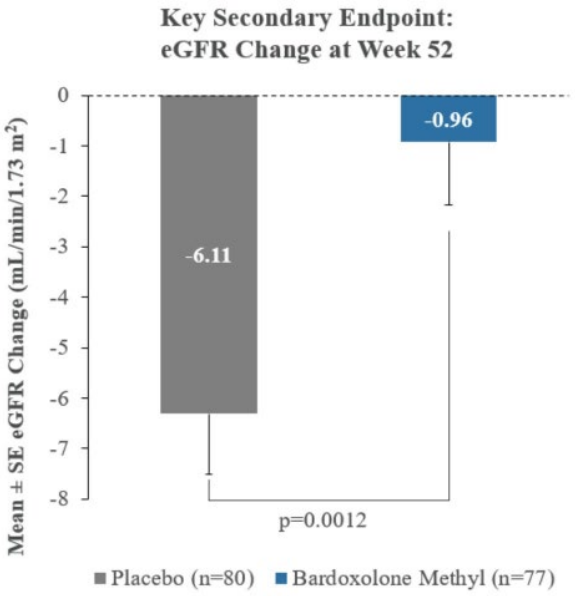
At Week 104 (four weeks after last dose in second year of treatment), patients in the ITT population treated with bardoxolone had a statistically significant improvement compared to placebo in mean change from baseline in eGFR of 4.3 mL/min/1.73 m2 (p=0.023). . . .

We submitted to the FDA our NDA filing for full marketing approval of bardoxolone in patients with CKD caused by Alport syndrome. In the fourth quarter of 2021, we plan to submit to the EMA an MAA filing for full approval of bardoxolone for the treatment of CKD caused by Alport syndrome.

CARDINAL Year 1 results:

The results of the Year 2 of the CARDINAL Phase 3 study are consistent with the results from Year 1. . . .

The key secondary endpoint for the study was the change in eGFR at 52 weeks, after 48 weeks of treatment and four weeks of off-treatment period. At Week 52, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean eGFR of 5.14 mL/min/1.73 m2 (p=0.0012) during the off-treatment period. Patients treated with bardoxolone experienced a nonsignificant decline from baseline in mean eGFR of -0.96 mL/min/1.73 m2 (p=0.45), while patients treated with placebo experienced a statistically significant decline from baseline in mean eGFR of -6.11 mL/min/1.73 m2 (p<0.0001) during the off-treatment period. Similar efficacy at Week 48 and Week 52 was observed across multiple subgroups, including among pediatric patients.



2020 10-K at 7, 15-16, 16-21.

311. During the Q4 2020 Conference Call, Defendant Meyer asserted at length that the data submitted by Reata in the Bard NDA, including the CARDINAL results and prior study results, supported FDA approval – and, in so doing, reiterated CARDINAL Retained eGFR Representations, Prior Study Retained eGFR Representations, and Bard NDA Representations:

> Our NDA contains data from three separate Alport syndrome trials that contain just under 200 unique patients, including the Phase 2 and Phase 3 CARDINAL studies, as well as the ongoing EAGLE open-label extension study that is continuing to accumulate data. . . .
>
> Next slide. Unlike most, where disease development programs that contain a relatively small data sets, based on the extensive development history our NDA concerns data from multiple clinical trials and disease states that have enrolled over 3,000 patients . . . .
>
> . . . Prior to our Alport syndrome trials, we have shown sustained improvements in eGFR for a year and significant improvements and off-treatment eGFR in two prior trials.
>
> ***
>
> As shown on the following slide and previously discussed CARDINAL also met its key secondary off treatment endpoints. The persisting significant increase in eGFR following washout observed twice in

> CARDINAL provides evidence that the on-treatment eGFR improvement is consistent with a beneficial and not harmful profile. While we believe the on-treatment effect represents the clinical benefits, the off-treatment improvements demonstrate disease modification.

Q4 2020 Conference Call, Bloomberg transcript at 3-4.

312. The March 1, 2021 assertions of Bard NDA Representations in the Bard NDA Release, the Q4 2020 Results Release, the 2020 10-K, and the Q4 2020 Conference Call were materially misleading because they omitted to disclose numerous facts then known by Defendants that were highly material to the evaluation of the Bard NDA and that indicated far greater risks to its approval than publicly understood in light of Defendants' other misstatements, including:

A. that Bard's PD effects did **not** wash out quickly (per the 10-14 Day Washout Representations), but instead required eight weeks for washout;

B. that as a result, the purported retained eGFR results from CARDINAL, BEAM, and BEACON (constantly repeated via CARDINAL Retained eGFR Representations and Prior Study Retained eGFR Representations) neither measured nor evidenced truly retained eGFR, and thus could not and did not support FDA approval; and

C. that the FDA had **repeatedly warned** Reata between December 2016 and September 2020 that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval.

313. The March 1, 2021 assertions of CARDINAL Retained eGFR Representations in the 2020 10-K and Q4 2020 Conference Call were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR measurements meant that: (i) CARDINAL had not actually measured what was claimed (*i.e.*, retained eGFR), and instead had measured PD effects;

(ii) CARDINAL's purported retained eGFR results neither constituted nor measured truly retained eGFR and thus provided no indication of disease-modifying effects; and (iii) CARDINAL's retained eGFR results therefore would not and could not provide a basis for FDA approval. *See* Section IV.G.3, *supra*.

314. The March 1, 2021 assertions of Prior Study Retained eGFR Representations in the 2020 10-K and Q4 2020 Conference Call were materially false and/or misleading. In truth, because BEAM and BEACON measured retained eGFR after an inadequate four-week washout period, they neither measured nor evidenced any retained eGFR benefit or disease-modifying effects for Bard. *See* Sections IV.G.2-3, *supra*.

315. The FDA Guidance Representations in the 2020 10-K were materially false and/or misleading. Specifically, the claims of acting in accord with FDA "guidance" purportedly supporting (i) use of a four-week washout period and (ii) the resulting retained eGFR as a basis for FDA approval, were materially misleading for failing to disclose that Reata had not in fact obtained FDA concurrence on these matters. *See* Section IV.G.1, *supra*. Defendants failed to disclose that the FDA had **repeatedly warned** Reata – beginning with the FDA's December 2016 Advice Letter, again in February 2019, and yet again in the January 2020 FDA Meeting and a September 2020 FDA meeting – that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval. *Id*. The representations were further misleading for failing to disclose that: (i) in September 2018 and February 2019, the FDA had requested an End-of-Phase 2 meeting and stressed the importance of such a meeting and of obtaining FDA concurrence on CARDINAL, but Reata ignored those requests; and (ii) in the January 2020 FDA Meeting and the September 2020 FDA meeting, the

FDA expressed additional concerns with the high level of Bard-treated patients in CARDINAL who discontinued treatment within the first year, and with Bard's effects on blood pressure and albuminuria.

316. Additionally, the 2020 10-K included a new subsection, titled "Potential Review Topics," that focused on the Bard NDA and presented several "potential NDA review topics" with respect to the Bard NDA and "how [Reata] plan[ned] to respond" on each topic. *See* 2020 10-K at 21-24. In this subsection, and under the topic identified as "Resolution of Acute Pharmacodynamic Effects," the 2020 10-K explained that measuring truly retained eGFR required that the "acute increases in eGFR must be resolved" (*i.e.*, Bard's PD effects) prior to measurement (*i.e.*, Bard must be washed out), "so that only the persisting, irreversible effect on kidney function is assessed." *Id.* at 23. However, the 2020 10-K thereafter reiterated 10-14 Day Washout Representations to assert that this was the case for Bard and in CARDINAL (the "off-treatment window used in CARDINAL is sufficient for resolution of acute PD changes in eGFR[]"):

> *Potential Review Topics*
>
> Below is a discussion of potential NDA review topics and how we plan to respond. This list is not comprehensive, and other matters may arise during the NDA review process.
>
> ***
>
> Resolution of Acute Pharmacodynamic Effects
>
> An off-treatment assessment was conducted after one and two years of treatment in the CARDINAL trial to characterize the impact of bardoxolone on the structure of the kidney. This assessment was intended to determine if bardoxolone improves the structure of the kidney, which would be consistent with disease-modifying activity. To perform this assessment, the acute increases in eGFR must be resolved so that only the persisting, irreversible effect on kidney function is assessed. In the clinical trial protocol, the target day for assessment of off-treatment eGFR was 28 days after the last dose, and the window in the Statistical Analysis Plan (SAP) allowed values as early as 14 days after the last dose to contribute to the analysis.
>
> The assessment of eGFR changes in the SAP after the last dose in CARDINAL

> allowed for sufficient drug washout and resolution of acute pharmacodynamic effects. Based on the drug's half-life of approximately 48 hours, 14 days represents seven half-lives, and by this time >99% of bardoxolone has been cleared, and there are no active metabolites. The time to resolution of the acute increases in eGFR was also evaluated using the integrated summary of safety (ISS) dataset, which contains data from over 3,000 patients and has off-treatment values that range from one day to many weeks post-discontinuation. Analyses of available serial off-treatment eGFR values in these patients demonstrate bardoxolone's resolution of acute pharmacodynamic (PD) effect occurs during the initial 14-day post-dose period. The resolution of PD effects on eGFR within 14 days after the last dose was also supported by analyses using all off-treatment eGFR values in the ISS dataset (n=652) collected between one to <42 days after the last dose from all completed bardoxolone trials that were not terminated prematurely. The collective multiple lines of evidence, including clinical eGFR data, clinical PK data, clinical and nonclinical PD data, and robust population PK and exposure-response modeling, strongly support the conclusion that bardoxolone's acute PD effects on eGFR are resolved within 14 days after stopping treatment. Consequently, for the purposes of evaluating bardoxolone's effect on the irreversible loss of kidney function, the off-treatment window used in CARDINAL is sufficient for resolution of acute PD changes in eGFR.

2020 10-K at 21, 23.

317. The 10-14 Day Washout Representations contained in the 2020 10-K were materially false and/or misleading. In truth, extended Bard treatment, such as in CARDINAL, BEAM, and BEACON, required eight weeks to wash out: a period at least four times longer than the represented 14 days. *See* Section IV.G.2, *supra*.

318. The 2020 10-K contained Risk Factor Disclosures that were: (i) substantively identical, in relevant part, to those in the 2016 10-K (*see* ¶ 177, *supra*); and (ii) inadequate and materially misleading. *See* 2020 10-K at 63-64, 85-86. They inaccurately described certain risks – specifically, that the FDA might not approve Bard due to "inadequate design or implementation of our clinical trials[,]" failure to demonstrate Bard's "safety and efficacy . . .[] to the satisfaction of the relevant regulatory authorities[,]" and FDA disagreement "that our completed clinical trials provide adequate data on safety or efficacy[]" – as **potential** risks, stated in a generalized and hypothetical manner, while omitting to disclose material then-existing facts – such as the FDA's

December 2016 Advice Letter, the FDA's September 2018 and February 2019 communications, the January 2020 FDA Meeting and the September 2020 FDA meeting – indicating that these risks were actually materializing.

22. The April 26, 2021 Statements

319. On April 26, 2021, Reata issued a press release announcing the FDA's formal acceptance of the Bard NDA, and disclosing (i) that FDA review would proceed under a standard rather than a priority review timeline, and (ii) that the FDA planned to hold an Advisory Committee meeting in connection with its review of the Bard NDA. The April 26, 2021 press release contained Bard NDA Representations and CARDINAL Retained eGFR Representations, and stated in relevant part:

> **About the CARDINAL Clinical Study** . . .
>
> The key secondary endpoint for Year 2 of the study was the change from baseline in eGFR at Week 104 (four weeks after the last dose in second year of treatment).
>
> Results from CARDINAL demonstrated that patients treated with bardoxolone experienced a statistically significant improvement in kidney function as measured by eGFR at Week 100 and Week 104, compared to patients treated with placebo. Bardoxolone was generally reported to be well tolerated in this study . . . .

320. The Bard NDA Representations in the April 26, 2021 press release, though accurate in and of themselves, were still materially misleading because they omitted to disclose numerous facts then known by Defendants that were highly material to evaluation of the Bard NDA and that indicated far greater risks to its approval than publicly understood in light of Defendants' other accumulated misstatements, including:

A. that Bard's PD effects did **not** wash out quickly (per the 10-14 Day Washout Representations), but instead required eight weeks for washout;

B. that as a result, the purported retained eGFR results from CARDINAL, BEAM, and BEACON (constantly repeated via CARDINAL Retained eGFR Representations and

Prior Study Retained eGFR Representations) neither measured nor evidenced truly retained eGFR, and thus could not and did not support FDA approval; and

C. that the FDA had **repeatedly warned** Reata between December 2016 and September 2020 that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval.

321. The CARDINAL Retained eGFR Representations in the April 26, 2021 press release were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR measurements meant that: (i) CARDINAL had not actually measured what was claimed (*i.e.*, retained eGFR), and instead had measured PD effects; (ii) CARDINAL's purported retained eGFR results neither constituted nor measured truly retained eGFR and thus provided no indication of disease-modifying effects; and (iii) CARDINAL's retained eGFR results therefore would not and could not provide a basis for FDA approval. *See* Section IV.G.3, *supra*.

322. Reata shares reacted positively to the April 26, 2021 statements, rising $11.66 per share from their prior closing of $88.41 per share on April 23, 2021 to close trading on April 26, 2021 at $100.07 per share, representing a one-day increase of 13.2%.

23. The May 6, 2021 Statements

323. On May 6, 2021, Reata: (i) issued a press release announcing first-quarter 2021 results (the "Q1 2021 Results Release"); (ii) filed with the SEC a Form 10-Q, signed by Defendants Huff and Soni, for the first quarter of 2021 (the "Q1 2021 10-Q"); and (iii) at 8:30 a.m. EST, hosted a conference call with analysts and investors (the "Q1 2021 Conference Call").

324. The Q1 2021 Press Release contained Bard NDA Representations:

Recent Company Highlights

Bardoxolone Methyl ("Bardoxolone") in Patients with Alport Syndrome

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. ". . . 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."

325. The Q1 2021 10-Q contained Bard NDA Representations and CARDINAL Retained eGFR Representations:

Recent Key Developments

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.

***

On April 26, 2021, we announced that the FDA accepted for filing the 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 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. We also plan to pursue marketing approval outside of the United States. We plan to submit a MAA with the EMA in the fourth quarter of 2021 for marketing approval of bardoxolone for the treatment of CKD caused by Alport syndrome in the European Union.

Q1 2021 10-Q at 16, 18-19.

326. The Q1 2021 10-Q also contained Prior Study Retained eGFR Representations and FDA Guidance Representations:

Historical Development of Bardoxolone

Prior to our CARDINAL Phase 3 trial, clinical trials enrolling over 2,000 patients exposed to bardoxolone have demonstrated consistent, clinically meaningful improvement in kidney function . . . .

. . . We believe these data, in addition to the CARDINAL Phase 3 data, support the potential for bardoxolone to delay or prevent GFR declines that cause the need for dialysis or kidney transplant, and eventually death in patients with Alport syndrome . . . .

Additional observations from the prior clinical trials of bardoxolone include the following: . . .

- Statistically significant improvement in eGFR above baseline or versus placebo during the off-treatment period in BEAM, BEACON, the Phase 2 portion of CARDINAL at one year, and the Phase 3 portion of CARDINAL at one and two years.
    - The FDA has provided guidance to us and other sponsors that clinical trials with an eGFR benefit versus placebo during the off-treatment period may support approval in certain rare forms of CKD.
    - We believe that the increase in off-treatment eGFR relative to placebo shows that increases in eGFR due to bardoxolone over longer durations do not have detrimental effects on kidney function. Most importantly, the observed eGFR benefit versus

> placebo during the off-treatment periods in these clinical trials demonstrates that bardoxolone treatment may have resulted in structural improvement, modifying the course of the disease, and delaying the need for dialysis or kidney transplant.

Q1 2021 10-Q at 21-22.

327. Defendant Huff began the Q1 2021 Conference Call with Bard NDA Representations, noting that he and other Reata executives had been "actively preparing for . . . the last several months" for the FDA's AdCom Meeting and adding that such preparations and the AdCom Meeting would be a "key focus" for Reata executives during 2021:

> J. Warren Huff
>
> Good morning, everyone, and thank you for joining us today. We have a number of updates that we're excited to share with you this morning. We'll start on Slide 4. First off, we're pleased with the US Food and Drug Administration's recent decision to accept our filing of our New Drug Application for bardoxolone for the treatment of patients with Chronic Kidney Disease caused by Alport syndrome. The FDA will review the application under Standard Review timeline and it assigned a PDUFA date for the application of February 25th, 2022. The FDA also advised us that it is planning to hold an Advisory Committee meeting to discuss the application. We've been actively preparing for this meeting the last several months, and it will be a key focus for our team during the year.

Q1 2021 Conference Call, Bloomberg transcript at 2.

328. After Defendant Huff's introductory remarks, Defendant Meyer then again presented Reata's case for Bard and its approval, reiterating CARDINAL Retained eGFR Representations and Prior Study Retained eGFR Representations within his larger comments concerning Bard's efficacy and safety:

> Colin Meyer . . .
>
> We have also demonstrated a persisting increase after withdrawing eGFR versus placebo after year 1 and year 2 in the Phase 3 CARDINAL trial. And we believe this increase is due to the anti-fibrotic effects of bardoxolone and is consistent with the disease modifying profile. These off treatment improvements also validate that the large durable on-treatment increases in eGFR are beneficial.
>
> When we analyze the off-treatment data using a longitudinal analysis to compute

> off-treatment slopes, as opposed to calculating changes at discrete time points, we have demonstrated that there is a reduction in progression by approximately 50% in the bardoxolone treated patients compared to placebo treated patients. The data from the CARDINAL trial are also supported by data from the BEAM and BEACON diabetic CKD trials, that also demonstrated significant on and off-treatment improvements in eGFR relative to placebo. Overall, the clinical profile of bardoxolone is well-characterized and the on and off-treatment differences in eGFR observed in the pivotal Phase 3 CARDINAL trial, demonstrate a meaningful benefit in patients with one of the most rapidly progressive forms of CKD.

Q1 2021 Conference Call, Bloomberg transcript at 4-6.

329. The May 6, 2021 assertions of CARDINAL Retained eGFR Representations in the Q1 2021 Results Release, Q1 2021 10-Q, and Q1 2021 Conference Call were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR measurement meant that: (i) CARDINAL had not actually measured what was claimed (*i.e.*, retained eGFR), and instead had measured PD effects; (ii) CARDINAL's purported retained eGFR results neither constituted nor measured truly retained eGFR and thus provided no indication of disease-modifying effects; and (iii) CARDINAL's retained eGFR results therefore would not and could not provide a basis for FDA approval. *See* Section IV.G.3, *supra*.

330. The May 6, 2021 assertions of Prior Study Retained eGFR Representations in the Q1 2021 10-Q and Q1 2021 Conference Call were materially false and/or misleading. In truth, because BEAM and BEACON measured retained eGFR after an inadequate four-week washout period, they neither measured nor evidenced any retained eGFR benefit or disease-modifying effects for Bard. *See* Sections IV.G.2-3, *supra*.

331. The May 6, 2021 assertions of Bard NDA Representations in the Q1 2021 Results Release, Q1 2021 10-Q, and Q1 2021 Conference Call, though accurate in and of themselves, were still materially misleading because they omitted to disclose numerous facts then known by Defendants that were highly material to evaluation of the Bard NDA and that indicated far greater

risks to its approval than publicly understood in light of Defendants' other accumulated misstatements, including:

A. that Bard's PD effects did **not** wash out quickly (per the 10-14 Day Washout Representations), but instead required eight weeks for washout;

B. that as a result, the purported retained eGFR results from CARDINAL, BEAM and BEACON (constantly repeated via CARDINAL Retained eGFR Representations and Prior Study Retained eGFR Representations) neither measured nor evidenced truly retained eGFR, and thus could not and did not support FDA approval; and

C. that the FDA had **repeatedly warned** Reata between December 2016 and September 2020 that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval.

332. The FDA Guidance Representations in the Q1 2021 10-Q were materially false and/or misleading. Specifically, the claims of acting in accord with FDA "guidance" purportedly supporting (i) use of a four-week washout period and (ii) the resulting retained eGFR as a basis for FDA approval, were materially misleading for failing to disclose that Reata had not obtained FDA concurrence on these matters. *See* Section IV.G.1, *supra*. Defendants failed to disclose that the FDA had **repeatedly warned** Reata – beginning with the FDA's December 2016 Advice Letter, again in February 2019, and yet again in the January 2020 FDA Meeting and in a September 2020 FDA meeting – that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval. *Id*. The representations were further misleading for failing to disclose that: (i) in September 2018 and

February 2019, the FDA had requested an End-of-Phase 2 meeting, and stressed the importance of such a meeting and of obtaining FDA concurrence on CARDINAL, but Reata ignored those requests; and (ii) in the January 2020 FDA Meeting and the September 2020 FDA meeting, the FDA expressed additional concerns with the high level of Bard-treated patients in CARDINAL who discontinued treatment within the first year, and with Bard's effects on blood pressure and albuminuria.

333. Additionally, during the Q&A portion of the Q1 2021 Conference Call, the first analyst question requested Defendants Huff and/or Meyer to identify the key issues they believed they would face at the AdCom Meeting for the Bard NDA, and what responses Reata had prepared. In his somewhat confused response, Defendant Huff first suggested that Reata would face "just the known issues around our program[,]" then proposed something only marginally more concrete – the novelty of Bard's theorized mechanism of action – and finally linked this novelty to CARDINAL's initial study design and its retained eGFR endpoint:

> Q - Yigal Nochomovitz [Citigroup analyst]
>
> Hi Warren and team, good morning. Congrats on the NDA acceptance for the Alport syndrome, and thanks for taking the questions. So, you mentioned Warren in the prepared remarks that you've been actively preparing for the Adcom, over the past several months. So could you discuss what you believe will be the key issues you expect to be raised by the Advisory Committee regarding the bardoxolone clinical program in Alport and how you are preparing to address these issues? Thank you.
>
> A - J. Warren Huff
>
> Yes, sure, Yigal. Thanks for that. Yes, I think that the -- we've been, as I mentioned, in active preparation, with first class outside help in review and of course, have gotten food review of the data and program by many outside key opinion leaders, as well as the advisors that I mentioned. I think the issues that we anticipate are basically just the known issues around our program. Bardoxolone is a new molecular entity with a novel mechanism of action. It has a very different mechanism than the agents that have previously been approved in the CKD space, like blood pressure medications and the SGLT2 inhibitors. It directly treats the inflammatory processes. We see nice improvements in GFR that are, have not been

> observed too frequently. Obviously, the effect of those was a key feature of the design at the clinical program, the off-treatment of key secondary analysis. I think that that -- that those issues will be kind of the key issues that will be explored in the -- in the -- in the review process, and at the Adcom.

Q1 2021 Conference Call, Bloomberg transcript at 10-11.

334. Defendant Huff's above-specified answer was materially false and/or misleading. In a somewhat stumbling fashion, it ultimately landed on CARDINAL's retained eGFR results but presented those results positively ("nice improvements in GFR that are, have not been observed too frequently") while omitting the fundamental and severe problems arising from CARDINAL's inadequate four-week washout period, that rendered CARDINAL's purported retained eGFR results invalid.

335. Relatedly, towards the close of the Q1 2021 Conference Call, another analyst proposed a concrete issue that "we along with most everyone else . . . expected . . . to be front and center at the AdCom[]" Meeting – the possibility that Bard was boosting eGFR through hyperfiltration – and asked Huff and Meyer how they could respond to the FDA on this issue. Defendant Huff, noting that Reata had spent the last decade working on decoding Bard's mechanism of action and that he had discussed this issue "on many calls over the past few years," provided a lengthy and forceful response. Reiterating the CARDINAL Retained eGFR Representations, Defendant Huff explained that the inclusion of a retained eGFR endpoint in CARDINAL was designed to test and evidence this very issue, and that CARDINAL's retained eGFR results provided a conclusive answer demonstrating that Bard was beneficial, rather than harmful via any hyperfiltration:

> A - J. Warren Huff
>
> Yes. So, we obviously, as I talked about on many calls over the past few years, we've spent literally over a decade to characterize, since the novel profile of bardoxolone. . . .

> And so, from our perspective, we've thoroughly characterized the specific mechanism of action in relevant animal models and there is actually no controversy about what the drug is doing. . . .
>
> And so, in FDA's view and the view of the National Kidney Foundation's working group with FDA and EMA, in settings where there is an acute effect of a drug, that either increases or decreases GFR, the way to appropriately assess for any disease modifying activity, is to withdraw the drug, which we've done twice in the Alport syndrome trial, and both times have demonstrated a persisting increase in GFR versus placebo, which not only [rules] out harm, but it validates that the on-treatment changes are beneficial and recall, that they're sustained for two years versus placebo and three years in the ongoing extension study.
>
> The one known profile of hyperfiltration is with amlodipine, a specific type of calcium channel blocker, that in a study called ASK resulted in a very small transient increase in GFR that peaked at month-six and was lost after that. And so, the profile is very different, we observed sustained large increases for three years. And once again, the purpose of the off-treatment endpoint was to address this very question. And so once again, I think clinically, this is well described, yes hyperfiltration, they come up, but we think we have literally spent years to address this question both mechanistically and clinically.
>
> Q - Nick Rubino
>
> Great. That was a -- that was an awesome review. Thank you.

Q1 2021 Conference Call, Bloomberg transcript at 13-14.

336. Defendant Huff's above-identified reiteration of the CARDINAL Retained eGFR Representations was materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR measurement meant that: (i) CARDINAL had not actually measured what was claimed (*i.e.*, retained eGFR), and instead had measured PD effects; (ii) CARDINAL's purported retained eGFR results neither constituted nor measured truly retained eGFR and thus provided no indication of disease-modifying effects; and (iii) CARDINAL's retained eGFR results therefore would not and could not provide a basis for FDA approval. *See* Section IV.G.3, *supra*.

337. Finally, the last question on the Q1 2021 Conference Call was from Leerink analyst Joseph Schwartz, who asked, with respect to the Bard NDA, whether Reata was still confident that

it was "on the same page" with the FDA with respect to the FDA's purported guidance. In his affirmative response, Defendant Meyer reiterated FDA Guidance Representations, insisting: (i) that Reata had done exactly what the FDA had asked, and had designed CARDINAL in full accord with the FDA's guidance; and (ii) that Reata had been "transparent" with respect to its discussions with the FDA concerning testing Bard as a treatment for Alport, going back all the way to the initial pre-IND meetings in 2016:

> Q - Joseph Schwartz [Leerink analyst]
>
> Hi, thanks and best wishes heading into a couple of very important FDA meetings soon. I was actually hoping to ask on both of them, for Bard and Omav. First on Bard, the FDA seems to be making life difficult for many sponsors lately by taking issue with things that seem to be taken for granted in the past. So, how confident are you that you're on the same page with the division reviewing bardoxolone and that you follow their guidance to a T, because this increasingly seems like it would be required to bring any new markets -- drugs to market nowadays?
>
> A - Colin Meyer
>
> Joe, so I think that we've been transparent with our discussions with the agency dating back to our pre-IND meeting with Alport syndrome, which we had in 2016. They gave us the design for the Alport syndrome trial, which we've executed. . . .
>
> And so from our perspective, the design is what they told us to do. We've executed it. We don't believe there is any discrepancies between what they told us to do and what we've executed. From an analysis perspective, we defined a statistical analysis plan. Of course, we have filed it with -- with FDA, being transparent in the way that we analyze the data.
>
> So, I think that we've done all that we can do to transparently conduct and analyze the trial and provide the data to FDA and I think it's distinct from other -- so, I don't think that -- I think the recent issues that you may be alluding to, are relevant to us.

Q1 2021 Conference Call, Bloomberg transcript at 17.

338. Defendant Meyer's above-identified response was materially false and/or misleading because:

A. directly contrary to his insistence that Reata had been "transparent" concerning its discussions with the FDA since 2016, Reata had for many years omitted material

information concerning those very discussions, which went to the very heart of and threatened Bard's FDA approvability;

B. although he said that the FDA "gave us the design for the Alport syndrome trial, which we've executed," the FDA, for the prior four years, had repeatedly advised Reata to modify CARDINAL's inadequate four-week washout period, and Reata had consistently ignored that advice; and

C. directly contrary to his insistence that there were no "discrepancies between what they told us to do and what we've executed[]" in CARDINAL, there were serious discrepancies between what the FDA had been requesting (retained eGFR data premised on an adequate and supported washout period) and what Reata had done (use an inadequate and unsupported washout period, which rendered CARDINAL's resulting eGFR measurements invalid), which went to the very heart of and threatened Bard's FDA approvability.

24. The August 9, 2021 Statements

339. After filing the Bard NDA on February 25, 2021, but prior to August 9, 2021, the FDA held a mid-review cycle meeting with Reata to discuss the Bard NDA. Mid-review cycle meetings provide the sponsor and the FDA with an opportunity to discuss the review status, key findings, and identify salient or open issues for the sponsor to address.

340. On August 9, 2021, Reata: (i) issued a press release announcing second-quarter 2021 results (the "Q2 2021 Results Release"); (ii) filed with the SEC a Form 10-Q, signed by Defendants Huff and Soni, for the second quarter of 2021 (the "Q2 2021 10-Q"); (iii) at 4:30 p.m. EST, hosted a conference call with analysts and investors (the "Q2 2021 Conference Call"); and (iv) published on its website a presentation that Defendants Huff and Meyer utilized during the Q2 2021 Conference Call (the "Q2 2021 Presentation").

341. Each of the above-identified August 9, 2021 disclosures contained Bard NDA Representations, and each focused primarily on (Reata's) account of the mid-review cycle meeting for the Bard NDA. Each explained that, in the mid-review cycle meeting, the FDA "identified four significant clinical and statistical review issues for [Reata] to address" and that "each of these issues are addressable with additional data and analyses [that Reata would provide in] follow-up submissions to the NDA." Q2 2021 Results Release; Q2 2021 10-Q at 17; *see also* Q2 2021 Presentation at 5-6; *see also* Q2 2021 Conference Call at 2-3. Each of the August 9, 2021 disclosures, apart from the Q2 2021 Results Release, contained extended discussions of each of the four issues. *See* Q2 2021 10-Q at 21-25; Q2 2021 Presentation at 9-13; Q2 2021 Conference Call at 3-8.

342. The third of these four FDA "issues" concerned CARDINAL's washout period and the retained eGFR results based on it. *See* Q2 2021 10-Q at 24; Q2 2021 Presentation at 12; Q2 2021 Conference Call at 7-8.[13] However, **the FDA's concerns with CARDINAL's washout period, as described by the Reata Defendants on August 9, 2021, were not the concerns that the FDA (i) had privately communicated to Reata repeatedly between December 2016 and September 2020, and (ii) publicly disclosed on December 6-8, 2021 – namely, that a four-week washout period was inadequate and an eight-week washout period was required**. Instead, the purported FDA washout concern disclosed on August 9, 2021 was that many of

[13] The first FDA issue related to CARDINAL's **on-treatment** eGFR results (*i.e.*, not retained eGFR after treatment had ceased, but rather eGFR measures while treatment was ongoing), and what they signified. *See* Q2 2021 10-Q at 21-23; Q2 2021 Presentation at 10; Q2 2021 Conference Call, Bloomberg transcript at 5-6. The second centered on arcane statistical issues (specifically, the use of treatment duration as a covariate in statistical analyses of CARDINAL data) and whether Reata had followed its pre-specified statistical analysis plan (it had). *See* Q2 2021 10-Q at 23-24; Q2 2021 Presentation at 11; Q2 2021 Conference Call, Bloomberg transcript at 6. The fourth concerned COVID-19's impact on CARDINAL. *See* Q2 2021 10-Q at 25; Q2 2021 Presentation at 13; Q2 2021 Conference Call, Bloomberg transcript at 8.

CARDINAL's retained eGFR measurements had actually been taken **less** than four weeks after treatment cessation – specifically, at various times between two weeks and four weeks (which CARDINAL's trial protocol had permitted). **Importantly, this purported issue left the purported validity of a four-week washout period intact**: per the August 9, 2021 statements, the FDA's concern arose only where CARDINAL **failed to employ the four-week washout period** and instead used periods shorter than four weeks.

343. For example, the Q2 2021 10-Q stated:

> CARDINAL pre-specified the Year 2 off-treatment analysis window to include eGFR values obtained at least 14 days after last dose, which is supported by pharmacokinetic and extensive off-treatment data demonstrating that the resolution of acute eGFR increases occurs by 14 days after the last dose.
>
> ***
>
> Two of the FDA's other sensitivity analyses only included values collected ≥28 days after last dose. These analyses excluded nearly one-half of the trial participants and violated randomization principles, which resulted in modeled estimates that meaningfully differed from observed Week 104 eGFR changes. We performed sensitivity analyses similar to those performed by the FDA that included more available off-treatment eGFR data by using a cutoff of at least 21 days after last dose. The results for these new analyses were similar to the primary Week 104 analyses and will be provided to the FDA as a follow-up to this meeting.

Q2 2021 10-Q at 24.

344. The representations in the Q2 2021 Presentation and Q2 2021 Conference Call were effectively identical:

> Turning to slide 12. In CARDINAL, we pre-specified the year 2 off-treatment analysis window to include EGFR values obtained at least 14 days after last dose, which is supported by pharmacokinetic and extensive off-treatment data demonstrating that the resolution of acute EGFR increases occurs by 14 days after the last dose.
>
> ***
>
> [Two of] the FDA's other sensitivity analyses, only included values collected at least 28 days after the last dose. These analyses excluded, nearly one-half the trial participants in violated randomization principles, which resulted in modeled

> estimates that meaningfully differs from observed week 104 EGFR changes.
>
> However, the treatment effect in these analyses favor bardoxolone. We perform sensitivity analyses, similar to those performed by the FDA that included more available off-treatment EGFR data by using a cut-off of at least 21 days after the last dose. The results for these new analyses were similar to the primary week 104 analyses and we provided to the FDA as a follow-up to this meeting.

Q2 2021 Conference Call, Bloomberg transcript at 7-8; *see also* Q2 2021 Presentation at 12.

345. The Reata Defendants' above-stated representations were materially false and/or misleading for two reasons.

A. First, and as stated just above at ¶ 342, each of the August 9, 2021 statements materially mischaracterized and trivialized the FDA's washout period concerns, by representing that those concerns related only to those instances where retained eGFR measurements were taken based on washout periods **shorter than four weeks** – which logically implied that a four-week washout period was valid. However, the FDA's real washout period concern, which the FDA had repeatedly communicated to Reata between December 2016 and September 2020, and which the FDA publicly disclosed five months later on December 6, 2021, was that **the four-week washout period was itself invalid** and that an eight-week washout period was instead required.

B. Second, each of the statements included 10-14 Day Washout Representations (the CARDINAL trial design allowing for collection of retained eGFR as soon as 14 days after the last dose was "supported by pharmacokinetic and extensive off-treatment data demonstrating that the resolution of acute EGFR increases occurs by 14 days after the last dose[]"). Q2 2021 Conference Call at 7. In truth, extended Bard treatment such as in CARDINAL required eight weeks to wash out: a period at least four times longer than the represented 14 days. *See* Section IV.G.2, *supra*.

346. Additionally, as Defendants' August 9, 2021 statements contained extensive

representations, including those identified above, concerning the Bard NDA, they were materially misleading because they omitted to disclose numerous facts then known by Defendants that were highly material to evaluation of the Bard NDA and that indicated far greater risks to its approval than publicly understood in light of Defendants' other accumulated misstatements, including:

A. that Bard's PD effects did **not** wash out quickly (per the 10-14 Day Washout Representations), but instead required eight weeks for washout;

B. that as a result, the purported retained eGFR results from CARDINAL, BEAM, and BEACON (constantly repeated via CARDINAL Retained eGFR Representations and Prior Study Retained eGFR Representations) neither measured nor evidenced truly retained eGFR, and thus could not and did not support FDA approval; and

C. that the FDA had **repeatedly warned** Reata between December 2016 and September 2020 that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval.

347. Even though the Reata Defendants' August 9, 2021 statements failed to disclose the FDA's most fundamental concerns – namely, that CARDINAL's retained eGFR data and results predicated on an inadequate four-week washout period rather than the required eight-week washout period, were not retained eGFR at all and thus provided no support for FDA approval – they revealed risks previously concealed by Defendants' misstatements: specifically, FDA concerns with CARDINAL's efficacy, data, and results, including concerns that at least some CARDINAL retained eGFR data was predicated on an inadequate washout period of less than four weeks. Following the August 9, 2021 materialization of these previously concealed risks, Reata shares fell $22.13 per share on August 10, 2021 to close at $100.00 per share (a one-day decline

of 18.1%).

348. Following the Reata Defendants' August 9, 2021 disclosures, and in advance of the AdCom Meeting, Leerink analyst Joseph Schwartz published a lengthy analyst report on October 21, 2021, titled "Where Will the FDA's View of Bardoxolone Land? Waiting on Briefing Docs & AdCom," in which he reviewed and synthesized years of prior Reata disclosures, including particularly the four FDA "issues" revealed on August 9, 2021. In his report's executive summary, Mr. Schwartz concluded that the four FDA issues "appeared fairly benign and addressable" and pronounced himself "cautiously optimistic" about Bard's chances, noting that: "although we must rely on management's characterization of their interactions with the agency [the FDA], we see no smoking gun that should prevent approval of bardoxolone . . . ."[14] Later in his report, when focusing on CARDINAL's design and its purported accord with FDA guidance, Mr. Schwartz took comfort from Reata executives' recent re-affirmations that CARDINAL indeed followed FDA guidance, but still sounded a note of concern over "relying on the company's interpretation of the guidance received[:]"

> As for the study design, when we previously asked management how well they have followed FDA guidance (Exhibit 13), the company noted that they have been transparent with their discussions with the agency dating back to the pre-IND meeting and the FDA provided RETA with the design for the AS trial, which the company has executed on. While RETA's messaging for the upcoming regulatory interactions seems to tell a straightforward story, we are relying on the company's interpretation of the guidance received. Furthermore, it remains unknown if there is any additional context around the guidance given, and we do not know if the FDA's viewpoint has changed . . . .

October 21, 2021 Leerink Report at 9; *see also id*. at Exhibits 13-14.

[14] Joseph P. Schwartz, *Where Will the FDA's View of Bardoxolone Land? Waiting on Briefing Docs & Adcom*, SVB SECURITIES LLC, F/K/A SVB LEERINK LLC, 1-2 (Oct. 21, 2021) (hereinafter, the "October 21, 2021 Leerink Report").

25. The November 8, 2021 Statements

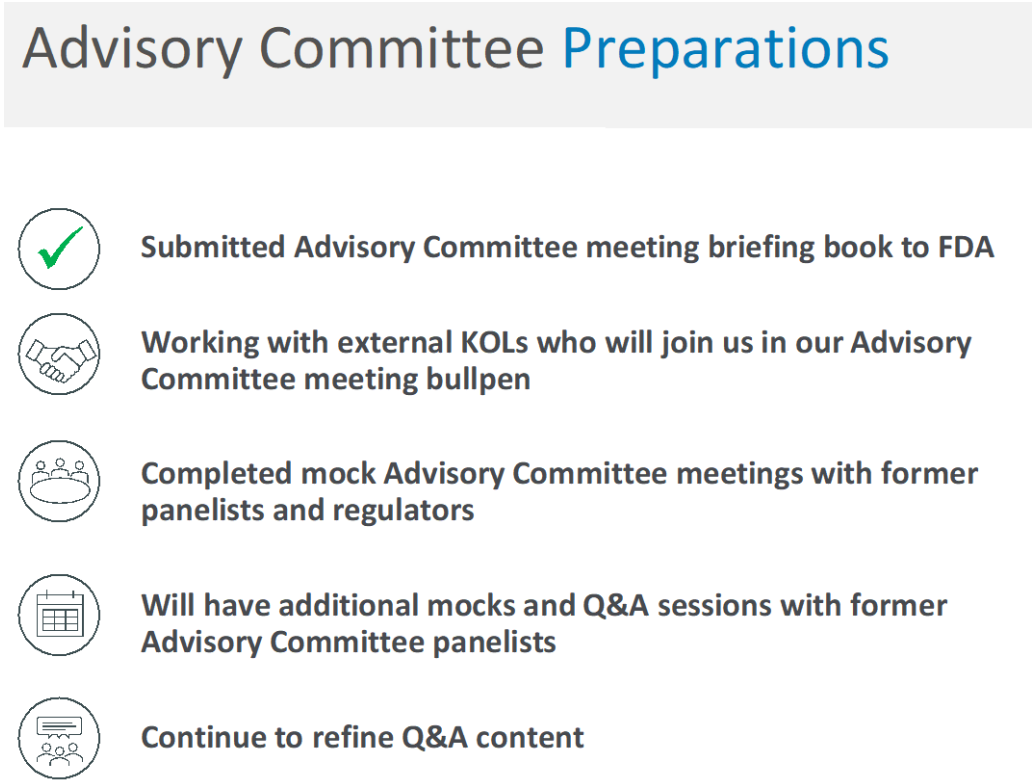
349. On November 8, 2021, Reata: (i) issued a press release announcing third-quarter 2021 results (the "Q3 2021 Results Release"); (ii) filed with the SEC a Form 10-Q, signed by Defendants Huff and Soni, for the third quarter of 2021 (the "Q3 2021 10-Q"); (iii) at 4:30 p.m. EST, hosted a conference call with analysts and investors (the "Q3 2021 Conference Call"); and (iv) published on its website a presentation, titled "Reata Pharmaceuticals Third Quarter 2021 Financial Results and Update on Clinical Development Programs," that Defendants Huff and Meyer utilized during the Q3 2021 Conference Call (the "Q3 2021 Presentation").

350. The Q3 2021 10-Q contained Bard NDA Representations and CARDINAL Retained eGFR Representations:

> ***Bardoxolone in Patients with CKD Caused by Alport Syndrome*** . . .
>
> In November 2020, we announced that the Phase 3 CARDINAL study met its primary and key secondary endpoints at the end of Year 2. . . . 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). . . .
>
> We also completed a mid-cycle communication meeting with the FDA and were advised that an Advisory Committee meeting is scheduled for December 8, 2021. The PDUFA date, the FDA action date for the application, is scheduled for February 25, 2022.

Q3 2021 10-Q at 17, 20-21.

351. The Q3 2021 Presentation included Bard NDA Representations providing further "color" on Reata's preparations for the AdCom Meeting:



Q3 2021 Presentation at 6.

352. The November 8, 2021 assertions of Bard NDA Representations in the Q3 2021 10-Q and Q3 2021 Presentation were materially misleading because they omitted to disclose numerous facts then known by Defendants that were highly material to evaluation of the Bard NDA and that indicated far greater risks to approval than publicly understood in light of Defendants' other accumulated misstatements, including:

A. that Bard's PD effects did **not** wash out quickly (per the 10-14 Day Washout Representations), but instead required eight weeks for washout;

B. that as a result, the purported retained eGFR results from CARDINAL, BEAM, and BEACON (constantly repeated via CARDINAL Retained eGFR Representations and Prior Study Retained eGFR Representations) neither measured nor evidenced truly retained eGFR, and thus could not and did not support FDA approval; and

C. that the FDA had **repeatedly warned** Reata between December 2016 and September 2020 that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that "retained eGFR" data predicated on such a washout period would be invalid and incapable of supporting FDA approval.

353. The CARDINAL Retained eGFR Representations in the Q3 2021 10-Q were materially false and/or misleading. Because PD effects remained for eight weeks after extended Bard treatment, the use of an inadequate four-week washout period for retained eGFR measurement meant that: (i) CARDINAL had not actually measured what was claimed (*i.e.*, retained eGFR), and instead had measured PD effects; (ii) CARDINAL's purported retained eGFR results neither constituted nor measured truly retained eGFR and thus provided no indication of disease-modifying effects; and (iii) CARDINAL's retained eGFR results therefore would not and could not provide a basis for FDA approval. *See* Section IV.G.3, *supra*.

B. The Price of Reata Shares Deflates as Previously Concealed Risks Materialize, and Plunges After the FDA's December 2021 Disclosures Correct Defendants' Prior Misstatements

354. FDA documents published on December 6, 2021, in connection with and in advance of the AdCom Meeting on December 8, 2021, together with the actual AdCom Meeting proceedings on December 8, 2021, served to correct Defendants' prior Class Period misstatements. The December 6-8, 2021 corrective disclosures revealed material facts were evident and known to Defendants throughout the Class Period but that had been concealed from Lead Plaintiff and Class members by Defendants' above-detailed misrepresentations, misleading statements, and omissions. Specifically, the December 6-8, 2021 corrective disclosures revealed that:

A. contrary to the FDA Guidance Representations, Reata had **not** operated CARDINAL in accord with FDA guidance, and that the FDA, for nearly the entirety of the Class Period, and ever since December 2016, had repeatedly (i) warned Reata of the same,

and (ii) advised Reata to obtain FDA concurrence with respect to CARDINAL's design and adequacy before proceeding with and/or completing CARDINAL Phase 3;

B. contrary to the 10-14 Day Washout Representations, CARDINAL required a far longer period for washout of Bard's PD effects – approximately eight weeks or 60 days, which was twice as long as the four-week washout period utilized in CARDINAL;

C. contrary to the CARDINAL Design Representations, CARDINAL had not been adequately designed to measure retained eGFR;

D. contrary to the CARDINAL retained eGFR Representations, and because resolution of Bard's PD effects required a washout period far longer than the four-week period used in CARDINAL, CARDINAL's purported retained eGFR results were:

   a) not truly retained eGFR at all;

   b) contaminated by the very thing they purported to be free of – Bard's PD effects; and thus

   c) incapable of supporting Bard's approval by the FDA, irrespective of any apparent success with respect to stated endpoints;

E. the Prior Study Retained eGFR Representations had been false and/or misleading for the same reasons as the CARDINAL Retained eGFR Representations;

F. the Reata Defendants' August 10, 2020 statements had materially mischaracterized the January 2020 FDA Meeting and the above-stated issues that arose therein;

G. the Reata Defendants' August 9, 2021 statements had materially mischaracterized and trivialized the FDA's washout period concerns; and

H. the Bard NDA Representations had omitted all the above-summarized adverse facts material to the Bard NDA.

355. The December 6-8, 2021 disclosures led the market to an immediate and sharp re-valuation of Reata, which fell $29.77 per share on December 6, 2021 to close at $48.92 per share. After rising slightly on December 7, 2021 to close at $54.42 per share, and not trading at all on December 8, 2021 (because of a trading halt imposed during the all-day AdCom Meeting), Reata shares plunged anew on December 9, 2021 to close at $29.11 per share. All told, the December 6-8, 2021 disclosures caused Reata's share price to fall by $49.58 per share, representing 63.0% of Reata's equity value immediately prior to the disclosures.

356. Prior to the December 6-8, 2021 corrective disclosures, two other disclosures – on August 10, 2020 and August 9, 2021 – functioned to partially materialize risks previously concealed by Defendants' misstatements, and thereby occasioned relevant, additional Reata share price declines.

A. The Reata Defendants' August 10, 2020 statements, disclosing *inter alia* FDA reluctance to entertain an immediate Bard NDA filing based on year-one CARDINAL data, while themselves materially false and misleading (*see* Section V.A.18, *supra*), nevertheless served as a first indication to the market that as-yet undisclosed stumbling blocks to FDA approval of Bard *might* exist. Reata shares therefore declined materially in response to the August 10, 2020 statements.

B. One year later, the Reata Defendants' August 9, 2021 statements disclosed four FDA concerns with CARDINAL data (*see* Section V.A.24, *supra*), constituting a further materialization of the risks previously concealed by Defendants' misstatements and intuited by the market following the year-ago August 10, 2020 disclosures. The August 9, 2021 statements, the first disclosure of concrete FDA concerns with the CARDINAL data, thus occasioned significant Reata share price declines. However, as set forth

above (*see* Section V.A.24, *supra*), this first disclosure was materially incomplete and therefore itself materially misleading, as it failed to disclose the FDA's fundamental concerns with CARDINAL's washout period and the (in)validity of CARDINAL's ensuing retained eGFR results.

1. The August 10, 2020 Disclosures

357. The August 10, 2020 disclosures, as detailed in Section V.A.18, *supra*, marked an end to the radio silence on FDA interactions during Reata's prior two quarterly disclosures (February 19, 2020 and May 11, 2020) after the January 2020 FDA Meeting. In their August 10, 2020 disclosures, the Reata Defendants discussed at length – and materially mischaracterized – a recent "Type C" meeting with the FDA (in fact, the January 2020 FDA Meeting). Per the Reata Defendants' account of that meeting, while Reata wished to file an NDA for Bard immediately, based on CARDINAL's year-one data and for accelerated FDA approval, the FDA appeared to think that Reata should wait for CARDINAL year-two data before filing any NDA.

358. The market intuited from this disclosure the existence of *potential* stumbling blocks to FDA approval of Bard. Given the uninterrupted string of uniformly positive CARDINAL Phase 2/3 results reported during the prior two years, and the Reata Defendants' preference for an immediate NDA filing and accelerated FDA approval, the FDA's reluctance to accept such an NDA appeared inexplicable – and thus concerning. Therefore, the August 10, 2020 statements led the market to suspect the existence of yet-undisclosed problems with the CARDINAL data that could make FDA approval more fraught than previously understood. For example, in his August 10, 2020 analyst report on Reata, Leerink analyst Joseph Schwartz wrote:

> **2Q20 Corporate Update Raises Questions on Bard/Omav Regulatory Paths**
>
> **Bottom Line**: Management provided investors with updates on their two key programs, bardoxolone and omaveloxolone, on their 2Q20 conference call this morning, which increase the uncertainty on the regulatory paths forward for these

> key programs. RETA still expects to file an NDA for bardoxolone in 4Q20, however, it is unclear whether the FDA's 'questions and comments' about 1-year data indicate that the FDA is apprehensive about approving the drug on the basis of the CARDINAL trial.[15]

359. Reata shares therefore fell sharply on August 10, 2020 trading to close at $104.41 per share – a one-day decline of $51.79 per share (or 33.2%) from the prior closing price of $156.20 per share. August 10, 2020 trading volume of approximately 4.05 million Reata shares – more than 14 times Reata's average daily trading volume during the Class Period (285,461 shares per day) – was the fourth most active trading day in Reata's existence, exceeded only by trading following the December 6 and 8, 2021 corrective disclosures (detailed immediately below at Section V.B.3, *infra*), and by the trading that followed Reata's initial disclosure of positive retained eGFR results from CARDINAL on July 23, 2018 (detailed above at Section V.A.10, *supra*).

360. However, the August 10, 2020 statements did not constitute anything close to full, corrective disclosure and were themselves materially false and/or misleading. As explained above, they mischaracterized the January 2020 FDA Meeting disputes as primarily procedural, rather than deeply substantive.[16] According to Defendants' August 10, 2020 statements, the disputes concerned little more than timing: whether Reata should file an NDA immediately, based on year-one CARDINAL data, for accelerated approval, or wait a little bit longer for CARDINAL year-two data and then file for full approval. Analysts following Reata took away exactly this message. For example, in his August 10, 2020 report, Jefferies analyst Maury Raycroft wrote:

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[15] Joseph P. Schwartz, *2Q20 Corporate Update Raises Questions on Bard/Omav Regulatory Paths*, SVB SECURITIES LLC, F/K/A SVB LEERINK LLC, 1 (Aug. 10, 2020).

[16] Yet, according to the FDA's December 6, 2021 account of the same meeting, the January 2020 FDA Meeting disputes concerned matters of fundamental substance: the validity of CARDINAL's retained eGFR data; whether, given the four-week washout period, they were retained eGFR at all; and thus, whether they provided any support for FDA approval. *See* ¶¶ 106-13, *supra*.

> **2Q: Reg Clarity Debunks Bear-Case View; Stock Overreaction Creates Buying Oppty**
>
> RETA provided clarity on reg filings, which we believe puts bear-case speculation to rest. Notably, we are encouraged by the Alport update . . . .
>
> . . . [I]t seems like there was no discussion around 1-yr data being sufficient, but FDA just thinks RETA might as well include all of the 2-yr data, since that part of the study is almost complete. . . . Notably, RETA believes the recommendation to file w/ the 2-yr data is primarily due to FDA's assumption that there would not be much delay in NDA submission by waiting for the 2-yr data -- RETA noted 2-yr data is on track for top-line readout 4Q20 . . . . These details and the fact that FDA still granted the pre-NDA mtg and is still enabling RETA to move forward as planned, gives us confidence FDA and RETA do not see anything unattainable w/ RETA's Alport path.[17]

2. The August 9, 2021 Disclosures

361. Reata's August 9, 2021 statements disclosed four issues that the FDA had identified in the CARDINAL data supporting the Bard NDA. *See* Section V.A.25, *supra*. However, and as also detailed above, the four FDA issues disclosed on August 9, 2021 failed to include the FDA's most fundamental concerns with CARDINAL: CARDINAL's design, specifically the adequacy of CARDINAL's four-week washout period, and the validity of the retained eGFR data based on and resulting from that washout period. *Id*.

362. As Reata's August 9, 2021 disclosures revealed, for the first time, FDA concerns with CARDINAL data, they constituted a materialization of risks previously concealed by Defendants (risks whose existence the market had first intuited from the year-ago August 10, 2020 statements). Therefore, and in reaction to the August 9, 2021 disclosures, Reata shares fell sharply on August 10, 2021 to close at $100.00 per share – a one-day decline of $22.13 per share (18.1%) from the August 9, 2021 closing price of $122.13 per share. Trading volume on August 10, 2021, more than 2.56 million Reata shares, was extremely high: approximately nine times greater than

[17] Maury Raycroft, *2Q: Reg Clarity Debunks Bear-Case View; Stock Overreaction Creates Buying Oppty*, JEFFERIES LLC, 1 (Aug. 10, 2020).

Reata's Class Period daily average (285,461 shares per day).

363. However, and insofar as Reata's August 9, 2021 disclosures failed to disclose the FDA's central and most substantive concerns with CARDINAL, which were then and long known to the Reata Defendants but remained publicly undisclosed until December 6-8, 2021, they did not constitute or provide full corrective disclosure.

3. The December 6-8, 2021 Disclosures

364. The FDA Cardiovascular and Renal Drugs Advisory Committee ("AdCom") was scheduled to meet on December 8, 2021, between 9:30 am and 5:00 pm EST, to review Reata's Bard NDA for Alport – the AdCom Meeting.

365. Three days in advance of the AdCom Meeting, on the morning of December 6, 2021, the FDA, per typical custom and practice, published to its website and made publicly available certain documents to be used during the AdCom Meeting, including an FDA-authored 96-page "briefing book" containing the FDA's assessments, evaluations, and recommendations/conclusions concerning the Bard NDA – the FDA Briefing Book – as well as an accompanying 46-page presentation – the FDA AdCom Slides, and together with the FDA Briefing Book, the "AdCom Advance Materials."

366. The AdCom Advance Materials published on December 6, 2021 provided the initial correction of Defendants' Class Period misstatements, and the AdCom Meeting itself, which occurred two days later on December 8, 2021, provided further correction.

a. The December 6, 2021 AdCom Advance Materials Correct Defendants' Class Period Misstatements and Indicate Likely FDA Rejection of the Bard NDA

367. The FDA Briefing Book, noting that the Bard NDA was supported by CARDINAL and that CARDINAL had met its prespecified primary and key secondary endpoints (respectively, on-treatment and retained eGFR), nevertheless concluded that CARDINAL failed to "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." *See* FDA Briefing Book at 11, 37.

368. As the FDA Briefing Book made clear, the FDA found CARDINAL's efficacy failures to stem from an inadequate study design – specifically, the four-week washout period for measurement of retained eGFR, when FDA analysis indicated that washout required a period approximately twice as long: 60 days or eight weeks. *See* FDA Briefing Book at 8-11, 18-20, 22-23, 35-37, 44-61. CARDINAL's inadequate washout period: (i) invalidated CARDINAL's retained eGFR data and findings; (ii) made it impossible to differentiate Bard's PD effects from its disease-modifying effects (if any); and (iii) thus provided no support for FDA approval of the Bard NDA. *Id.*

369. As the FDA Briefing Book explained:

> 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.
>
> The Applicant 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 from 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.
>
> ***
>
> The FDA developed a fit-for-purpose PK/PD model with the primary objective to address the adequacy of the 4-week washout period in CARDINAL Phase 3. . . .
>
> Based on the PK/PD model, it is predicted that at the Week 104 visit, 28% of the reversible PD effect on eGFR remains, and that the time to resolution of the reversible PD effect is 60 days (based on a PD half- life of 15 days, Table 20). This analysis suggests that the duration of the 4-week washout in CARDINAL Phase 3 is insufficient to resolve the reversible PD effect of bardoxolone.

***

> The design of CARDINAL Phase 3 with a 4-week washout does not allow for the evaluation of the potential of bardoxolone to slow disease progression. The eGFR values collected 4 weeks after treatment cessation at Week 52 or Week 104 still represent the reversible PD effect of bardoxolone based on the PK/PD model developed by the FDA and the exposure-response model developed by the Applicant, and neither model suggests that bardoxolone slows the progression of decline in kidney function.

FDA Briefing Book at 19-20, 22-23, 61-62.

370. Perhaps the only thing more surprising than the FDA Briefing Book's criticisms of CARDINAL's design, specifically with respect to the washout period, and consequently CARDINAL's evidentiary adequacy and/or validity, was that – as the FDA Briefing Book further revealed – **these criticisms should not have been a surprise at all**. In fact, as the FDA Briefing Book made clear, the FDA had long and repeatedly communicated to Reata these very criticisms (*i.e.*, concerning CARDINAL's design and specifically its four-week washout period):

> During the course of development, the FDA voiced concern about the design of CARDINAL Phase 3 and specifically the ability of the trial, as designed, to differentiate bardoxolone's pharmacodynamic effect on kidney function from its effect on disease progression. For further discussion of this issue and other concerns raised by the Agency, see Appendix 6.1.

***

> **6. APPENDICES**
>
> **6.1. Regulatory History**
>
> Discussions with the Applicant centered around the issues highlighted below. The Applicant declined an end-of-phase 2 meeting with the Agency; nevertheless, the Agency encouraged the Applicant to obtain Agency concurrence on the adequacy and acceptability of the study to support a marketing application.[2]
>
> • *Bardoxolone's pharmacodynamic effect on eGFR and assessing for effects on disease progression*: At a pre[-]IND 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.

[2] FDA provided extensive written feedback on the Applicant's phase 2/3 trial of bardoxolone in patients with Alport Syndrome in December 2016. In September 2018, FDA encouraged the Applicant to request an end-of-phase 2 meeting to discuss the development program and ensure alignment. The Applicant declined, noting that they were running a phase 2/3 trial and were "not seeking input from the Division on the program at this time." In follow-up correspondence sent in February 2019, the Division emphasized the importance of obtaining FDA concurrence that a study intended to support a marketing application was adequate and acceptable for this purpose. The FDA also encouraged the Applicant to submit a written response to the comments in the FDA's December 2016 advice letter and reiterated its offer to meet with the Applicant to discuss the development program and a path forward.

FDA Briefing Book at 10-11, 39.

371. The FDA Briefing Book, as summarized above, thus provided corrective disclosure with respect to:

A. the FDA Guidance Representations, by revealing that the FDA, far from being in accord with or having "guided" CARDINAL's design, had, in fact, from December 2016 onwards, expressed repeated concerns with CARDINAL's design, and specifically with CARDINAL's four-week washout period;

B. the 10-14 Day Washout Representations, by revealing that Bard's PD effects required an eight-week washout period in CARDINAL;

C. the CARDINAL Design Representations, by revealing that CARDINAL had not measured retained eGFR;

D. the CARDINAL Retained eGFR Representations, by revealing that CARDINAL's retained eGFR data/results were not truly retained eGFR at all, but instead, by virtue of CARDINAL's inadequate four-week washout period, were substantially contaminated by the very matter they were supposed to exclude – Bard's PD effects, and thus provided no support for FDA approval;

E. the Prior Study Retained eGFR Representations, for identical reasons to the CARDINAL Retained eGFR Representations, given the similar four-week washout periods utilized in those prior studies;

F. the Reata Defendants' August 10, 2020 statements, by accurately revealing the issues discussed in the January 2020 FDA Meeting, which the Reata Defendants' August 10, 2020 statements materially mischaracterized;

G. the Bard NDA Representations, which had omitted all the foregoing material adverse facts concerning, *inter alia*: the FDA's repeated warnings to Reata that concurrence and/or alignment with respect to CARDINAL's design had not been obtained; the FDA's repeated warnings to Reata that CARDINAL's four-week washout period was inadequate and that determination of an adequate washout period was necessary; the resulting invalidity of CARDINAL and prior study (BEAM/BEACON) retained eGFR data; and the January 2020 FDA Meeting at which all the above issues were raised.

372. For these reasons, Reata's share price immediately plummeted following

publication of the FDA Briefing Book on the morning of Monday, December 6, 2021. After having last closed trading on Friday, December 3, 2021 at $78.69 per share, Reata shares fell sharply on December 6, 2021 to close at $48.92 per share – a one-day decline of $29.77 per share (37.8%). December 6, 2021's trading volume of 5.5 million shares – more than 19 times Reata's average daily trading volume during the Class Period (285,461 shares per day) – marked it as the second most active trading day in Reata's existence, and was exceeded just once, three days later, by trading on December 9, 2021 following the AdCom Meeting.

b. The December 8, 2021 AdCom Meeting Further Confirms the CARDINAL and Bard NDA Deficiencies Identified on December 6, 2021, and AdCom's Unanimous Vote Against Bard NDA Approval Indicates All but Certain FDA Rejection

373. Although the CARDINAL and Bard NDA deficiencies identified in the December 6, 2021 FDA Briefing Book were devastating, AdCom's expert and independent stance on those deficiencies was, until the actual December 8, 2021 AdCom Meeting, still unknown. As analysts noted, the AdCom members could conceivably dispute, discredit, and/or look past the FDA Briefing Book's critiques and recommend approval of the Bard NDA. For example, in their December 6, 2021 report on Reata titled "Correction: Bard' Adcom Briefing Docs Leave a Sour Taste Re FDA Interactions, but May Still Result in Approvability," Cantor analysts Charles Duncan and Peter Stavropoulos concluded that while the FDA Briefing Book indicated that FDA approval would likely be "an uphill battle," FDA "rejection of bard' [wa]s not yet set in stone" and they "continue[d] to believe there is a realistic possibility bard' will be approved for [Alport]."[18]

[18] Charles C. Duncan, Ph.D. & Pete Stavropoulos, Ph.D., *Correction: Bard' Adcom Briefing Docs Leave a Sour Taste Re FDA Interactions, but May Still Result in Approvability*, CANTOR FITZGERALD & CO., 1-2 (Dec. 6, 2021).

374. The December 8, 2021 AdCom Meeting demonstrated conclusively that the independent and expert AdCom members agreed with the FDA critiques expressed two days earlier in the December 6, 2021 FDA Briefing Book.[19] For example, during the final stage of the AdCom Meeting in which AdCom members stated their views and votes, AdCom member Dr. Paul Palevsky expressed "concerns about . . . aspects of the design [of CARDINAL], and in particular, the fact that it was only a 4-week washout period," and premised his vote to recommend against Bard approval on that issue ("I voted no. . . . [W]e need to have data with a larger time off of treatment to be able to see the sustained effect of the medication after the acute pharmacodynamic effect has worn off."). *See* AdCom Meeting transcript at 278, 321. AdCom member Dr. Thomas Cook identified the same issue as his "biggest" concern, suggesting that Reata should have measured off-treatment eGFR "at several time points during their post-treatment period . . . because then we could get a much better sense of when the pharmacodynamic effect goes away . . . because given what we've seen and from the FDA, it's not clear to me that they ever actually reached that point, and I think that's a pretty crucial analysis that we would need to see to really definitively nail this things down." *Id*. at 285. Similarly, AdCom member Dr. Susan Mendley found "the concerns about the adequacy of the washout phase at 28 days truly compelling, considering the gene expression augmentation that's postulated." *Id*. at 295. At the close of the AdCom Meeting, AdCom members voted unanimously that the evidence proffered in support of the Bard NDA (*i.e*., the CARDINAL results) did **not** demonstrate that Bard was effective in

[19] The FDA's Center for Drug Evaluation and Research provided a live webcast of the AdCom Meeting, enabling the public to listen in, in real time, to the entire meeting. After the AdCom Meeting concluded, the FDA prepared and made publicly available thereafter: (i) an audio recording of the AdCom Meeting, accompanied by the slides used by each presenter; and (ii) a transcript of the AdCom Meeting. The meeting recording can be viewed at: https://collaboration.fda.gov/p9hmmfaqmy3l/. The transcript is available from the FDA's website at: https://www.fda.gov/media/155463/download (hereinafter, the "AdCom Meeting transcript").

slowing the progression of Alport and, relatedly, did not demonstrate that Bard's benefits outweighed its risks. *See* AdCom Meeting Transcript at 319-32.

375. Following the December 8, 2021 AdCom Meeting, Reata shares, which had last closed trading on December 7, 2021 at $54.42 per share (and which did not trade on December 8, 2021),[20] fell sharply on December 9, 2021 to close at $29.11 per share – a one-day decline of $25.31 per share, or 46.5% of Reata's remaining value. Trading volume was extreme: more than 9.8 million Reata shares traded hands, more than on any other day in Reata's existence, and 34 times Reata's average daily trading volume during the Class Period.

4. Following and Consistent with the December 6-8, 2021 AdCom Disclosures, the FDA Formally Rejects Reata's Bard NDA on or About February 25, 2022

376. After the close of trading on February 25, 2022, Reata issued a press release titled "Reata Pharmaceuticals Receives Complete Response Letter from The FDA for Bardoxolone for the Treatment of Patients with Chronic Kidney Disease Caused by Alport Syndrome," disclosing that the FDA had issued a CRL rejecting Reata's Bard NDA "in its present form" based on the concerns expressed in the FDA Briefing Book and in the AdCom Meeting:

> [T]he FDA concluded that it does not believe the submitted data demonstrates that bardoxolone is effective in slowing the loss of kidney function in patients with Alport syndrome and reducing the risk of progression to kidney failure and has requested additional data to support the efficacy and safety of bardoxolone. Their conclusion was based on efficacy and safety concerns primarily set forth in the FDA's briefing book and discussed at the Cardiovascular and Renal Drugs Advisory Committee meeting held on December 8, 2021.
>
> The FDA stated that the issues could be resolved by providing evidence of effectiveness that includes evidence from an adequate and well-controlled study showing a clinically relevant effect on the rate of loss of kidney function in patients with Alport syndrome or, alternatively, an effect on a clinical outcome (*i.e.*, an endpoint that captures how patients with Alport syndrome feel, function, or

[20] In recognition of the AdCom Meeting's materiality to Reata, Nasdaq halted trading of Reata's shares for the entire day of December 8, 2021.

> survive). In addition, the FDA stated that we would need to address whether bardoxolone has a clinically relevant effect on the QT interval and show that the demonstrated clinical benefits of bardoxolone outweigh its risks.

377. Defendant Huff, quoted in the February 25, 2022 press release, termed the FDA's decision a "significant disappointment for our company . . . ."[21]

C. Additional Allegations Regarding the Individual Defendants' Scienter

378. 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.

[21] The FDA's formal rejection of the Bard NDA had been a foregone conclusion after the December 8, 2021 AdCom Meeting, and had already been incorporated by the market in Reata's share price immediately after the AdCom Meeting. Reata's share price increase following the February 25, 2022 press release (on February 28, 2022, when Reata shares rose $6.61 per share from their prior closing price of $26.13 per share to close at $32.74 per share) was: (i) therefore entirely unrelated to the FDA's rejection of the Bard NDA; and (ii) instead, a reflection of contrasting, positive FDA developments concerning an NDA for Reata's other major product, Omav, which Reata disclosed on the morning of February 28, 2022 in its 2021 results announcements.

1. The FDA Briefing Book, Which Describes What the FDA Told Reata and When, Supports Scienter

379. The FDA Briefing Book revealed that the FDA had repeatedly warned Reata, in December 2016, September 2018, February 2019, and January and September 2020, that Reata had **not** obtained FDA concurrence on the adequacy and acceptability of CARDINAL. *See* Sections IV.G.1 and V.B.3.a, *supra*.

380. One of the FDA's primary concerns with CARDINAL was its inadequate four-week washout period, upon which the accuracy and validity of CARDINAL's key secondary endpoint – retained eGFR – was based. The FDA Briefing Book makes clear that the FDA communicated this particular concern to Reata no later than January 2020. *See* FDA Briefing Book at 39 ("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 . . . .").

381. This, together with the additional facts pled below, most particularly in Sections V.C.6-7, *infra* (Defendants Huff's and Meyer's dramatic change in tone immediately after the January 2020 FDA meeting; and the erasure of retained eGFR terminology from SEC filings following the January 2020 FDA Meeting), gives rise to an **effectively airtight inference of scienter** from January 2020 onwards.

382. Additionally, the most plausible inference from the FDA's disclosures in the FDA Briefing Book is that the FDA communicated its concerns to Reata over CARDINAL's washout period, and the validity of retained eGFR data predicated on that washout period, **before the January 2020 FDA Meeting: in February 2019 or December 2016**.

383. The FDA Briefing Book informed that the FDA "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)." FDA Briefing Book at 39. While the FDA's terminology ("ultimately") creates some uncertainty as to when exactly the FDA made these investigations to Reata, simple logic dispels some of this uncertainty and yields further clarity as to the timing of these recommendations. Specifically, given that the FDA's recommendation was to "modify" CARDINAL Phase 3 to provide for additional eGFR measurements more than four weeks after cessation of Bard treatment, such modification was only possible **before the time when the recommended additional measurements would have taken place** – *i.e.*, prior to CARDINAL Phase 3 patients reaching one year of Bard treatment. According to Reata's own disclosures, it had begun enrolling Phase 3 patients in August 2017, had completed Phase 3 enrollment in the second half of 2018, and therefore expected to and did report one-year results in the second half of 2019. *See* ¶¶ 191 and 238, *supra*. Therefore, **modification of CARDINAL to accord with the FDA's suggestions was only possible prior to the second half of 2019** – *i.e.*, prior to July 2019 – when most CARDINAL Phase 3 patients began to complete or near their completion of one year of Bard treatment. This indicates that the FDA must have communicated specific concerns to Reata regarding the adequacy of CARDINAL's washout period in at least one of the FDA's February 2019, September 2018, or December 2016 communications to Reata.

384. Therefore, the most plausible inference to be drawn from the FDA Briefing Book's information as to the timeline of FDA communications with Reata is that the FDA communicated specific concerns to Reata concerning the adequacy of CARDINAL's four-week washout period,

and the retained eGFR data predicated on it, no later than February 2019.

2. Bard was Reata's Lead Product, Greatest Source of Value, and a "Core Operation"

385. At all relevant times, Bard was a "core operation" for Reata. Consequently, knowledge of the fraud may be imputed to the Individual Defendants.

386. At all relevant times, and in all its Class Period Form 10-Q and 10-K filings, Reata described itself as having two lead product candidates: Bard and Omav. *See, e.g.*, 2016 10-K at 3; 2017 10-K at 3; 2018 10-K at 5; 2019 10-K at 5; 2020 10-K at 3, 7.

387. More particularly, Bard was, at all relevant times, Reata's single most important product candidate.

A. This is evident facially in Reata's SEC filings, which (i) ordered their discussions of Reata's drug development programs in descending order of importance, and (ii) uniformly described Bard developments first and Omav second. *See, e.g.*, 2016 10-K at 3-24; 2017 10-K at 3-19; 2018 10-K at 5-25; 2019 10-K at 5-23; 2020 10-K at 7-34.

B. This is evident substantively, as Bard was both (i) being developed for more indications than Omav (*i.e.*, not just Alport, but also multiple other CKD etiologies with aggregate patient populations approximately 10-20 times that of Alport alone), and (ii) farther along in development and closer to commercial introduction.

C. This is evident practically, as, at all times, analysts ascribed the largest part of their valuations of Reata to Bard.

388. Because no Reata products were approved for sale during the Class Period, the centrality of Bard to Reata cannot be traced via comparative product revenues. However, and as mentioned above, examination of Reata's R&D expenses provides alternative indication of Bard's relative importance. During the Class Period, Bard was Reata's single-largest R&D expenditure,

accounting for 37% of total R&D expenses and outweighing Omav (which accounted for 15%).

389. For and/or consistent with the above reasons, Reata's Class Period SEC filings themselves asserted and warned that Reata was "substantially dependent on . . . our lead product candidates" Bard and Omav. *See, e.g.*, 2016 10-K at 46; 2017 10-K at 39; 2018 10-K at 52; 2019 10-K at 51; 2020 10-K at 3, 63.

3. Reata's Small Size Supports the "Core Operations" Inference

390. Reata was, at all relevant times, a very small company, with less than 100 employees until 2018 and less than 300 employees at all times until 2021:

Reata Full-Time Employees (year-end)

	R&D	Other*	Total
2016	49	26	75
2017	62	31	93
2018	80	43	123
2019	145	75	220
2020	187	74	261
2021	241	105	346

* Other includes business development, finance, information technology, human resources, administrative, legal, and facilities functions.

See 2016 10-K at 41; 2017 10-K at 34; 2018 10-K at 46; 2019 10-K at 44; 2020 10-K at 56; 2021 10-K at 53.

391. Reata's very small size intensifies the logic and functioning of the "core operations" inference. The larger the organization, the less likely and/or possible it is for individual executives to have detailed knowledge into every corner of consolidated operations. Conversely, the smaller the company, the more likely and/or possible it is for individual executives to have full information concerning all company operations.

4. Reata's Exclusive Rights to Bard, and Defendants Huff's and Meyer's Long Tenures at Reata, Provided Them with Better Information on Bard than Anyone Else

392. In 2004, shortly after Reata's 2003 founding, Reata obtained "exclusive" worldwide rights to manufacture, use, and sell Bard. *See, e.g.*, 2021 10-K at 51-52. In 2009, Reata agreed to a strategic collaboration with Kyowa Kirin, in which Kyowa Kirin was granted a sub-license to develop and commercialize Bard in Asia.

393. Reata's exclusive rights with respect to Bard, since 2004, indicate that Reata is more familiar with Bard than any other person or organization. For nearly the past 20 years, Reata has effectively controlled the ability to study, develop, and commercialize Bard. Reata-employed scientists have conducted dozens of studies of Bard and published dozens of scientific reports on it. Consequently, no one has more or better data on Bard than Reata. Reata's unparalleled knowledge concerning Bard further supports scienter.

394. Furthermore, Defendants Huff and Meyer have been with Reata since its inception. Defendant Huff is Reata's founder and has been its sole CEO and Chairman from 2002 onwards. Defendant Meyer was one of Reata's first employees: after joining Reata in 2003, he became the Vice President of Product Development from 2007 to 2013, Chief Medical Officer between 2013 and July 2020, Chief R&D Officer between July 2020 and January 2022, and Chief Innovation Officer from February 2022 onwards.

395. Defendants Huff and Meyer have worked at Reata for the entire time that Reata had exclusive Bard rights (acquired in 2004). During that time, Defendant Huff has been Reata's top officer and Chairman, while Defendant Meyer, for nearly all of that time, has been one of Reata's top medical and/or development executives. Their long tenures and particular roles at Reata, during the entire time that Reata has owned exclusive rights to Bard, indicate that Defendants Huff and Meyer have extensive, long-standing familiarity with and knowledge of Bard – and arguably, more

extensive knowledge and familiarity than any other persons.

5. Defendants Huff's and Meyer's Evident Mastery of Bard Details and FDA Interactions, in Class Period Conference Calls, Further Indicates Their Scienter

396. During Class Period conference calls, Defendants Huff and Meyer frequently chose to, and/or were asked to, speak about Bard. Their performances during these calls confirm in practice what their tenures and positions indicated in theory: fluent mastery with respect to all Bard details.

397. During all Class Period conference calls, Defendant Meyer was tasked with the most technical and detailed work: presenting the results of different Bard studies, such as CARDINAL; and answering analyst questions indicating that he was fully conversant with Bard's safety, efficacy, and mechanism of action, etc. Defendant Meyer frequently presented on these matters at length and in breadth. *See e.g.*, ¶ 213 (CARDINAL Phase 2 Results Conference Call); ¶ 213 (Q3 2018 Conference Call); ¶ 296 (Q3 2020 Conference Call); ¶ 311 (Q4 2020 Conference Call).

398. With Defendant Meyer functioning as the medical/data expert during Reata's conference calls, Defendant Huff was free to assume a "big picture" role and focus on wider strategic framing and perspective. Yet Defendant Huff demonstrated broad and deep fluency with respect to Bard, often choosing to answer analyst questions that required a detailed understanding of Bard and Bard data, and often supplemented Defendant Meyer's answers to make additional, more detailed/technical points during the Q&A portion of the calls. *See e.g.*, ¶ 292 (Q3 2020 Conference Call), ¶ 335 (Q1 2021 Conference Call).

399. Likewise, Defendants Huff and Meyer often spoke during the same conference calls about Reata's interactions with the FDA. Their accounts appear to be first-hand: *i.e.*, accounts of interactions in which they directly participated.

400. In sum, the performance of Defendants Huff and Meyer during Reata's Class Period conference calls demonstrates broad and deep mastery of information with respect to Bard and the FDA, which further supports their scienter.

6. Defendants Huff's and Meyer's Dramatic Change in Tone Immediately Following the January 2020 FDA Meeting Confirms Their Scienter

401. Defendants Huff and Meyer, in Reata's two quarterly conference calls immediately following the January 2020 FDA Meeting (*i.e.*, the Q4 2019 Conference Call on February 19, 2020, and the Q1 2020 Conference Call on May 11, 2020), exhibited a then-inexplicable, dramatic change in disclosure content and tone by suddenly refusing to provide any commentary on, or answer any analyst questions concerning, Reata's interactions with the FDA.

402. For example, at the outset of the Q4 2019 Conference Call, Defendant Huff warned that he and other Reata executives would refuse to make any comments, in their introductory remarks and in the ensuing Q&A, concerning Reata's interactions with the FDA:

> Warren Huff . . .
>
> The lead indication in our CKD franchise is Alport syndrome, which is a rare, hereditary and severe form of CKD affecting approximately 30,000 to 60,000 patients in the United States. The ongoing Phase 3 portion of CARDINAL is the largest global interventional study ever conducted in Alport syndrome. Secondary endpoint for CARDINAL is the off treatment analysis at week 52 and in this analysis, patients treated with bardoxolone demonstrated a statistically significant placebo-corrected 5.14 milliliter per minute improvement compared to placebo with a p-value of 0.0012.
>
> Based on these positive results and of course, subject to discussions with regulatory authorities, we plan to proceed with the submission of regulatory filings this year for marketing approval in the United States. We will not be commenting in the call or Q&A on our ongoing interactions with the regulatory agencies.

Q4 2019 Conference Call, Bloomberg transcript at 3.

403. During the Q&A portion of the Q4 2019 Conference Call, Defendants Huff and Meyer repeatedly asserted their new refusal to comment on Reata's interactions with the FDA (or

ongoing Bard trials such as CARDINAL):

> Q - Maury Raycroft [Jefferies analyst]
>
> Hi everyone. Thanks for taking my questions. So, I guess you can comment on ongoing interactions with the regulatory agencies, but can you comment on timing for when you could file for bard and omav. And then whether you'll provide an update to the street post pre-NDA meetings?
>
> A - Colin Meyer
>
> Sure, Maury. So as Warren noted in his prepared remarks, we're planning to file the NDAs in U.S. for bardoxolone in Alport syndrome and omav in FA this year. We will not comment on ongoing the regulatory interactions other than that.
>
> Q - Maury Raycroft
>
> Okay. And then also, as you approach to the filing for bardoxolone in Alport syndrome, do you have a better sense of how much two-year data or how many patients you will have two-year data on for when you file?
>
> A - Colin Meyer
>
> We're not going to comment on the two-year data.

Q4 2019 Conference Call, Bloomberg transcript at 7.

404. Similarly, during the Q1 2020 Conference Call, Defendant Huff began with a warning that no commentary would be made on such matters:

> J. Warren Huff . . .
>
> Regarding our regulatory paths for bardoxolone and omav, our policy is to comment only when we have a major event to announce and so as in our earlier calls, we will not be answering questions regarding regulatory activities on this call. Having said that, I will take this opportunity to reiterate that our plan is to file NDAs for each of bardoxolone and omav this year of course subject to ongoing discussions with the FDA.

Q1 2020 Conference Call, Bloomberg transcript at 3.

405. During the Q&A portion of the Q1 2020 Conference Call, Defendant Meyer likewise asserted the new refusal to comment on Reata's interactions with the FDA:

> Q - Maurice Thomas Raycroft [Jefferies analyst]

> Hi, everyone. Thanks for taking my questions. I think in the prepared remarks, you said 75% have completed the Phase 3 Alport study. Just wondering if you can speak to the merits of potentially waiting to hit stats a difference on two-year data and filing to get full approval and if this could be one reason why you're waiting to file for approval in Alport syndrome?
>
> A - Colin John Meyer
>
> Yeah. So first of all, we're not going to comment beyond what we have about the regulatory status and as Warren said we're planning to file the NDA for Alport syndrome this year. I think secondly, to clarify, about half of patients have completed their full two-year treatment duration of treatment period in CARDINAL.

Q1 2020 Conference Call, Bloomberg transcript at 10.

406. With the benefit of the "Regulatory History" disclosures contained in the FDA Briefing Book published on December 6, 2021, the explanation for Defendants' sudden and dramatic shift in disclosure content and tone is now clear. The FDA met with Reata in January 2020 "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." FDA Briefing Book at 39. Accelerated approval was Reata's preference and first choice (*see* ¶ 279, *supra*), but at the January 2020 meeting, the FDA "did not agree with the proposed approach . . . ." FDA Briefing Book at 39. As the FDA Briefing Book makes clear, the FDA's disagreement was not rooted in matters of procedure or timing (as the Reata Defendants would later represent in their August 10, 2020 disclosures), but in the FDA's fundamental and substantive doubts that Reata's retained eGFR results from CARDINAL actually constituted retained eGFR at all. *Id*. As the FDA explained on December 6, 2021, at the January 2020 FDA Meeting, the FDA had "voic[ed] concerns about the interpretability of the eGFR findings given the available information on the time course for resolution of bardoxolone's pharmacodynamic effect . . . ." *Id*.

407. Defendant Huff's and Meyer's newfound refusal to speak about FDA-related matters in the Q4 2019 Conference Call – the **first** conference call postdating the January 2020

FDA Meeting – and in the Q1 2020 Conference Call indicates their awareness of how troubling the matters raised by the FDA in the January 2020 FDA Meeting were. After years of telling investors that they had designed the protocol with the FDA's guidance while failing to meet with the FDA to obtain its advice and concurrence and rejecting the FDA's warnings, the Defendants now fully understood CARDINAL's washout period would likely not be accepted, crystalizing the threat to Bard's approval.

408. Defendants Huff's and Meyer's contemporaneous representations in February and May 2020 that their newfound refusals to disclose were rooted in purportedly long-standing Company policies (namely, to provide disclosure only for major FDA interactions) are not credible. First, such policies had never been cited or evident before and to the extent they ever existed, had been more honored in their breach than in their observance. Second, the real issue was not that there was no major FDA interaction to disclose – to the contrary, the January 2020 FDA Meeting was just such a major event – but, rather, that the Reata Defendants wished to avoid disclosing that interaction and the issues it raised.

7. Defendants' Erasure of the Retained eGFR Term from SEC Filings Following the January 2020 FDA Meeting Further Indicates Scienter

409. Relatedly, and also shortly after the January 2020 FDA Meeting, Reata changed the terminology used in its SEC filings by eliminating references to or discussions of retained eGFR. *See* ¶¶ 285-86, *supra*. What previously had been referred to as "retained eGFR" was renamed, beginning in the Q2 2020 10-Q, as the "eGFR benefit during the off-treatment period." *Id*.

410. The nature and timing of this change further support an inference of scienter.

411. "Retained eGFR" communicates a more powerful claim than "eGFR benefit during the off-treatment period." The "retained" part of retained eGFR implies an adequate washout, **after which the eGFR is retained**. The new terminology, more anodyne, does not contain a similar

implication of eGFR **retained after washout** but instead merely describes an eGFR level measured at some, or any, time after cessation of treatment.

412. This disclosure change was so slight that there was no contemporaneous public notice of it. Even if it were a slightly less misleading disclosure than prior references to retained eGFR, it was not in any sense a corrective disclosure.

413. In the scienter context, the disclosure change is most important for the manner in which it further indicates Defendants' state of mind: their awareness, following the January 2020 FDA Meeting, that CARDINAL's retained eGFR results might not be retained eGFR at all.

8. Reata's Four Class Period Secondary Stock Offerings Provided Defendants with Motive and Opportunity

414. As Reata had no approved products throughout the Class Period, it could not fund itself through product sales and instead required capital markets funding to continue operating.

415. Reata secured such funding in spades – through four secondary stock offerings that provided Reata with aggregate net proceeds exceeding **$1.1 billion**, as summarized below:

Reata's Class Period Secondary Stock Offerings

Offering Date	Shares Sold	Share Price	Net Proceeds to Reata	Connection to CARDINAL Disclosures
July 26, 2017	3,737,500	$31.00	$108,900,000	2 days after the July 24, 2017 disclosure of positive CARDINAL Phase 2 eGFR results, occasioning a 14.1% share price rise on July 24, 2017
July 25, 2018	3,450,000	$72.00	$233,500,000	2 days after the July 23, 2018 disclosure of positive CARDINAL Phase 2 one-year retained eGFR results, occasioning a 65% share price rise on July 23, 2018 from $46.40 to $76.55

November 14, 2019	2,760,000	$183.00	$491,900,000	2 days after the November 11-12, 2019 disclosure of positive CARDINAL Phase 3 one-year retained eGFR results
December 1, 2020	2,000,000	$140.85	$277,800,000	3 weeks after the November 9, 2020 disclosure of positive CARDINAL Phase 3 year-two retained eGFR results, occasioning a 32.4% share price rise on November 9, 2020 from $131.89 to $174.66
Total	11,947,500		$1,112,100,000	

416. Reata's reliance on capital markets for funding, and the four above-identified Class Period secondary stock offerings through which Defendants secured such funding, provided Defendants with both motive and opportunity for the here-alleged misconduct.

417. Moreover, as the above table further indicates, Defendants themselves tied each of the four Class Period secondary stock offerings to their CARDINAL-related disclosures by launching each of the four offerings shortly – and most often, immediately – after announcing positive CARDINAL results. The positive CARDINAL results disclosures that preceded the secondary stock offerings generated material – and in two of the four instances, eye-popping – increases in Reata's share price, thereby allowing Defendants to materially increase the prices at which they sold Reata's shares in the offerings and Reata's net proceeds therefrom.

418. Defendants thus not only had motive and opportunity to inflate offering proceeds through CARDINAL-related misstatements, but, as the above table illustrates, made it their standard operating procedure.

9. Insider Selling Provided Defendants Huff and Meyer, and other Reata Officers, with Motive and Opportunity

419. During the Class Period, Defendants Huff and Meyer, together with further below-identified Reata officers, sold substantial amounts of the Reata shares they held (the "Insider

Sales"). The nature and timing of the Insider Sales further support *scienter*.

420. During the Class Period, Defendant Meyer sold 110,000 Reata shares, for total proceeds of $17,169,054, as summarized in the table below.

Defendant Meyer's Class Period Insider Sales

Transaction Date(s)	Transaction Type	Shares Traded	Average Price	Sale Proceeds
6/14-15/2021	sale	60,000	$142.58	$8,554,906
11/16-17/2020	sale	25,000	$169.57	$4,239,148
11/9/20	sale	25,000	$175.00	$4,375,000
Total		110,000		$17,169,054

421. Defendant Meyer's Insider Sales were suspicious in timing and amount.

422. With respect to timing, Defendant Meyer had never previously sold any Reata shares: neither at any prior time during the Class Period, nor indeed at any time at all during Reata's entire existence as a publicly traded company. Yet, shortly after the above-detailed January 2020 FDA Meeting and the September 2020 FDA meetings, at which the FDA reiterated its long-standing and previously-stated concerns with CARDINAL's washout period, and hence with the validity of CARDINAL's results, and **immediately** after the Reata Defendants' misleading November 9, 2020 disclosures of CARDINAL phase 3 year-two results, which caused Reata's share price to appreciate 32.4%, from $131.89 to $174.66 on that day, Defendant Meyer turned into a significant seller of Reata stock. All of Defendant Meyer's Insider Sales occurred during the approximate nine-month window between (i) the Reata Defendants' November 9, 2020 disclosures, and (ii) the Reata Defendants' partial corrective disclosures of August 9, 2021, during which time Reata shares traded at inflated prices that neared their Class Period highs. Defendant Meyer's Insider Sales benefitted from share price levels ($140.00 to $175.00) that approximately **quintupled** Reata's share price after the AdCom Meeting corrective disclosures of December 6-

8, 2021 (*i.e.*, Reata's $29.11 per share closing price on December 9, 2021).

423. With respect to amount, Defendant Meyer's Insider Sales – 110,000 shares sold between November 9, 2020 and June 15, 2021 – constituted a substantial portion of Defendant Meyer's total Reata holdings. As of April 16, 2020, Defendant Meyer reported beneficial ownership of 433,712 Reata shares (an amount including shares actually held and shares issuable pursuant to exercisable options or warrants). The 110,000 shares Defendant Meyer thereafter sold constituted 25.4% of his total Reata holdings.

424. Lastly, although Defendant Meyer's first Class Period sale (25,000 shares at $175.00 on November 9, 2020) was purportedly made under a 10b5-1 trading plan that Defendant Meyer had purportedly adopted on November 19, 2019, there is no indication that any such plan was operative. For example, although the 10b5-1 trading plan was purportedly adopted on November 19, 2019, there were no transactions made under that plan until nearly one year later – Defendant Meyer's November 9, 2020 sale. Moreover, the **only** transaction ever made pursuant to that purported plan was Defendant Meyer's November 9, 2020 sale. Defendant Meyer's November 9, 2020 sale therefore does not appear to be part of a series of pre-planned transactions, but rather appears to coincide with and constitute part of Defendant Meyer's elective, concentrated, and suspiciously timed Insider Sales.

425. Similarly, Defendant Huff sold 81,657 Reata shares during the Class Period, for total proceeds of approximately $14,290,976, as summarized in the table below:

Defendant Huff's Class Period Insider Sales

Transaction Date(s)	Transaction Type	Shares Traded	Average Price	Sale Proceeds
11/10/2020	sale	64,970	$175.00	$11,369,750
11/9/2020	sale	16,687	$175.06	$2,921,226
Total		81,657		$14,290,976

426. Defendant Huff's Insider Sales exhibited suspicious timing identical to Defendant Meyer's. Just as with Defendant Meyer, Defendant Huff, prior to November 9, 2020, had not sold any Reata shares during the Class Period or during Reata's entire existence as a publicly traded company. Yet, shortly after Reata's meetings with the FDA in January and September 2020, and immediately after the Reata Defendants' November 9, 2020 disclosures, Defendant Huff, like Defendant Meyer, turned into a substantial seller of Reata stock. Just as with Defendant Meyer, Defendant Huff's Insider Sales occurred when Reata shares traded near their highest-ever prices, and prior to corrective disclosures in August and December 2021 that left Reata shares at prices less than one-fifth of the prices Defendant Huff realized in his Insider Sales. Additionally, and just as with Defendant Meyer, although Defendant Huff's November 9-10, 2020 Insider Sales were purportedly made pursuant to a 10b5-1 trading plan purportedly adopted one year earlier, on November 19, 2019, the **only** transaction ever made pursuant to that purported plan was Defendant Huff's November 9-10, 2020 sales. Those sales thus do not appear to be part of a series of pre-planned transactions, but rather appear to be one-off, elective, and suspiciously timed Insider Sales.

427. Other Reata officers also became sizable sellers of Reata shares at the same suspicious time and in the same suspicious manner as Defendants Meyer and Huff. For example, on November 9, 2020, Reata's Chief Commercial Officer, Bir Dawn Carter, sold 60,000 Reata shares (25.2% of her total Reata holdings reported as of April 16, 2020) at an average price of $162.51, for total proceeds of $9,750,300. Similarly, on November 11, 2020, Reata's Chief Legal Officer, Michael Wortley, sold 51,429 Reata shares (32.4% of his total Reata holdings reported as of April 16, 2020) at an average price of $179.37 per share, for total proceeds of $9,224,669.

D. Additional Allegations Regarding Loss Causation

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

429. Defendants' misstatements concerning Bard, CARDINAL, and the FDA were material. As each of Reata's Class Period Forms 10-K explained: (i) Reata and its "near-term prospects" were "substantially dependent" on its two "lead product candidates," Bard and Omav; and (ii) consequently, Reata's share price could be expected to move materially "in response to," *inter alia*, the "results of clinical trials of our product candidates, including [Bard] and [Omav]," and "the timing of the release of results of and regulatory updates regarding our clinical trials[.]" *See* 2016 10-K at 46, 69; 2017 10-K at 39, 62; 2018 10-K at 52, 82; 2019 10-K at 51,82; 2020 10-K at 63, 94; 2021 10-K at 61, 92.

430. And in fact, Reata's share price **did move** in response to such disclosures, providing a concrete, real-world demonstration of the materiality, particularly of disclosures concerning Bard as a treatment for Alport (including disclosures concerning CARDINAL's purported FDA guidance, design, and results, and the Bard NDA). When Defendants issued positive news on these matters, Reata's share price rose sharply and immediately, including: (i) the 14.1% share price increase on July 24, 2017 following the announcement of positive CARDINAL Phase 2 eGFR results; (ii) the 65% share price increase on July 23, 2018 (from $46.40 to $76.55) following the announcement of positive CARDINAL Phase 2 one-year retained eGFR results; and (iii) the 32.4% share price increase on November 9, 2020 (from $131.89 to $174.66) following the announcement of positive CARDINAL Phase 3 year-two retained eGFR results. Conversely, bad news on these matters – such as the August 10, 2020 and August 9, 2021 disclosures revealing the existence of previously-concealed risks, and the December 6-8, 2021 corrective disclosures – caused Reata's share price to plunge. *See* Section V.B.1-3, *supra*.

431. Additionally, Defendants' statements concerning the development of Bard as a treatment for Alport were material to the market, and caused significant movements in Reata's share price, because: (i) from late 2018 onwards, development of Bard for Alport had advanced further in the regulatory approval process than any other Reata development program, making Bard for Alport Reata's most immediate prospect; (ii) Defendants' representations indicated not only the specific evidence that the FDA needed for approval of Bard (namely, a retained eGFR benefit) but also that **CARDINAL appeared to generate that very evidence** (*i.e.*, the CARDINAL Retained eGFR Representations); and (iii) the FDA's "orphan drug" designation for Bard for Alport, which, in the event of Bard approval, would provide Reata with seven years of "market exclusivity" during which Bard would be the sole treatment for Alport, and which analysts estimated would allow Reata's annual revenues from Bard for Alport to exceed $1 billion per year.

432. During the Class Period, Lead Plaintiff and the Class purchased Reata securities at prices artificially inflated by Defendants' misstatements 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 or materialized, causing investors' losses.

433. Artificial inflation in Reata's stock price was removed when concealed risks materialized and/or the truth about the material misrepresentations and omissions was partially revealed to the public on August 10, 2020 and August 9, 2021, and entirely revealed on December 6 and 8, 2021. As more particularly described above (*see* Sections V.B.1-3, *supra*), these disclosures reduced the amount of inflation in the price of Reata's publicly traded securities, causing economic injury to Lead Plaintiff and other members of the Class.

E. Presumption of Reliance

1. General Allegations

434. The market for Reata securities was open, well developed, and efficient at all relevant times.

435. As a result of the materially false and/or misleading statements and/or failures to disclose, Reata securities traded at artificially inflated prices during the Class Period. Buoyed by the misstatements complained of, Reata's share price rose ten-fold during the Class Period, from approximately $20-$30 per share, where Reata shares traded from November 2016 through April 2018, to above $200 per share between November 2019 and February 2020, when Reata shares peaked at a Class Period high of $247.74 per share on February 4, 2020. Subsequent corrective disclosures thereafter – on August 10, 2020, August 9, 2021, and December 6 and 8, 2021 – caused Reata's share price to sink back below $30 per share and return to the levels at which Reata shares had traded prior to Defendants' Class Period misstatements and/or omissions.

436. Lead 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 securities and market information relating to Reata and have been damaged thereby.

437. 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 Lead 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, operations, and prospects. 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's shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Lead 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.

438. 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 were listed and actively traded on the NASDAQ, a highly efficient and automated market, with an average daily trading volume of 285,461 shares during the Class Period;

(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 including Citigroup, Barclays, Jefferies, Leerink, Stifel, Baird, Cantor, and LT&Co, 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.

439. 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.

440. 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.

2. Class Period Analyst Reports Reflected and Transmitted Defendants' Misstatements

441. Defendants' misstatements concerning the FDA, CARDINAL, Bard, and retained eGFR were considered and relied upon by securities analysts and featured in their Class Period published reports on Reata. After each of the Reata Defendants' quarterly results disclosures, and most of their *ad hoc* disclosures concerning CARDINAL or related matters, several analyst reports would immediately issue, reflecting Defendants' misstatements. Illustrative examples include: (i) the Leerink and Jefferies analyst reports following the July 23, 2018 statements (¶ 218, *supra*); (ii) the Leerink report following the November 11-12, 2019 statements (¶ 258, *supra*); (iii) the Leerink and Jefferies analyst reports following the August 10, 2020 statements (¶ 358, *supra*); (iv) the Leerink report following the November 9, 2020 statements (¶ 300, *supra*); and (v) the October 21, 2021 report following the Reata Defendants' accumulated misstatements and shortly preceding the AdCom Meeting (¶ 348, *supra*).

F. Inapplicability of the Statutory Safe Harbor and the Bespeaks Caution Doctrine

442. 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 that the forward-looking statement was authorized or approved by an executive officer of the Company who knew that the statement was false when made.

VI. CLASS ACTION ALLEGATIONS

443. Lead Plaintiff brings this action as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3) on behalf of the following Class: all persons and entities who purchased or otherwise acquired the publicly-traded common stock of Reata during the period between November 14, 2016 and December 8, 2021, inclusive (the "Class Period"), and were damaged thereby, including all persons or entities who purchased or otherwise acquired Reata common stock pursuant and/or traceable to Reata's 2019 Offering and/or December 2020 Offering during the Class Period, and were damaged thereby (the "Offerings Subclass"). Excluded from the Class are: (i) Defendants; (ii) members of the immediate family of any Defendant who is an individual; (iii) any person who

was an officer or director of Reata during the Class Period; (iv) any firm, trust, corporation, or other entity in which any Defendant has or had a controlling interest; and (v) the legal representatives, affiliates, heirs, successors-in-interest, or assigns of any such excluded person.

444. The members of the Class and the Offerings Subclass are so numerous that joinder of all members is impracticable. Throughout the Class Period, Reata's common shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Defendants issued and sold at least 10.65 million shares of Reata common stock during the Class Period via four secondary public stock offerings (including 4.76 million shares in the 2019 Offering and 2020 Offering), and millions of shares of Reata common stock were traded publicly during the Class Period on the NASDAQ. As of February 23, 2022, Reata had 31,484,670 shares of Class A common stock outstanding. 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.

445. Lead Plaintiff's claims are typical of the claims of the members of the Class and the Offerings Subclass, as all members of the Class and the Offerings Subclass sustained damages from Defendants' wrongful conduct alleged herein.

446. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class, including the Offerings Subclass, and has retained counsel competent and experienced in class and securities litigation.

447. 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, including in the 2019 Offering Documents and the 2020 Offering Documents, omitted and/or misrepresented material facts about the Company's business, operations, and prospects;

C. whether Defendants made false and/or misleading statements;

D. whether Defendants' statements omitted material facts necessary to make the statements made, in light of circumstances under which they were made, not misleading; and

E. to what extent the members of the Class, including the Offerings Subclass, have sustained damages and the proper measure of such damages.

448. 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.

VII. CLAIMS FOR RELIEF UNDER THE EXCHANGE ACT

FIRST CLAIM
Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder
Against Reata and the Officer Defendants

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

450. During the Class Period, Reata and the Officer 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 Lead Plaintiff and other Class members, as alleged herein; and (ii) cause Lead 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, Reata and the Officer Defendants took the actions set forth herein.

451. Reata and the Officer 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 promulgated thereunder. Reata and the Officer Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

452. Reata and the Officer 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.

453. Reata and the Officer Defendants: (i) employed devices, schemes, and artifices to defraud, while in possession of material adverse non-public information; (ii) engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Reata's value, 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 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 (iii) 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.

454. Each of the Officer Defendants' primary liability and controlling person liability arises from the following facts: (i) the Officer 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 the Officer 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 the Officer 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 the Officer 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.

455. Reata and the Officer 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 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 their overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Reata and the Officer 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.

456. 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 Reata and the Officer 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 Reata and the Officer Defendants, but not disclosed in public statements by them during the Class Period, Lead Plaintiff and the other members of the Class acquired Reata's securities during the Class Period at artificially high prices and were damaged thereby.

457. At the time of said misrepresentations and/or omissions, Lead Plaintiff and other members of the Class were ignorant of their falsity and believed them to be true. Had Lead 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 Reata and the Officer Defendants, Lead 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.

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

459. As a direct and proximate result of Reata and the Officer Defendants' wrongful

conduct, Lead 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 Officer Defendants

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

461. The Officer 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, the Officer 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 Lead Plaintiff contends are false and misleading. The Officer Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Lead 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.

462. In particular, the Officer 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.

463. As set forth above, Reata and the Officer 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, the Officer Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of the Officer Defendants' wrongful conduct, Lead Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

VIII. DEFENDANTS' VIOLATIONS OF THE SECURITIES ACT

464. Lead Plaintiff's claims under the Securities Act do not sound in fraud and Lead Plaintiff expressly disavows and disclaims any allegations of fraud, scheme, or intentional conduct as part of its claims under the Securities Act. Any allegations of fraud, fraudulent conduct, or motive are specifically disclaimed from the following allegations for the purpose of Lead Plaintiff's claims under the Securities Act, which do not have scienter, fraudulent intent, or motive as required elements. To the extent that these allegations incorporate factual allegations pled elsewhere in this Complaint, those allegations are incorporated only to the extent that such allegations do not allege fraud, scienter, or the intent of Defendants to defraud Lead Plaintiff or members of the Class.

465. As alleged below, Reata, together with the Officer, Director, and Underwriter Defendants, made materially untrue statements and omissions of material facts in:

A. the 2019 Offering Documents, in connection with the 2019 Offering of 2.76 million shares of Reata Class A common stock at $183.00 per share; and

B. the 2020 Offering Documents, in connection with the 2020 Offering of 2.0 million shares of Reata Class A common stock at $140.85 per share.

A. The 2019 Offering

466. On or about November 14, 2019, the below-specified Defendants registered, issued, and sold to Lead Plaintiff and other Class members 2.76 million Reata shares at $183.00 per share in a secondary public offering underwritten by Defendants Citigroup, Jefferies, Leerink, Stifel,

Baird, Cantor, and LT&Co. The 2019 Offering Underwriter Defendants received approximately $12.6 million in fees, paid by Reata from gross offering proceeds of $505.1 million, for their willingness and efforts to underwrite the 2019 Offering and market and sell the 2.76 million Reata shares offered therein. Net proceeds to Reata from the 2019 Offering were $491.9 million.

1. The 2019 Offering Documents

467. The 2019 Offering was made pursuant to: (i) an automatically effective "shelf" registration statement filed with the SEC on Form S-3 on July 23, 2018, which included a prospectus (the "Shelf Registration Statement"), signed by Defendants Huff, Bass, McClellan, McGaughy, Nielsen, and Rose; and (ii) a final prospectus supplement filed with the SEC on Form 424B5 and dated November 13, 2019 (the "2019 Offering ProSupp").

468. The 2019 Offering ProSupp also "incorporated by reference" certain documents that Reata had previously filed with the SEC, which thereby became part of the 2019 Offering ProSupp. *See* 2019 Offering ProSupp at S-30. Among the documents so incorporated were:

A. the 2018 10-K;

B. the Q1 2019 Form 10-Q, Q2 2019 Form 10-Q, and Q3 2019 Form 10-Q; and

C. a Reata Form 8-K filed with the SEC on November 12, 2019, which included as an exhibit the CARDINAL Phase 3 Results Release. *See* 2019 Offering ProSupp at S-30.

469. The above-specified documents are referred to herein as the "2019 Offering Incorporated Documents." The Shelf Registration Statement, 2019 Offering ProSupp, and 2019 Offering Incorporated Documents are referred to herein as the "2019 Offering Documents."

2. Defendants' Preparation of the 2019 Offering Documents

470. Reata, each of the Individual Defendants, and the 2019 Offering Underwriter Defendants prepared the 2019 Offering Documents.

471. Defendant Huff, together with Director Defendants McGaughy, Nielsen, Rose,

McClellan, and Bass, signed the Shelf Registration Statement.

472. Director Defendants McGaughy, Nielsen, Rose, McClellan, and Bass, and Officer Defendants Huff and Meyer, were, respectively, directors and officers of Reata at the time the Shelf Registration Statement was filed with the SEC, and reviewed, edited, approved, and/or authorized the Shelf Registration Statement.

473. Director Defendants McGaughy, Nielsen, Rose, McClellan, and Bass, and Officer Defendants Huff, Meyer, and Soni, were, respectively, directors and officers of Reata at the time the 2019 Offering ProSupp was filed with the SEC, and reviewed, edited, approved, and/or authorized the 2019 Offering ProSupp.

474. The 2019 Offering Underwriter Defendants helped to prepare the 2019 Offering ProSupp and the disclosures to investors therein. To do so, the 2019 Offering Underwriter Defendants:

A. undertook a "due diligence" investigation into Reata, and in so doing, had continual access to confidential information concerning Reata's operations and prospects;

B. met with Reata's management, including certain of the Officer Defendants and Director Defendants, to discuss and reach an agreement on, *inter alia*: (i) the strategy to best accomplish the 2019 Offering; (ii) the terms of the 2019 Offering, including the price at which Reata shares would be sold; and (iii) the disclosures to be made about Reata and the language to be used in the 2019 Offering ProSupp; and

C. drafted, reviewed, edited, and/or approved the 2019 Offering ProSupp prior to its filing.

3. The 2019 Offering Documents Omitted and/or Misstated Material Facts

475. The 2019 Offering Documents were negligently prepared and, as a result, contained untrue statements of material facts and/or omitted to state facts necessary to make the statements

made therein not misleading, and failed to make adequate disclosures required under the rules and regulations governing their preparation.

476. The 2019 Offering ProSupp contained FDA Guidance Representations and CARDINAL Retained eGFR Representations:

> **Company Overview** . . .
>
> On November 11, 2019, we announced that the Phase 3 portion of the CARDINAL study of bardoxolone in patients with CKD caused by Alport syndrome met its primary and key secondary Year 1 endpoints. . . . After 48 weeks of treatment and a four-week withdrawal period, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean retained eGFR of 5.14 mL/min/1.73 m2 (p=0.0012). Bardoxolone treatment was generally reported to be well-tolerated and showed a similar safety profile to the Phase 2 portion of the CARDINAL study. Based on these positive results, and subject to discussions with regulatory authorities, we plan to proceed with the submission of regulatory filings for marketing approval in the United States and internationally.
>
> ***
>
> **Bardoxolone in CKD Caused by Alport Syndrome** . . .
>
> On November 11, 2019, we announced the topline, Year 1 results from the Phase 3 portion of CARDINAL studying bardoxolone in Alport syndrome patients. . . . The FDA has provided us with written guidance that, in patients with CKD caused by Alport syndrome, an analysis of retained eGFR demonstrating an improvement versus placebo after one year of bardoxolone treatment may support a New Drug Application (NDA) submission for accelerated approval and an improvement versus placebo after two years of treatment may support full approval. . . .
>
> Patients' retained eGFR was also assessed at Week 52, after 48 weeks of treatment and withdrawal of drug for four weeks. At Week 52, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean retained eGFR of 5.14 mL/min/1.73 m2 (p=0.0012).

2019 Offering ProSupp at S-1, S-2 – S-3.

477. The FDA Guidance Representations in the 2019 Offering ProSupp – *i.e.*, the representation that the FDA had provided Reata with "written guidance that, in patients with CKD caused by Alport syndrome, an analysis of retained eGFR demonstrating an improvement versus placebo after one year of bardoxolone treatment may support a New Drug Application (NDA)

submission for accelerated approval and an improvement versus placebo after two years of treatment may support full approval" – were materially misleading, and omitted to state additional facts necessary to make them not misleading, for two principal reasons. *Id.* at S-3.

A. First, although the 2019 Offering ProSupp referenced the FDA guidance received in October 2016 concerning adequate CARDINAL design and data, it omitted to make any mention of the FDA's subsequent communications – in December 2016, September 2018, and February 2019 – informing Reata that (i) Reata had **not** obtained FDA concurrence on adequate CARDINAL design and data, and (ii) that CARDINAL's design and data – and specifically, its utilization of a four-week washout period, and the resulting retained eGFR data generated on the basis of that four-week washout period – had strayed from and did not accord with FDA guidance.

B. Second, although the 2019 Offering ProSupp correctly informed that FDA approval could be based on demonstration of a retained eGFR benefit for Bard, it omitted to state that the purported retained eGFR data and results produced by CARDINAL were **neither the retained eGFR described by the FDA nor in fact retained eGFR at all**. Because CARDINAL utilized an inadequate four-week washout period insufficient to extinguish Bard's PD effects, the eGFR results it measured and labeled as retained eGFR were not in fact valid retained eGFR but were contaminated by the very thing retained eGFR was supposed to exclude: PD effects.

478. The CARDINAL Retained eGFR Representations in the 2019 Offering ProSupp – *i.e.*, the related representations that "[a]t Week 52, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean retained eGFR of 5.14 mL/min/1.73 m2[,]" and that this statistically significant improvement in retained eGFR meant

that "CARDINAL . . . met its . . . key secondary Year 1 endpoints" – were materially false and/or misleading, and omitted to state additional facts necessary to make them not misleading.

479. First, the 2019 Offering ProSupp mischaracterized CARDINAL's week 52 results as retained eGFR when in fact they were not. In fact, and as a result of CARDINAL's inadequate four-week washout period, some substantial portion and/or all of the "statistically significant improvement compared to placebo in mean retained eGFR of 5.14 mL/min/1.73 m2" was not in fact truly retained eGFR, but the very thing that retained eGFR was supposed to be free of: PD effects remaining from treatment. In truth and put simply, due to its inadequate washout period, CARDINAL did not show a 5.14-point improvement in retained eGFR from Bard. In fact, it did not generate **any** evidence of **any** retained eGFR benefit from Bard at all.

480. Second, the related representation that "CARDINAL . . . met its . . . key secondary Year 1 endpoints" was materially false and/or misleading for the same reasons. CARDINAL's "key secondary Year 1 endpoint" was retained eGFR (specifically, change in eGFR over baseline versus placebo). This endpoint was purportedly "met" by the above-discussed represented result: a "statistically significant improvement compared to placebo in mean retained eGFR of 5.14 mL/min/1.73 m2." But, due to CARDINAL's inadequate four-week washout period, CARDINAL's actual results were not as represented: they were neither a 5.14-point improvement in retained eGFR nor retained eGFR at all. In truth and put simply, the representation that CARDINAL results succeeded on the key secondary endpoint of retained eGFR was illusory, as CARDINAL had not in fact generated **any** evidence of **any** retained eGFR benefit from Bard.

481. The 2019 Offering ProSupp – and specifically the above-identified CARDINAL Retained eGFR Representations and FDA Guidance Representations therein – omitted to disclose the material facts that:

A. valid measurement of retained eGFR in CARDINAL required a washout period of eight weeks – twice as long as the four-week washout period actually utilized;

B. CARDINAL, with a washout period insufficient and inadequate to extinguish Bard's PD effects, was not generating accurate or valid measurements of retained eGFR;

C. as CARDINAL's retained eGFR results were not actually retained eGFR at all, they were incapable of supporting or serving as a basis for FDA approval; and

D. the FDA had repeatedly warned Reata of the foregoing in its December 2016 Advice Letter and September 2018 and February 2019 communications to Reata.

482. The 2019 Offering ProSupp, additionally, contained further material misstatements incorporated by reference.

483. The 2019 Offering ProSupp contained 10-14 Day Washout Representations, representing that Bard was fully "washed out" within 14 days after cessation of treatment, and/or that all PD effects of Bard treatment had resolved, or ceased, within 14 days after cessation of treatment, via its incorporation of such representations in the 2018 10-K (*see* ¶ 240, *supra*).

484. The 10-14 Day Washout Representations incorporated into the 2019 Offering Documents were materially false and/or misleading. In fact, after extended Bard treatment such as in CARDINAL, Bard did not wash out within 14 days, but instead continued to be active and exert PD effects for as long as eight weeks.

485. This untruth was material, and served as a requisite predicate for many of the other alleged misstatements. An eight-week washout period – four times longer than Defendants had represented in the 10-14 Day Washout Representations, and twice as long as the washout period employed in Reata's CARDINAL, BEAM, and BEACON studies – meant:

A. that CARDINAL was not adequately designed to measure, or generate evidence

concerning, retained eGFR, as measurement of eGFR at only four weeks following Bard discontinuation would actually still measure Bard's PD effects, rather than, as represented, eGFR benefits retained after Bard's PD effects had fully resolved;

B. that the purported retained eGFR benefits purportedly evidenced by CARDINAL's data and results were no such thing, but rather were contaminated by the very thing Defendants represented them to be free of – Bard's PD effects; and

C. that the same was the case for the purported retained eGFR benefits purportedly evidenced in Reata's prior BEAM and BEACON studies, which utilized similarly inadequate four-week washout periods.

486. The 2019 Offering ProSupp contained CARDINAL Design Representations – representations that CARDINAL was designed to measure, and was measuring, **retained** eGFR – via its incorporation of such representations in the CARDINAL Phase 3 Results Release (*see* ¶ 249, *supra*).

487. The CARDINAL Design Representations incorporated into the 2019 Offering Documents were materially false and/or misleading. The CARDINAL measurements and data that Defendants represented to be retained eGFR were not in fact retained eGFR. Because the extended Bard treatment in CARDINAL required eight weeks to wash out, CARDINAL's measurement of eGFR after a washout of only four weeks would actually measure some substantial portion of Bard's PD effects that still remained after four weeks, rather than, as Defendants represented, purported eGFR benefits retained after PD effects had resolved.

488. The 2019 Offering ProSupp contained CARDINAL Retained eGFR Representations – representations that CARDINAL data/results had in fact demonstrated a statistically significant retained eGFR benefit for Bard (four weeks after treatment

discontinuation), and thereby purportedly succeeded in meeting CARDINAL's key secondary endpoint – via its incorporation of such representations in the 2018 10-K (*see* ¶¶239-40, *supra*), the Q3 2019 10-Q (*see* ¶¶ 250-51, *supra*), and the CARDINAL Phase 3 Results Release (*see* ¶ 249, *supra*).

489. The CARDINAL Retained eGFR Representations incorporated into the 2019 Offering Documents were materially false and/or misleading. Extended treatment with Bard, as in CARDINAL, required eight weeks to wash out – as indicated *inter alia* by the TSUBAKI study – before a true, valid, and accurate retained eGFR measure could be made. CARDINAL's retained eGFR measurements, however, were made only four weeks after cessation of treatment with Bard: *i.e.*, only halfway through, rather than following the end of, the requisite washout period. Consequently, the purported retained eGFR benefits purportedly evidenced in CARDINAL's results were no such thing, but rather were contaminated and elevated by the very thing Defendants represented them to be free of – Bard's PD effects. This contamination made them not only inaccurate (*i.e.*, not the 5.14-point retained eGFR benefit claimed), but fundamentally invalid, and not retained eGFR at all (*i.e.*, no evidence of any retained eGFR benefit). Defendants' claims that CARDINAL had succeeded on its key secondary endpoint (retained eGFR benefit) were therefore illusory and materially misleading.

490. The 2019 Offering ProSupp contained Prior Study Retained eGFR Representations – representing that Reata's prior BEAM and BEACON Bard studies also demonstrated statistically significant retained eGFR benefits for Bard (four weeks after treatment discontinuation) – via its incorporation of such representations in the 2018 10-K (*see* ¶ 240, *supra*) and the Q3 2019 10-Q (*see* ¶ 251, *supra*).

491. The Prior Study Retained eGFR Representations incorporated into the 2019

Offering Documents were materially false and/or misleading for the same reasons that the CARDINAL Retained eGFR Representations were. BEAM and BEACON's retained eGFR measurements, just like CARDINAL's, were made only four weeks after treatment cessation: *i.e.*, only halfway through, rather than following the end of, the requisite washout period indicated *inter alia* by TSUBAKI. Consequently, the purported retained eGFR benefits purportedly evidenced in the BEAM and BEACON results were no such thing, but rather were contaminated and elevated by the very thing Defendants represented them to be free of – Bard's PD effects.

492. Finally, the 2019 Offering ProSupp contained additional FDA Guidance Representations, over and above the above-identified statements made directly in the 2019 Offering ProSupp (*see* ¶ 476, *supra*), via its incorporation of such representations in the 2018 Form 10-K (*see* ¶¶ 239-40, *supra*), the Q3 2019 10-Q (*see* ¶¶ 250-51, *supra*), and the CARDINAL Phase 3 Results Release (*see* ¶ 249, *supra*).

493. The FDA Guidance Representations incorporated by reference into the 2019 Offering ProSupp were materially misleading for the same reasons that the FDA Guidance Representations made directly in the 2019 Offering ProSupp were, as set forth in ¶ 477, *supra*.

494. Additionally, the 2019 Offering ProSupp purported to provide requisite "risk factor" disclosures by incorporating by reference the Risk Factor Disclosures contained in the 2018 10-K. *See* 2019 Offering ProSupp at S-13.[22] The 2018 10-K's Risk Factor Disclosures were, however, inadequate and materially misleading. *See* 2018 10-K at 52-53, 73-74. They inaccurately described certain risks – specifically, that the FDA might not approve Bard due to "inadequate design or implementation of our clinical trials[,]" failure to demonstrate Bard's "safety and

[22] The 2019 Offering ProSupp also incorporated by reference the single, here-irrelevant risk factor contained in Reata's Q2 2019 10-Q (the risk of computer system failures or security breaches). *See* 2019 Offering ProSupp at S-13; Q2 2019 10-Q at 32-33.

efficacy . . . to the satisfaction of the relevant regulatory authorities[,]" and FDA disagreement "that our completed clinical trials provide adequate data on safety or efficacy[]" – as **potential** risks, stated in a generalized and hypothetical manner, while omitting to disclose material, then-existing facts – such as the FDA's December 2016 Advice Letter, and the FDA's September 2018 and February 2019 communications – indicating that these risks were actually materializing.

B. The 2020 Offering

495. On or about December 1, 2020, the below-specified Defendants registered, issued, and sold to Lead Plaintiff and other Class members 2.0 million Reata shares at $140.85 per share, in a secondary public offering underwritten by Defendants Barclays and Goldman (the "2020 Offering Underwriter Defendants"). The 2020 Offering Underwriter Defendants received $3.8 million in fees, paid by Reata from 2020 Offering gross proceeds of $281.7 million, for their willingness and efforts to underwrite the 2020 Offering and to market and sell the 2.0 million Reata shares offered therein. Net proceeds to Reata were approximately $277.5 million.

1. The 2020 Offering Documents

496. The 2020 Offering was made pursuant to: (i) the Shelf Registration Statement; and (ii) a final prospectus supplement filed with the SEC on Form 424B5 and dated December 1, 2020 (the "2020 Offering ProSupp").

497. The 2020 Offering ProSupp also "incorporated by reference" certain documents that Reata had previously filed with the SEC, which thereby became part of the 2020 Offering ProSupp. *See* 2020 Offering ProSupp at S-30. Among the documents incorporated were:

A. the 2019 10-K;

B. the Q1 2020 Form 10-Q, Q2 2020 Form 10-Q, and Q3 2020 Form 10-Q; and

C. a Reata Form 8-K filed on November 9, 2020, which included as an exhibit the CARDINAL Year 2 Results Release.

2020 Offering ProSupp at S-30.

498. The above-specified documents are referred to herein as the "2020 Offering Incorporated Documents." The Shelf Registration Statement, 2020 Offering ProSupp, and 2020 Offering Incorporated Documents are referred to herein as the "2020 Offering Documents."

2. Defendants' Preparation of the 2020 Offering Documents

499. Reata, the Individual Defendants, and the 2020 Offering Underwriter Defendants prepared the 2020 Offering Documents.

500. Defendant Huff, together with Director Defendants McGaughy, Nielsen, Rose, McClellan, and Bass, signed the Shelf Registration Statement. Director Defendants McGaughy, Nielsen, Rose, McClellan, and Bass, and Officer Defendants Huff and Meyer, were, respectively, directors and officers of Reata at the time the Shelf Registration Statement was filed with the SEC, and reviewed, edited, approved, and/or authorized the Shelf Registration Statement.

501. Director Defendants McGaughy, Nielsen, Rose, and McClellan, and Officer Defendants Huff, Meyer, and Soni, were, respectively, directors and officers of Reata at the time the 2020 Offering ProSupp was filed with the SEC, and reviewed, edited, approved, and/or authorized the 2020 Offering ProSupp.

502. The 2020 Offering Underwriter Defendants helped to prepare the 2020 Offering ProSupp and the disclosures made therein. To do so, the 2020 Offering Underwriter Defendants:

A. undertook a "due diligence" investigation into Reata, and in so doing, had continual access to confidential information concerning Reata's operations and prospects;

B. met with Reata's management, including certain of the Officer Defendants and Directors Defendants, to discuss and reach agreement on, *inter alia*: (i) the strategy to best accomplish the 2020 Offering; (ii) the terms of the 2020 Offering, including the price at which Reata shares would be sold; and (iii) the disclosures to be made and the

language to be used in the 2020 Offering ProSupp; and

C. drafted, reviewed, edited, and/or approved the 2020 Offering ProSupp prior to its filing.

3. The 2020 Offering Documents Omitted and/or Misstated Material Facts

503. The 2020 Offering Documents were negligently prepared and, as a result, contained untrue statements of material facts and/or omitted to state facts necessary to make the statements made therein not misleading, and failed to make adequate disclosures required under the rules and regulations governing their preparation.

504. The 2020 Offering ProSupp contained CARDINAL Retained eGFR Representations:

> **Recent Key Developments** . . .
>
> 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 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-New Drug Application (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.
>
> ***
>
> **Bardoxolone in 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 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).

2020 Offering ProSupp at S-1 – S-2, S-4.

505. The CARDINAL Retained eGFR Representations in the 2020 Offering ProSupp –

i.e., the related representations that "[a]t Week 104 (four weeks after last dose in second year of treatment), patients . . . 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" and that this statistically significant improvement in retained eGFR meant that "CARDINAL . . . met its . . . key secondary endpoints at the end of Year 2" – were materially false and/or misleading and omitted to state additional facts necessary to make them not misleading. *Id.* at S-4.

506. First, the 2020 Offering ProSupp mischaracterized CARDINAL's week 104 results as retained eGFR when in fact they were not. In fact, and as a result of CARDINAL's inadequate four-week washout period, some substantial portion and/or all of the purported 4.3 mL/min/1.73 m2 retained eGFR benefit was not in fact truly retained eGFR, but the very thing that retained eGFR was supposed to be free of: PD effects remaining from treatment. In truth and put simply, due to its inadequate washout period, CARDINAL did not show a 4.3-point improvement in retained eGFR from Bard and did not generate **any** evidence of **any** retained eGFR benefit from Bard at all.

507. Second, the related representation that "CARDINAL . . . met its . . . key secondary endpoints at the end of Year 2" was materially false and/or misleading for the same reasons. CARDINAL's "key secondary endpoint" was retained eGFR. This endpoint was purportedly "met" by the above-discussed represented result: a "statistically significant improvement compared to placebo in mean change from baseline in eGFR of 4.3 mL/min/1.73 m2." But, due to CARDINAL's inadequate four-week washout period, CARDINAL's actual results were not as represented: they were neither a 4.3-point improvement in retained eGFR nor retained eGFR at all. In truth and put simply, the representation that CARDINAL results succeeded on the key secondary endpoint of retained eGFR was illusory, as CARDINAL had not in fact generated **any**

evidence of **any** retained eGFR benefit from Bard at all.

508. The 2020 Offering ProSupp contained Prior Study Retained eGFR Representations:

> ***Historical Development of Bardoxolone***
>
> Clinical trials enrolling over 2,000 patients exposed to bardoxolone have demonstrated consistent, clinically meaningful improvement in kidney function across several disease states as measured by eGFR . . . .
>
> . . . We believe these data, in addition to the CARDINAL Phase 3 Year 2 data, support the potential for bardoxolone to delay or prevent dialysis, kidney transplant, and death in patients with Alport syndrome and other forms of CKD.
>
> Additional observations from the prior clinical trials of bardoxolone include the following: . . .
>
> • Statistically significant improvement in eGFR during the off-treatment period in BEAM, BEACON, the Phase 2 portion of CARDINAL at Year 1, and the Phase 3 portion of CARDINAL at Year 2. We believe the eGFR benefit during the off-treatment period observed in these clinical trials demonstrates that bardoxolone treatment improved the structure of the kidney, modified the course of the disease, and may prevent or delay kidney failure and the need for dialysis or a kidney transplant.

2020 Offering ProSupp at S-6 – S-7.

509. The Prior Study Retained eGFR Representations in the 2020 Offering ProSupp were materially false and/or misleading for the same reasons that the CARDINAL Retained eGFR Representations were false and/or misleading. BEAM and BEACON's retained eGFR measurements, just like CARDINAL's, were made only four weeks after treatment cessation: *i.e.*, only halfway through, rather than following the end of, the requisite washout period indicated *inter alia* by TSUBAKI. Consequently, the "eGFR benefit during the off-treatment period" purportedly evidenced in BEAM and BEACON were not retained eGFR at all, but rather were contaminated and elevated by the very thing Defendants represented them to be free of – Bard's PD effects.

510. The 2020 Offering ProSupp contained Bard NDA Representations:

> **Recent Key Developments** . . .
>
> 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 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-New Drug Application (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 recently completed the previously announced pre-NDA meeting with the FDA to discuss the NDA submission content and plans. Based on that meeting and the FDA's responses and the subsequently announced positive results of the Year 2 data of the CARDINAL Phase 3 study, we plan to proceed with an NDA filing for full marketing approval of bardoxolone in patients with CKD caused by Alport syndrome in the first quarter of 2021. We will also continue preparations to file for marketing approval in Europe.

2020 Offering ProSupp at S-1 – S-2, S-5.

511. The Bard NDA Representations in the 2020 Offering ProSupp were materially misleading because they omitted to disclose numerous facts then known by Defendants that were highly material to evaluation of the Bard NDA and that indicated far greater risks to its approval than publicly understood in light of Defendants' other accumulated misstatements, including:

A. that Bard's PD effects did **not** wash out quickly (per the 10-14 Day Washout Representations), but instead required eight weeks for washout;

B. that as a result, the purported retained eGFR results from CARDINAL, BEAM, and BEACON (constantly repeated via CARDINAL Retained eGFR Representations and Prior Study Retained eGFR Representations) neither measured nor evidenced truly retained eGFR, and thus could not and did not support FDA approval; and

C. that the FDA had **repeatedly warned** Reata between December 2016 and September

2020 that it did **not** concur with CARDINAL's design, that the four-week washout period was inadequate and/or without basis, and that retained eGFR data predicated on such a washout period would be invalid and incapable of supporting FDA approval.

512. These omissions meant that Defendants, on the one hand, and Lead Plaintiff and other Class members on the other hand, had substantially different sets of information for understanding the Bard NDA's merits and likelihood of FDA approval. Defendants were privy to the FDA's concerns that the washout period used in CARDINAL was too short to measure true retained eGFR, that the purported retained eGFR data from CARDINAL might not constitute or evidence retained eGFR at all, and hence that key efficacy data supporting the Bard NDA's approvability, and purporting to indicate that Bard evidenced disease-modifying effects rather than simply PD effects, was a hollow simulacrum.

513. On the other hand, and as a result of Defendants' above-summarized material misrepresentations and omissions, Lead Plaintiff and Class members were aware of none of this. In the world created by Defendants' disclosures:

A. Bard washed out quickly (per the 10-14 Day Washout Representations), which supported the apparent validity of the retained eGFR results from CARDINAL, BEAM, and BEACON (as constantly repeated via the CARDINAL Retained eGFR Representations and Prior Study Retained eGFR Representations); and

B. the FDA had always supported – rather than long questioned – the validity of retained eGFR data produced and adduced by Reata (per the FDA Guidance Representations).

514. Lead Plaintiff and Class members were thereby led to a far more sanguine – and materially incomplete and inaccurate – view of Reata's prospects and the prospects for FDA approval of the Bard NDA.

515. The 2020 Offering ProSupp – and specifically the above-identified CARDINAL Retained eGFR Representations, Prior Study Retained eGFR Representations, and Bard NDA Representations therein – omitted to disclose the material facts that:

A. valid measurement of retained eGFR in CARDINAL required a washout period of eight weeks – twice as long as the four-week washout period actually utilized;

B. CARDINAL, with a washout period insufficient and inadequate to extinguish Bard's PD effects, was not generating accurate or valid measurements of retained eGFR;

C. as CARDINAL's retained eGFR results were not actually retained eGFR at all, they were incapable of supporting or serving as a basis for FDA approval; and

D. the FDA had repeatedly warned Reata of the foregoing in its December 2016 Advice Letter, its September 2018 and February 2019 communications to Reata, and its January 2020 and September 2020 meetings with Reata.

516. The 2020 Offering ProSupp, additionally, contained further material misstatements incorporated by reference.

517. The 2020 Offering ProSupp contained FDA Guidance Representations – representing that (i) CARDINAL, including its four-week washout period for retained eGFR, had been designed pursuant to and in accordance with FDA guidance, and (ii) successful retained eGFR results from CARDINAL would support FDA approval – via its incorporation of such representations in the 2019 10-K (*see* ¶ 268, *supra*), the Q1 2020 10-Q (*see* ¶ 275, *supra*), and the Q2 2020 10-Q (*see* ¶ 282, *supra*).

518. The FDA Guidance Representations, incorporated by reference into the 2020 Offering ProSupp, were materially misleading and omitted to state additional facts necessary to make them not misleading, for two principal reasons.

A. First, although the 2020 Offering ProSupp's incorporated statements referenced the FDA guidance received in October 2016 concerning adequate CARDINAL design and data, they omitted to make any mention of the FDA's subsequent communications – in December 2016, September 2018, February 2019, January 2020, and September 2020 – informing Reata that (i) Reata had **not** obtained FDA concurrence on adequate CARDINAL design and data, and (ii) CARDINAL's design and data – and specifically, utilization of a four-week washout period, and the resulting retained eGFR data generated based on that four-week washout period – had strayed from and did not accord with FDA guidance.

B. Second, although the 2020 Offering ProSupp's incorporated statements correctly informed that FDA approval could be based on demonstration of a retained eGFR benefit for Bard, they omitted to state that the purported retained eGFR data and results produced by CARDINAL were **neither the retained eGFR described by the FDA nor in fact retained eGFR at all**. Because CARDINAL utilized an inadequate four-week washout period insufficient to extinguish Bard's PD effects, the eGFR results it measured and labeled as retained eGFR were not valid retained eGFR but were contaminated by the very thing retained eGFR was supposed to exclude: PD effects.

519. The 2020 Offering ProSupp contained additional CARDINAL Retained eGFR Representations – over and above those made directly in the 2020 Offering ProSupp – via its incorporation of such representations in the 2019 10-K (*see* ¶ 268, *supra*), Q1 2020 10-Q (*see* ¶ 275, *supra*), Q2 2020 10-Q (*see* ¶ 282, *supra*), Q3 2020 10-Q (*see* ¶ 291, *supra*) and the CARDINAL Year 2 Results Release (*see* ¶ 289, *supra*).

520. The CARDINAL Retained eGFR Representations incorporated into the 2020

Offering Documents were materially false and/or misleading for the same reasons that the CARDINAL Retained eGFR Representations made directly in the 2020 Offering ProSupp were, as set forth at ¶¶ 504-07, *supra*.

521. The 2020 Offering ProSupp contained additional Prior Study Retained eGFR Representations – over and above those made directly in the 2020 Offering ProSupp – via its incorporation of such representations in the 2019 10-K (*see* ¶ 268, *supra*), Q1 2020 10-Q (*see* ¶ 275, *supra*), Q2 2020 10-Q (*see* ¶ 282, *supra*) and Q3 2020 10-Q (*see* ¶ 291, *supra*).

522. The Prior Study Retained eGFR Representations incorporated into the 2020 Offering Documents were materially false and/or misleading for the same reasons that the Prior Study Retained eGFR Representations made directly in the 2020 Offering ProSupp were, as set forth at ¶¶ 508-09, *supra*.

523. The 2020 Offering ProSupp contained additional Bard NDA Representations – over and above those made directly in the 2020 Offering ProSupp – via its incorporation of such representations in the Q3 2020 10-Q (*see* ¶ 291, *supra*) and the CARDINAL Year 2 Two Results Release (*see* ¶ 289, *supra*).

524. The Bard NDA Representations incorporated into the 2020 Offering Documents were materially false and/or misleading for the same reasons that the Bard NDA Representations made directly in the 2020 Offering ProSupp were, as set forth at ¶¶ 510-15, *supra*.

525. Additionally, the 2020 Offering ProSupp purported to provide requisite "risk factor" disclosures by incorporating by reference the Risk Factor Disclosures contained in the 2019 10-K. *See* 2020 Offering ProSupp at S-13.[23] The 2019 10-K's Risk Factor Disclosures were,

[23] The 2020 Offering ProSupp also incorporated by reference the single, here-irrelevant risk factor contained in the Q1 2020 10-Q (the risk that COVID-19 presented to business operations and results). *See* 2020 Offering ProSupp at S-13; Q1 2020 10-Q at 29.

however, inadequate and materially misleading. *See* 2019 10-K at 51-52, 73-74. They inaccurately described certain risks – specifically, that the FDA might not approve Bard due to "inadequate design or implementation of our clinical trials[,]" failure to demonstrate Bard's "safety and efficacy . . . to the satisfaction of the relevant regulatory authorities[,]" and FDA disagreement "that our completed clinical trials provide adequate data on safety or efficacy[]" – as **potential** risks, stated in a generalized and hypothetical manner, while omitting to disclose material, then-existing facts – such as the FDA's December 2016 Advice Letter, the FDA's September 2018 and February 2019 communications, and the January 2020 FDA Meeting and September 2020 FDA meeting – indicating that these risks were actually materializing.

C. Post-Secondary Public Offering Events

526. On December 20, 2021, when the initial complaint in this action was filed, Reata shares closed trading at $29.12 per share. This price represented a decline of: (i) $153.88 per share, or 84.1%, from the 2019 Offering price ($183.00); and (ii) $111.73 per share, or 79.3%, from the 2020 Offering price ($140.85).

IX. CLAIMS FOR RELIEF UNDER THE SECURITIES ACT

THIRD CLAIM
Violation of Section 11 of the Securities Act
Against Reata, Defendants Huff and Meyer, the Director Defendants,
and the 2019 Underwriter Defendants
(Relating to the 2019 Offering)

527. Lead Plaintiff repeats and realleges the allegations in ¶¶ 19-93, 464-94 and 526 as if alleged fully in this claim, but only to the extent that such allegations do not allege fraud, scienter, or the intents of the Defendants named in this claim to defraud Lead Plaintiff or other Class members within the scope of this cause of action.

528. This claim is brought by Lead Plaintiff pursuant to Section 11 of the Securities Act, 15 U.S.C. § 77k, on behalf of all members of the Class who purchased or otherwise acquired Reata

common stock pursuant or traceable to the 2019 Offering and were damaged thereby.

529. This claim expressly excludes and disclaims any allegation of fraud or intentional or reckless conduct, as this claim is solely based upon claims of strict liability and/or negligence under the Securities Act. For purposes of asserting this claim, Lead Plaintiff does not allege that Defendants acted with scienter or fraudulent intent, which are not elements of a Section 11 claim.

530. The 2019 Offering Documents were false and/or misleading, contained untrue statements of material facts, omitted to state facts necessary to make the statements not misleading, and omitted material facts required to be stated therein.

531. Reata is the registrant and issuer of the common stock offered pursuant to the 2019 Offering Documents in the 2019 Offering. As such, Reata is strictly liable under Section 11 of the Securities Act to Lead Plaintiff and to relevant Class members for the materially inaccurate statements contained in the 2019 Offering Documents, and the failure of 2019 Offering Documents to be complete and accurate.

532. None of the Defendants named in this cause of action made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the 2019 Offering Documents were true, without omissions of any material facts, and not misleading.

533. The Officer and Director Defendants caused the issuance of the 2019 Offering. Defendant Huff and the Director Defendants signed the Shelf Registration Statement, and together with Defendant Meyer, were Reata officers or directors at the time of the 2019 Offering. Defendants Huff and Meyer, and each of the Director Defendants, are therefore statutorily liable under Section 11 of the Securities Act.

534. Defendants Huff and Meyer, and the Director Defendants, each had a duty to make a reasonable and diligent investigation into the truthfulness and accuracy of the statements

contained in the 2019 Offering Documents. They each had a duty to ensure that such statements were true and accurate and that there were no omissions of material fact that would make the statements misleading. By virtue of these Defendants' failures to exercise reasonable care, the 2019 Offering Documents contained misstatements of material facts and omissions of material facts. As such, each of these Defendants is liable under Section 11 of the Securities Act to Lead Plaintiff and to relevant members of the Class within the scope of this cause of action.

535. The 2019 Offering Underwriter Defendants served as the underwriters for the 2019 Offering and qualify as such according to the definition contained in Section 2(a)(11) of the Securities Act. As such, the 2019 Offering Underwriter Defendants participated in the solicitation, offering, and sale of the securities to the investing public pursuant to the 2019 Offering Documents. As such, the 2019 Offering Underwriter Defendants had a duty to make a reasonable and diligent investigation of the truthfulness and accuracy of the statements contained in the 2019 Offering Documents. The 2019 Offering Underwriter Defendants had a duty to ensure that such statements were true and that there were no omissions of material fact that would make the statements misleading. By virtue of the 2019 Offering Underwriter Defendants' failure to exercise reasonable care, the 2019 Offering Documents contained misstatements of material facts and omissions of material facts necessary to make the statements therein not misleading. As such, the 2019 Offering Underwriter Defendants are liable under Section 11 of the Securities Act to Lead Plaintiff and relevant Class members within the scope of this cause of action.

536. None of the untrue statements or omissions of material fact in the 2019 Offering Documents alleged herein were forward-looking statements. Rather, each statement concerned existing facts. Moreover, the 2019 Offering Documents did not properly identify any of the untrue statements as forward-looking statements and did not disclose information that undermined the

putative validity of those statements.

537. Each of the Defendants named in this cause of action issued, caused to be issued, and participated in the issuance of materially false and misleading written statements to the investing public contained in the 2019 Offering Documents, which misstated and failed to disclose, *inter alia*, the facts set forth above.

538. By reason of the foregoing, each of the Defendants named in this claim are each jointly and severally liable for violations of Section 11 of the Securities Act to Lead Plaintiff and the Class members within the scope of this cause of action pursuant to Section 11(f) of the Securities Act.

539. Lead Plaintiff and other members of the Class within the scope of this cause of action purchased Reata shares in the 2019 Offering and/or traceable to the defective 2019 Offering Documents.

540. Lead Plaintiff and Class members within the scope of this cause of action have sustained damages. The value of Reata common stock has declined substantially subsequent to, and due to, the violations by Defendants named in this cause of action.

541. At the time Lead Plaintiff and other members of the Class within the scope of this cause of action purchased Reata stock, they were without knowledge of the facts concerning the wrongful conduct alleged herein, and could not have reasonably discovered those facts prior to the disclosures specified herein.

542. Less than one year elapsed between the time that Lead Plaintiff discovered, or could have reasonably discovered, the facts upon which this Complaint is based and the filing of the initial complaint in this action. Less than three years has elapsed since the time that the securities at issue in this Complaint were bona fide offered to the public.

FOURTH CLAIM
Violation of Section 12(a)(2) of the Securities Act
Against the Reata Defendants and the 2019 Offering Underwriter Defendants
(Relating to the 2019 Offering)

543. Lead Plaintiff repeats and realleges the allegations in ¶¶ 19-93, 464-94, and 526-42 as if alleged fully in this claim, but only to the extent that such allegations do not allege fraud, scienter, or the intents of the Defendants named in this claim to defraud Lead Plaintiff or other Class members within the scope of this cause of action.

544. This claim is brought by Lead Plaintiff pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. § 77l(a)(2), on behalf of itself and all members of the Class who purchased or otherwise acquired Reata common stock in and/or traceable to the 2019 Offering and who were damaged thereby, against Reata, each of the Officer Defendants and Director Defendants, and the 2019 Offering Underwriter Defendants.

545. This claim expressly excludes and disclaims any allegation that could be construed as alleging fraud or intentional or reckless conduct, as this claim is solely based on claims of strict liability and/or negligence under the Securities Act. For purposes of asserting this claim, Lead Plaintiff does not allege that any of these Defendants acted with scienter or fraudulent intent, which are not elements of a Section 12(a)(2) claim.

546. Each of the Defendants named in this claim were sellers, offerors, and/or solicitors of purchasers of Reata stock pursuant to the defective 2019 Offering ProSupp. The actions of solicitation by the Defendants named in this claim included participating in the preparation of the false and misleading 2019 Offering ProSupp, a part of the Shelf Registration Statement, and marketing the 2019 Offering to investors, such as Lead Plaintiff and the other members of the Class within the scope of this cause of action. By means of the 2019 Offering Documents, Defendants sold approximately 2.76 million Reata shares in the 2019 Offering to Lead Plaintiff

and other members of the Class within the scope of this cause of action.

547. The 2019 Offering Documents contained untrue statements of material fact and omitted other facts necessary to make the statements not misleading, and failed to disclose material facts, as set forth herein.

548. Each of the Defendants named in this cause of action owed, to Lead Plaintiff and other members of the Class within the scope of this cause of action, the duty to make a reasonable and diligent investigation of the statements contained in the 2019 Offering ProSupp, to ensure that such statements were true and that there was no omission to state a material fact required to be stated to make the statements contained therein not misleading. By virtue of each of these Defendants' failure to exercise reasonable care, the 2019 Offering ProSupp contained misstatements of material facts and omissions of material facts necessary to make the statements therein not misleading.

549. Lead Plaintiff and other members of the Class within the scope of this cause of action purchased Reata stock pursuant to and/or traceable to the defective 2019 Offering ProSupp.

550. Lead Plaintiff did not know, nor in the exercise of reasonable diligence could Lead Plaintiff have known, of the untruths and omissions contained in the 2019 Offering ProSupp at the time Lead Plaintiff acquired Reata shares in the 2019 Offering.

551. By reason of the conduct alleged herein, the Defendants named in this cause of action violated and/or controlled a person who violated Section 12(a)(2) of the Securities Act, and are each jointly and severally liable for violations of Section 12(a)(2) of the Securities Act to Lead Plaintiff and the other members of the Class.

552. As a direct and proximate result of such violations, Lead Plaintiff and other Class members within the scope of this cause of action who acquired Reata shares pursuant to the 2019

Offering Documents sustained damages. Accordingly, Lead Plaintiff and the other members of the Class within the scope of this cause of action who hold shares issued pursuant to the Shelf Registration Statement have the right to rescind and recover the consideration paid for their shares with interest thereon or damages as allowed by law or in equity. Class members within the scope of this cause of action who have sold their shares seek damages to the extent permitted by law.

553. This cause of action is brought within one year of when Lead Plaintiff discovered or reasonably could have discovered the untrue statements and omissions in the 2019 Offering ProSupp, and within three years of the 2019 Offering ProSupp's effective date.

FIFTH CLAIM
Violation of Section 15 of the Securities Act
Against the Individual Defendants
(Relating to the 2019 Offering)

554. Lead Plaintiff repeats and realleges the allegations in ¶¶ 19-93, 464-94, and 526-53 as if alleged fully in this claim, but only to the extent that such allegations do not allege fraud, scienter, or the intents of the Defendants named in this claim to defraud Lead Plaintiff or other Class members within the scope of this cause of action.

555. This claim is brought by Lead Plaintiff pursuant to Section 15 of the Securities Act, 15 U.S.C. § 77o, on behalf of itself and relevant members of the Class within the scope of this cause of action, against each of the Officer Defendants and Director Defendants.

556. This claim does not sound in fraud. For purposes of asserting this claim under the Securities Act, Lead Plaintiff does not allege that any of these Defendants acted with scienter or fraudulent intent, which are not elements of a Section 15 claim.

557. Each of the Defendants named in this cause of action participated in the preparation and dissemination of the 2019 Offering Documents, and otherwise participated in the process necessary to conduct the 2019 Offering.

558. At all relevant times, each of the Officer Defendants and Director Defendants named in this cause of action were controlling persons of Reata within the meaning of Section 15 of the Securities Act. As set forth herein, because of their positions at Reata and/or because of their positions on Reata's Board, each of these Defendants had the requisite power to directly or indirectly control or influence the decision making of the Company and the conduct of Reata's business, including the wrongful conduct complained of herein.

559. In their capacities as senior corporate officers of the Company, and as more fully described above, the Officer Defendants had direct involvement in the day-to-day operations of the Company, and therefore are presumed to have had the power to control or influence the particular transactions giving rise to the securities law violations as alleged herein. They were also directly involved in providing false information and certifying and/or approving the false and/or misleading statements disseminated by Reata during the Class Period, including the 2019 Offering Documents which contained materially untrue information or omitted material information required to be disclosed to prevent the statements made therein from being misleading. As a result of the foregoing, the Officer Defendants, as a group and individually, were controlling persons of Reata within the meaning of Section 15 of the Securities Act.

560. The Officer Defendants named in this cause of action each signed the Shelf Registration Statement and/or controlled the contents and dissemination of the 2019 Offering Documents.

561. Similarly, each of the Director Defendants named in this cause of action, and Defendant Huff, served on Reata's Board of Directors at the time the 2019 Offering was conducted and at the time that the Shelf Registration Statement was signed. As directors of a publicly owned company, these defendants had a duty to disseminate accurate and truthful information with

respect to Reata's financial condition and operations. The Director Defendants named in this cause of action, and Defendant Huff, each signed the Shelf Registration Statement and controlled the contents and dissemination of the 2019 Offering Documents.

562. Each of the Officer and Director Defendants were culpable participants in the violations of Sections 11 and 12(a)(2) of the Securities Act alleged above, based on having signed the Shelf Registration Statement and/or having otherwise participated in the process that allowed the 2019 Offering to be completed.

563. As control persons of Reata, each of the Officer and Director Defendants are liable jointly and severally, under Section 15 of the Securities Act, with and to the same extent as Reata for its violations of Sections 11 and 12(a)(2) of the Securities Act.

564. As a direct and proximate result of the conduct of these Defendants, Lead Plaintiff and other members of the Class within the scope of this cause of action have suffered damages.

SIXTH CLAIM
Violation of Section 11 of the Securities Act
Against Reata, Defendants Huff and Meyer, the Director Defendants,
and the 2020 Underwriter Defendants
(Relating to the 2020 Offering)

565. Lead Plaintiff repeats and realleges the allegations in ¶¶ 19-93, 464-65 and 495-526 as if alleged fully in this claim, but only to the extent that such allegations do not allege fraud, scienter, or the intents of the Defendants named in this claim to defraud Lead Plaintiff or other Class members within the scope of this cause of action.

566. This claim is brought by Lead Plaintiff pursuant to Section 11 of the Securities Act, 15 U.S.C. § 77k, on behalf of all members of the Class who purchased or otherwise acquired Reata common stock pursuant or traceable to the 2020 Offering and were damaged thereby.

567. This claim expressly excludes and disclaims any allegation of fraud or intentional

or reckless conduct, as this claim is solely based on claims of strict liability and/or negligence under the Securities Act. For purposes of asserting this claim, Lead Plaintiff does not allege that Defendants acted with scienter or fraudulent intent, which are not elements of a Section 11 claim.

568. The 2020 Offering Documents were false and/or misleading, contained untrue statements of material facts, omitted to state facts necessary to make the statements not misleading, and omitted material facts required to be stated therein.

569. Reata is the registrant and issuer of the common stock offered pursuant to the 2020 Offering Documents in the 2020 Offering. As such, Reata is strictly liable under Section 11 of the Securities Act to Lead Plaintiff and to relevant Class members for the materially inaccurate statements contained in the 2020 Offering Documents, and the failure of the 2020 Offering Documents to be complete and accurate.

570. None of the Defendants named in this cause of action made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the 2020 Offering Documents were true, without omissions of any material facts, and not misleading.

571. The Officer and Director Defendants caused the issuance of the 2020 Offering. Defendant Huff and the Director Defendants signed the Shelf Registration Statement, and together with Defendant Meyer, were Reata officers or directors at the time of the 2020 Offering (excepting Defendant Bass). Defendants Huff and Meyer, and each of the Director Defendants, are therefore statutorily liable under Section 11 of the Securities Act.

572. Defendants Huff and Meyer, and the Director Defendants, each had a duty to make a reasonable and diligent investigation of the truthfulness and accuracy of the statements contained in the 2020 Offering Documents. They each had a duty to ensure that such statements were true and accurate and that there were no omissions of material fact that would make the statements

misleading. By virtue of these Defendants' failures to exercise reasonable care, the 2020 Offering Documents contained misstatements of material facts and omissions of material facts. As such, each of these Defendants is liable under Section 11 of the Securities Act to Lead Plaintiff and to relevant members of the Class within the scope of this cause of action.

573. The 2020 Offering Underwriter Defendants served as the underwriters for the 2020 Offering and qualify as such according to the definition contained in Section 2(a)(11) of the Securities Act. As such, the 2020 Offering Underwriter Defendants participated in the solicitation, offering, and sale of the securities to the investing public pursuant to the 2020 Offering Documents. As such, the 2020 Offering Underwriter Defendants had a duty to make a reasonable and diligent investigation of the truthfulness and accuracy of the statements contained in the 2020 Offering Documents. The 2020 Offering Underwriter Defendants had a duty to ensure that such statements were true and that there were no omissions of material fact that would make the statements misleading. By virtue of the 2020 Offering Underwriter Defendants' failure to exercise reasonable care, the 2020 Offering Documents contained misstatements of material facts and omissions of material facts necessary to make the statements therein not misleading. As such, the 2020 Offering Underwriter Defendants are liable under Section 11 of the Securities Act to Lead Plaintiff and relevant Class members within the scope of this cause of action.

574. None of the untrue statements or omissions of material fact in the 2020 Offering Documents alleged herein were forward-looking statements. Rather, each statement concerned existing facts. Moreover, the 2020 Offering Documents did not properly identify any of the untrue statements as forward-looking statements and did not disclose information that undermined the putative validity of those statements.

575. Each of the Defendants named in this cause of action issued, caused to be issued,

and participated in the issuance of materially false and misleading written statements to the investing public contained in the 2020 Offering Documents, which misstated and failed to disclose, *inter alia*, the facts set forth above.

576. By reason of the foregoing, each of the Defendants named in this claim are each jointly and severally liable for violations of Section 11 of the Securities Act to Lead Plaintiff and the Class members within the scope of this cause of action pursuant to Section 11(f) of the Securities Act.

577. Lead Plaintiff and other members of the Class within the scope of this cause of action purchased Reata shares in the 2020 Offering and/or traceable to the defective 2020 Offering Documents.

578. Lead Plaintiff and Class members within the scope of this cause of action have sustained damages. The value of Reata common stock has declined substantially subsequent to, and due to, the violations by Defendants named in this cause of action.

579. At the time Lead Plaintiff and other members of the Class within the scope of this cause of action purchased Reata stock, they were without knowledge of the facts concerning the wrongful conduct alleged herein, and could not have reasonably discovered those facts prior to the disclosures specified herein.

580. Less than one year elapsed between the time that Lead Plaintiff discovered, or could have reasonably discovered, the facts upon which this Complaint is based and the initial complaint in this action was filed. Less than three years has elapsed since the time that the securities at issue in this Complaint were bona fide offered to the public.

SEVENTH CLAIM
Violation of Section 12(a)(2) of the Securities Act
Against the Reata Defendants and the 2020 Offering Underwriter Defendants
(Relating to the 2020 Offering)

581. Lead Plaintiff repeats and realleges the allegations in ¶¶ 19-93, 464-65, 495-526 and 565-80 as if alleged fully in this claim, but only to the extent that such allegations do not allege fraud, scienter, or the intents of the Defendants named in this claim to defraud Lead Plaintiff or other Class members within the scope of this cause of action.

582. This claim is brought by Lead Plaintiff pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. § 77l(a)(2), on behalf of itself and all members of the Class who purchased or otherwise acquired Reata common stock in and/or traceable to the 2020 Offering and who were damaged thereby, against Reata, each of the Officer Defendants and Director Defendants, and the 2020 Offering Underwriter Defendants.

583. This claim expressly excludes and disclaims any allegation that could be construed as alleging fraud or intentional or reckless conduct, as this claim is solely based on claims of strict liability and/or negligence under the Securities Act. For purposes of asserting this claim, Lead Plaintiff does not allege that any of these Defendants acted with scienter or fraudulent intent, which are not elements of a Section 12(a)(2) claim.

584. Each of the Defendants named in this claim were sellers, offerors, and/or solicitors of purchasers of Reata stock pursuant to the defective 2020 Offering ProSupp. The actions of solicitation by the Defendants named in this claim included participating in the preparation of the false and misleading 2020 Offering ProSupp, a part of the Shelf Registration Statement, and marketing the 2020 Offering to investors, such as Lead Plaintiff and the other members of the Class within the scope of this cause of action. By means of the 2020 Offering Documents, Defendants sold approximately 2.0 million Reata shares in the 2020 Offering to Lead Plaintiff and

other members of the Class within the scope of this cause of action.

585. The 2020 Offering Documents contained untrue statements of material fact and omitted other facts necessary to make the statements not misleading, and failed to disclose material facts, as set forth herein.

586. Each of the Defendants named in this cause of action owed, to Lead Plaintiff and other members of the Class within the scope of this cause of action, the duty to make a reasonable and diligent investigation of the statements contained in the 2020 Offering ProSupp, to ensure that such statements were true and that there was no omission to state a material fact required to be stated to make the statements contained therein not misleading. By virtue of each of these Defendants' failure to exercise reasonable care, the 2020 Offering ProSupp contained misstatements of material facts and omissions of material facts necessary to make the statements therein not misleading.

587. Lead Plaintiff and other members of the Class within the scope of this cause of action purchased Reata stock pursuant to and/or traceable to the defective 2020 Offering ProSupp.

588. Lead Plaintiff did not know, nor in the exercise of reasonable diligence could Lead Plaintiff have known, of the untruths and omissions contained in the 2020 Offering ProSupp at the time Lead Plaintiff acquired Reata shares in the 2020 Offering.

589. By reason of the conduct alleged herein, the Defendants named in this cause of action violated and/or controlled a person who violated Section 12(a)(2) of the Securities Act, and are each jointly and severally liable for violations of Section 12(a)(2) of the Securities Act to Lead Plaintiff and the other members of the Class.

590. As a direct and proximate result of such violations, Lead Plaintiff and other Class members within the scope of this cause of action who acquired Reata shares pursuant to the 2020

Offering Documents sustained damages. Accordingly, Lead Plaintiff and the other members of the Class within the scope of this cause of action who hold shares issued pursuant to the Shelf Registration Statement have the right to rescind and recover the consideration paid for their shares with interest thereon or damages as allowed by law or in equity. Class members within the scope of this cause of action who have sold their shares seek damages to the extent permitted by law.

591. This cause of action is brought within one year of when Lead Plaintiff discovered or reasonably could have discovered the untrue statements and omissions in the 2020 Offering ProSupp, and within three years of the 2020 Offering ProSupp's effective date.

EIGHTH CLAIM
Violation of Section 15 of the Securities Act
Against the Individual Defendants
(Relating to the 2020 Offering)

592. Lead Plaintiff repeats and realleges the allegations in ¶¶ 19-93, 464-65, 495-526 and 565-91 as if alleged fully in this claim, but only to the extent that such allegations do not allege fraud, scienter, or the intents of the Defendants named in this claim to defraud Lead Plaintiff or other Class members within the scope of this cause of action.

593. This claim is brought by Lead Plaintiff pursuant to Section 15 of the Securities Act, 15 U.S.C. § 77o, on behalf of itself and relevant members of the Class within the scope of this cause of action, against each of the Officer Defendants and Director Defendants.

594. This claim does not sound in fraud. For purposes of asserting this claim under the Securities Act, Lead Plaintiff does not allege that any of these Defendants acted with scienter or fraudulent intent, which are not elements of a Section 15 claim.

595. Each of the Defendants named in this cause of action participated in the preparation and dissemination of the 2020 Offering Documents, and otherwise participated in the process necessary to conduct the 2020 Offering.

596. At all relevant times, each of the Officer Defendants and Director Defendants named in this cause of action were controlling persons of Reata within the meaning of Section 15 of the Securities Act. As set forth herein, because of their positions at Reata and/or because of their positions on Reata's Board, each of these Defendants had the requisite power to directly or indirectly control or influence the decision making of the Company and the conduct of Reata's business, including the wrongful conduct complained of herein.

597. In their capacities as senior corporate officers of the Company, and as more fully described above, the Officer Defendants had direct involvement in the day-to-day operations of the Company, and therefore are presumed to have had the power to control or influence the particular transactions giving rise to the securities law violations as alleged herein. They were also directly involved in providing false information and certifying and/or approving the false and/or misleading statements disseminated by Reata during the Class Period, including the 2020 Offering Documents which contained materially untrue information or omitted material information required to be disclosed to prevent the statements made therein from being misleading. As a result of the foregoing, the Officer Defendants, as a group and individually, were controlling persons of Reata within the meaning of Section 15 of the Securities Act.

598. The Officer Defendants named in this cause of action each signed the Shelf Registration Statement and/or controlled the contents and dissemination of the 2020 Offering Documents.

599. Similarly, each of the Director Defendants named in this cause of action, and Defendant Huff, served on Reata's Board of Directors at the time the 2020 Offering was conducted and/or at the time that the Shelf Registration Statement was signed. As directors of a publicly owned company, these defendants had a duty to disseminate accurate and truthful information with

respect to Reata's financial condition and operations. The Director Defendants named in this cause of action, and Defendant Huff, each signed the Shelf Registration Statement and controlled the contents and dissemination of the 2020 Offering Documents.

600. Each of the Officer and Director Defendants were culpable participants in the violations of Sections 11 and 12(a)(2) of the Securities Act alleged above, based on having signed the Shelf Registration Statement and/or having otherwise participated in the process that allowed the 2019 Offering to be completed.

601. As control persons of Reata, each of the Officer and Director Defendants are liable jointly and severally, under Section 15 of the Securities Act, with and to the same extent as Reata for its violations of Sections 11 and 12(a)(2) of the Securities Act.

602. As a direct and proximate result of the conduct of these Defendants, Lead Plaintiff and other members of the Class within the scope of this cause of action have suffered damages.

X. PRAYER FOR RELIEF

WHEREFORE, Lead 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 Lead 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 Lead 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.

XI. JURY TRIAL DEMANDED

Lead Plaintiff hereby demands a trial by jury.

Dated: June 21, 2022

Respectfully submitted,

STECKLER WAYNE CHERRY & LOVE PLLC

/s/ Bruce W. Steckler
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CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of June 2022, a true and correct copy of the foregoing document was served by CM/ECF to the parties registered to the Court's CM/ECF system.

/s/ Bruce W. Steckler
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