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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE CORCEPT THERAPEUTICS INCORPORATED SECURITIES LITIGATION	Case No. 3:26-cv-1525 **AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** CLASS ACTION DEMAND FOR JURY TRIAL Assigned to: Honorable Trina L. Thompson

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Lead Plaintiffs Allegheny County Employees' Retirement System ("ACERS"), Local #817 IBT Pension Fund ("Local 817"), and City of Tallahassee Pension Plan ("Tallahassee") (together, "Lead Plaintiffs"), by and through their counsel ("Lead Counsel"), bring this action individually and on behalf of all persons and entities that purchased or otherwise acquired the publicly traded common stock of Corcept Therapeutics Incorporated ("Corcept" or the "Company") after market close on October 30, 2024 and before market open on December 31, 2025, both dates inclusive (the "Class Period"), and who were damaged thereby (the "Class"). Lead Plaintiffs assert claims for violations of Sections 10(b), 20(a), and 20A of the Securities Exchange Act of 1934 (the "Exchange Act"), and Rule 10b-5 issued thereunder, against Defendants Corcept, Joseph K. Belanoff, M.D. ("Belanoff"), William Guyer ("Guyer"), Gary Charles Robb ("Robb"), and Sean Maduck ("Maduck," together with Belanoff, Guyer, and Robb, the "Individual Defendants").

Lead Plaintiffs allege the following upon information and belief, except as to those allegations concerning Lead Plaintiffs, which are alleged upon personal knowledge. Lead Plaintiffs' information and belief are based upon Lead Counsel's investigation, which included review and analysis of, among other things: (i) Corcept's regulatory filings with the Securities and Exchange Commission ("SEC"); (ii) press releases, presentations, and media statements issued and disseminated by Corcept; (iii) analyst reports and media commentary concerning Corcept; (iv) information supplied by former Corcept employees, industry professionals, and other knowledgeable persons described below; (v) documents made public by the U.S. Food and Drug Administration ("FDA"); and (vi) other public information regarding Corcept. Lead Counsel's investigation into the allegations contained in this Complaint is ongoing, and many of the relevant facts are known only by Defendants or are exclusively within their custody or control.

I. INTRODUCTION

1. Between October 2024 and December 2025, Defendants repeatedly misled investors about "relacorilant," the drug developed by Corcept to control certain effects of excessive cortisol and upon which the Company's financial future depended. Defendants highlighted what they called "***powerful evidence***" of the drug's efficacy, assured investors it was "***well tolerated***," and touted FDA's "***agreement***" with the drug's clinical trials and Defendants' conversations with

the agency as "***ordinary course [and] routine***." These statements convinced investors that relacorilant had a clear, easy path to regulatory approval, which Defendants projected would at least quadruple Corcept's annual revenues.

2. But none of this was true. Before the Class Period, FDA had privately warned Defendants "on several occasions" that Corcept's supposedly pivotal Phase 3 trial, upon which the drug's application was based, would not suffice to establish relacorilant's effect in the intended patient population and "to expect significant review issues" if they submitted the application based on such a trial. Defendants never disclosed this critical fact. Instead, Defendants decided to try to save their application with the results of a second, ongoing Phase 3 trial for relacorilant in a smaller population. But when that trial failed altogether, as Defendants publicly acknowledged, Defendants decided to forge ahead anyway, without telling investors the touted proof of efficacy they claimed from that second trial had been cobbled together from a post-hoc and therefore inherently biased analysis of a subset of the trial's data, entirely outside of the trial's governing protocols. The drug had also likely damaged four patients' livers, so it was not "well-tolerated."

3. Meanwhile, behind the scenes and while assuring the market that relacorilant's approval and $3 to $5 billion in annual revenue were on the horizon, the Individual Defendants and other Corcept executives sold nearly $100 million of Corcept stock to unsuspecting investors, including to Lead Plaintiffs. These sales were unusual, both in scope and timing. For example, Corcept's CEO, Defendant Belanoff, sold over $25 million in Corcept stock in 2025, after selling no stock at all since 2022, and did so pursuant to a trading plan executed during the Class Period.

4. Investors relied on Defendants' statements. Corcept's stock increased from a price of $48.97 per share on the first day of the Class Period to a Class Period peak closing price of just over $114 per share, and analysts gave relacorilant between a 90% and 95% chance of approval.

5. The music stopped when, on December 31, 2025, Corcept announced that FDA had refused to approve relacorilant and had issued a Complete Response Letter ("CRL") to Corcept the day before. Corcept's stock price collapsed more than 50% in a single trading day, erasing billions of dollars in market value and causing massive losses to investors. Later, when FDA publicly released the CRL itself, the full extent of Defendants' deception was laid bare.

6. By way of background, from 2012 and throughout the Class Period, Corcept's only revenue-generating product was Korlym, the commercial name of a drug Corcept sold to control certain symptoms of a rare condition caused by excessive cortisol called Cushing's syndrome. But Korlym's target patient population was limited from inception, including because the drug had safety risks and political baggage as its key active ingredient is mifepristone, a drug at the center of political debates. Moreover, Corcept's Korlym marketing exclusivity period was coming to an end, posing a direct and existential threat to Corcept's dominant revenue stream.

7. Starting in the mid-2010s, Corcept developed various compounds in search of a drug to replace its aging Korlym franchise. Relacorilant became the leading candidate because, as Defendants told investors, it would not carry Korlym's most serious side effects.

8. In 2018, Defendants began enrollment for a Phase 3 trial for relacorilant called "GRACE." GRACE consisted of two phases: (1) a 22-week "open-label" phase where every patient was given relacorilant, and (2) a "randomized-withdrawal" phase where patients who achieved prespecified improvements during the open-label phase could enter the withdrawal phase and then be randomized into a relacorilant or a placebo treatment arm for 12 weeks. For years, Defendants told investors that GRACE would be the sole basis for a future new drug application ("NDA") for relacorilant, but also steadily pushed back the expected NDA submission date—from early 2021 to, eventually, the end of 2024.

9. In 2020, Defendants announced a second Phase 3 trial for relacorilant called "GRADIENT." This trial studied a smaller subset of Cushing's patients than GRACE and, unlike GRACE, was designed as a fully randomized, double-blind trial. From the outset, Defendants told investors that GRADIENT's results were not needed for the relacorilant NDA and that GRADIENT was more like a "post-approval" study they happened to be conducting early.

10. As the Phase 3 trials dragged on, Corcept's efforts to develop other drugs and to maintain market dominance with its Korlym patent foothold faltered. In 2021, Corcept had to abruptly halt a trial for a drug that operates like relacorilant because it appeared to be seriously harming patients' livers. In 2023, Defendants' efforts to stop generic Korlym from flooding the market suffered a fatal blow when a court ruled Corcept's competitors could sell generic Korlym.

11. With the clock ticking away at their Korlym franchise, in April and May 2024 Defendants finally released GRACE's results. Defendants highlighted to investors that GRACE's second phase had met its primary endpoint (i.e., was successful), which, Defendants claimed, was powerful evidence of relacorilant's efficacy and would lead to its approval.

12. At the same time, Defendants shifted their message to investors about the upcoming NDA Defendants would submit to FDA. After years saying GRADIENT would not be part of the NDA, Defendants now told investors that the results from GRADIENT would be needed as "part of [the] NDA," to provide confirmatory evidence of relacorilant's efficacy.

13. But Defendants did not disclose to investors the reasons GRADIENT's data would now be needed. The reason was that, as Defendants knew, including from what FDA told the Individual Defendants in their private meetings, GRACE's trial results alone did not establish efficacy sufficient to garner approval, both because GRACE had studied a biased sample of the population and because Defendants had decided to conclude the GRACE trial before it could reach the originally targeted enrollment size. Relacorilant's approval now hinged on data from GRADIENT, but Defendants did not disclose this fact to investors, nor did they disclose FDA's specific warnings that GRACE's results would likely be insufficient for approval.

14. Instead, Defendants also rushed to complete the GRADIENT trial in April 2024, determined to submit the relacorilant NDA by the end of that year at all costs, as they privately messaged to Corcept's employees.

15. On October 30, 2024, the start of the Class Period, when Defendants announced GRADIENT's results, they were forced to acknowledge that GRADIENT had ***failed*** to meet its primary endpoint, failing to find relacorilant had a statistically significant effect in treating Cushing's-related hypertension. But Defendants nevertheless insisted, on that day and throughout the Class Period, that, based on their conversations with FDA and their understanding of FDA guidance, Defendants had an "***easy … argument to present to the FDA***" for approval. Defendants repeatedly told investors, including in SEC filings and earnings calls, that this was so because GRADIENT, despite failing to meet its primary endpoint, provided "***support***" for and "***further evidence***" of relacorilant's efficacy and that the trial had found "***clinically meaningful and***

statistically significant" improvements in treating Cushing's-related hypertension. Without disclosing FDA's warnings to the contrary, Defendants also told investors that GRACE showed "***meaningful improvements***" in patients' Cushing's symptoms and that its open-label results were part of the "***powerful evidence***" showing efficacy. They also told investors that "***no new safety signals were seen***" in relacorilant during the trials and that the drug was "***well tolerated***." And they insisted that they had "***agreement with FDA***" about the trials and the path to approval, and that their communications with FDA had been "***ordinary course***" and "***routine***." All this, Defendants claimed, pointed to a "successful path" for relacorilant's NDA and $3 to $5 billion in annual revenue, quelling any concerns about Corcept's sunsetting Korlym franchise.

16. Investors and analysts were persuaded. Relying on Defendants' representations, analysts pointed confidently to Phase 3 trial results as being key "derisking events" for Corcept's business and as providing meaningful evidence of relacorilant's efficacy and safety. Analysts and market insiders also took special comfort in FDA's supposed alignment with Corcept on the significance of the data and the path to approval. By the end of the Class Period, on the eve of FDA's decision deadline on the NDA, some analysts assigned a "90% probability of launch" because "[a]ccording to [Corcept] management, ***all pre-approval interactions with the FDA have been positive***." Another analyst gave even higher 95% odds for relacorilant's approval, also "from [their] conversation with management."

17. Unfortunately for investors, Defendants' representations were materially false and misleading. In truth, as Defendants knew all along but omitted from their public statements, FDA had privately expressed serious concerns about the clinical development program for relacorilant and told Defendants to expect significant review issues from an NDA based on those trials.

18. In private meetings, FDA had warned Defendants that because GRACE's primary endpoint came from studying patients selected precisely because they were already known to be highly responsive to relacorilant in the first place, and even then only studied a limited sample size of 43 patients, whatever efficacy was demonstrated in that small group overestimated relacorilant's true efficacy in the population at large and thus could not alone support a claim of efficacy. Defendants also knew that results from GRACE's open-label phase provided no meaningful

evidence of efficacy because it was unblinded and had no control group. All this was directly contrary to Defendants' Class Period insistence that data from GRACE was evidence of efficacy.

19. In addition, Defendants' claim that GRADIENT provided evidence of efficacy was based on an ***after-the-fact unblinded*** analysis of a small subset of data not originally contemplated by the study, rendering the analysis biased and unreliable—not strong proof of efficacy. This critical fact—that the supposedly "meaningful" or "significant" results from GRADIENT were plucked from a post-hoc analysis—was also not disclosed to investors.

20. As to statements about the drug's safety, in fact, as Defendants knew from the study results, four patients taking relacorilant in the Phase 3 trials experienced what is known as "drug-induced liver injury" or "DILI"—a serious condition that can lead to jaundice and even death—and had to be taken off the drug. As a result, relacorilant was ***not*** "well-tolerated."

21. Finally, Defendants' interactions with FDA about relacorilant were not "routine" or "ordinary course." Instead, across various pre-NDA submission meetings, the agency had "***on several occasions***" informed Defendants of its "***concerns***" with these trials and, essentially, told them to proceed at their own risk and "***expect significant review issues***" if they decided to do so.

22. The Individual Defendants, the architects of relacorilant's clinical development program, knew all of this because they personally attended the meetings where FDA repeatedly expressed its concerns. But the Individual Defendants decided to forge ahead anyway. Having committed themselves to a December 2024 NDA submission date to investors after years of delays, and while facing the end of their Korlym franchise, Defendants not only expected to receive substantial bonuses if they met this arbitrary, self-imposed deadline for the NDA's submission, but also maximized their personal wealth by selling Corcept shares while they alone knew the truth about FDA's warnings and relacorilant's true efficacy and safety profile.

23. The Individual Defendants and other Corcept executives adopted new Rule 10b5-1 trading plans at the start of the Class Period (or shortly before) and, as soon as those plans permitted, began dumping Corcept stock into the market, netting nearly ***$100 million*** for themselves—an increase of nearly ***650%*** from their pre-Class Period sales—all while insisting that approval and increasing revenues were fast approaching. Defendant Belanoff's Class Period $25

million in sales surpassed ***all his other*** Corcept stock sales in the Company's history. As FDA's decision date on relacorilant neared, the insiders sold more than $6.78 million, at prices roughly $45 per share above the $34.80 closing price four weeks later, and fundamentally at odds with Defendants' professed confidence in approval.

24. Corcept's investors did not fare so well. Before the market opened on December 31, 2025, Defendants were forced to disclose that FDA had summarily rejected the relacorilant NDA the previous day, unable to arrive at a favorable benefit-risk analysis for relacorilant. Even then, Defendants continued to obscure the truth, professing to be "surprised and disappointed" by a decision FDA had told them to expect, and characterizing the rejection as a mere request for "additional evidence" while claiming the agency had "acknowledged" the strength of their data.

25. But investors understood what Defendants' assurances had concealed: relacorilant was not on a clear path to approval. Investors were stunned by the denial, explicitly questioning the truthfulness of Defendants' earlier assertions that relacorilant was effective and would be granted FDA approval. By market close on December 31, 2025, the last day of the Class Period, Corcept's stock price plummeted by over 50% in just one day, causing investors massive losses.

26. Weeks later, when FDA publicly released a slightly updated version of its December 30, 2025 CRL, FDA publicly confirmed what investors had by then understood: Defendants had not been truthful about what the Phase 3 trials showed or about the relacorilant NDA, and had misled them into thinking FDA was in agreement with the Phase 3 trials and the NDA when, in reality, FDA had expressed serious concerns to Defendants about these matters and warned them to proceed at their own risk. This action seeks redress for Defendants' knowing decision to pass on that risk to unsuspecting investors, while cashing out their own holdings.

II. JURISDICTION AND VENUE

27. The claims herein arise under Sections 10(b), 20(a), and 20A of the Exchange Act, 15 U.S.C. §§ 78j(b), 78t(a), 78t-1, and Rule 10b-5(a)-(c) thereunder, 17 C.F.R. § 240.10b-5(a)-(c).

28. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337 and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

29. Venue is proper in this District under 28 U.S.C. § 1391(b) and Section 27 of the

Exchange Act, 15 U.S.C. § 78aa(b), because Corcept maintains its headquarters here and certain of the acts giving rise to the violations complained of in this action, including the preparation and dissemination of materially false and misleading statements, occurred in this District.

30. In connection with the acts alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to the mails, interstate telephone communications, and the facilities of the national securities exchanges.

III. PARTIES

A. Lead Plaintiffs

31. ACERS is a single employer defined benefit, contributory retirement benefit plan covering substantially all employees of the County of Allegheny, Pennsylvania, including, among others, police officers, firefighters, and other emergency service workers, as well as employees in the county's health department, public parks, and community living centers for the elderly and disabled. ACERS provides retirement, disability, and death benefits for employees and their families and has nearly 12,000 active and retired members.

32. Local 817 is a pension fund for members of the International Brotherhood of Teamsters Local 817, which represents workers in transportation, casting, and locations for theater, film, and television in the northeast United States. Local 817 has over $750 million in assets under management.

33. Tallahassee is a defined benefit plan for active and retired government employees of Tallahassee, Florida. Tallahassee manages retirement assets on behalf of the City's active and retired government employees, including policemen, firefighters, and general employees, providing retirement, disability, and death benefits to eligible participants and their beneficiaries.

34. As indicated in the certifications filed with this Court (ECF No. 33-2), Lead Plaintiffs purchased Corcept common stock at artificially inflated prices during the Class Period and suffered substantial losses as a result of the violations alleged herein.

B. Defendants

35. Corcept is a pharmaceutical company that develops and sells drugs that treat certain endocrine and oncological disorders, including by modulating the effects of the hormone

cortisol. Corcept was founded in 1998, including by Defendant Belanoff. Corcept is incorporated in Delaware, has its headquarters in Redwood City, California, and its common stock has traded on the NASDAQ under the ticker symbol "CORT" since 2004.

36. Belanoff co-founded Corcept and has been Corcept's Chief Executive Officer ("CEO") since 1999 and the President of the Company since 2014. Belanoff is a medical doctor who has been involved in all major Corcept business and strategic decisions since its founding. During the Class Period, Belanoff signed and certified each of Corcept's periodic SEC filings and made statements to investors and others about relacorilant's Phase 3 trials and NDA submission and Corcept's discussions with FDA about these matters.

37. Guyer, a clinical pharmacist by training, has been Corcept's Chief Development Officer ("CDO") since joining the Company in August 2021. Prior to joining Corcept, Defendant Guyer spent nearly 20 years at Gilead Sciences, Inc., including as Senior Vice President and Global Head of Medical Affairs. During the Class Period, Guyer made statements to investors and others about relacorilant's Phase 3 trials and NDA submission and Corcept's discussions with FDA about these matters, and reported directly to Belanoff.

38. Robb has been Corcept's Chief Business Officer ("CBO") since 2021 and served as Chief Financial Officer ("CFO") from 2011 to 2021. During the Class Period, Robb made statements to investors and others about relacorilant's Phase 3 trials and NDA submission and Corcept's discussions with FDA about these matters, and reported directly to Belanoff.

39. Maduck has been the President of Corcept's Endocrinology Division since April 2022. During the Class Period, Maduck made statements to investors and others about relacorilant's Phase 3 trials and NDA submission and Corcept's discussions with FDA about these matters. Maduck is one of the five senior executives identified in Corcept's Class Period Proxy Statements (along with Defendants Belanoff, Robb, and Guyer, and Corcept's CFO).

40. The Individual Defendants, because of their positions with Corcept, possessed the power and authority to control the contents of Corcept's reports to the SEC, press releases, and presentations to analysts and investors. Each of the Individual Defendants was 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, each of the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading.

C. Relevant Non-Parties

41. FE-1[1] served as Corcept's Senior Director of Regulatory Affairs and Program Management from March 2024 through April 2025. FE-1's responsibilities in this role included providing management support for Corcept's NDAs. FE-1 first reported to the Vice President of Corporate Regulatory Affairs, Ayse Baker. Once Baker was terminated in early December 2024, FE-1 reported to the Vice President of Quality Assurance & Regulatory Affairs, Christopher Golis. Both Baker and Golis reported directly to Defendant Robb.

42. FE-2 served as Corcept's Associate Director, Clinical Data Management from October 2021 through March 2026. FE-2 oversaw clinical data management quality systems and vendors supporting the GRACE and GRADIENT Cushing's program. In their role, FE-2 reported to Corcept's Senior Director of Clinical Data Management, who reported to Corcept's Head of Biometrics, who in turn reported to Defendant Guyer.

43. FE-3 was a member of the clinical development team who was employed at Corcept in 2018 and left the Company before the start of the Class Period.

IV. SUMMARY OF THE FRAUD

A. Corcept Has Only Ever Had One Revenue-Generating Product—Korlym

44. Corcept's principal focus since its founding in 1998 has been developing medications to treat disorders caused by the effects of the stress hormone cortisol.

45. Cortisol is the body's primary stress hormone that helps regulate the body's

[1] The terms "Former Employees" and "FE" refer to the former employees at Corcept whose accounts are discussed in this Complaint. To preserve their anonymity, the Complaint uses the pronouns "they" and "them" in connection with all Former Employees. Each FE is designated by number, such that Former Employee 1 is referred to as "FE-1," etc.

metabolism, blood pressure, and response to stress. However, prolonged exposure to excessive cortisol levels—a rare condition known as hypercortisolism or Cushing's syndrome—puts the body into a chronic stress-hormone overdrive and can lead to many serious medical problems and complications, such as high blood sugar (hyperglycemia) and high blood pressure (hypertension).

46. Hypercortisolism often results from a tumor in the glands that produce cortisol. The preferred treatment for Cushing's syndrome is surgery to remove the tumor responsible for generating excessive cortisol. But for the small subset of patients for whom surgery is not an effective option, some medications attempt to block the production of excess cortisol altogether, while other drugs attempt to block cortisol's effects on the body.

47. In 2007, Corcept filed an NDA to evaluate a product to treat hyperglycemia secondary to hypercortisolism in adult patients with Cushing's syndrome who have type 2 diabetes or glucose intolerance and have failed or are not candidates for surgery. In 2012, FDA granted Corcept an "orphan drug" designation for this product, which Corcept called Korlym. Drugs that treat rare conditions are commonly known as "orphan drugs," and this designation includes seven years of marketing exclusivity after approval.

48. Korlym's active ingredient is mifepristone, a drug that has existed since the 1980s and that has become well-known as the cornerstone of early abortion and pregnancy loss care.

49. Throughout the Class Period, virtually 100% of Corcept's total revenues derived from sales of its sole marketed product, Korlym, including its authorized generic version.

B. Investors Were Focused on Trials for Corcept's New Drug, Relacorilant, Given Defendants' Emphasis on Its Approval as Integral To Corcept's Future

1. Starting in 2017, Defendants Repeatedly Told Investors Relacorilant Would Replace Corcept's Aging Korlym Franchise

50. Korlym has always had a limited scope, both because of its narrow approved indication and because its active ingredient, mifepristone, can terminate pregnancies and cause serious side effects like endometrial thickening and vaginal bleeding.

51. Korlym's orphan drug marketing exclusivity period was set to expire in February 2019, after which competitors would have been legally permitted to seek FDA approval for generic equivalents, eating into Corcept's revenue from its only commercial product.

52. Given these intractable problems for Corcept's sole revenue-generating product, it was critical to Corcept's financial survival to develop and commercialize another product, which Defendants highlighted to investors repeatedly, before and throughout the Class Period.

53. To that end, Corcept developed four distinctive series of cortisol modulating drugs and eventually narrowed in on one such compound to replace Korlym for the treatment of Cushing's syndrome: relacorilant. Corcept's Phase I trial for relacorilant began in 2014. In October 2017, Defendant Belanoff and others published its results in a medical journal. Corcept's Phase II trial for relacorilant began in 2016 and was completed by early 2018.

54. Generally, when a company wants FDA approval for a new drug, it has to test the drug in people through a sequence of studies, each phase bigger and more demanding than the last. Phase 1 trials have small patient pools and are generally focused on testing the drug's safety and dose range, as opposed to whether it works. Phase 2 trials have a larger patient pool and test whether the drug *seems to work*, without conclusively testing efficacy. Phase 3 trials are larger, decisive trials, where a company must prove both efficacy and safety. The results of Phase 3 trials are the core of the application submitted to FDA for approval to market the drug.

55. Starting in 2017, Defendants repeatedly told investors they expected relacorilant would replace Korlym as Corcept's future core product. In a November 2, 2017 Press Release, Corcept's then-Chief Medical Officer announced relacorilant as Corcept's "top priority, with planning underway for an end-of-Phase 2 FDA meeting and the start of Phase 3 in the third quarter of next year."[2] Defendant Belanoff said: "I can't really think of any particular reason why anyone would stay on Korlym, if [relacorilant] actually proves to be as efficacious as we think it is."

56. Relacorilant, like Korlym, works by modulating the glucocorticoid receptor in human cells—which bind to steroid hormones like cortisol—but, according to Corcept, *does not* bind to the progesterone receptor, so it does not have some of Korlym's most serious side effects.

[2] Starting in 2019, Corcept also began developing relacorilant for use in certain types of ovarian cancer. Unless otherwise noted, all references to relacorilant in this Complaint, including references to relacorilant made in Defendants' materially false and misleading statements, are references to relacorilant for treating Cushing's syndrome, not cancer.

57. As Korlym's orphan drug marketing exclusivity came to an end and competitors began to seek FDA approval to market generic versions of Korlym, Defendants tried to extend their control over the market by initiating patent litigation against Corcept's potential competitor for the limited Korlym market. In March 2018, Corcept sued Teva Pharmaceuticals, its principal competitor, in the U.S. District Court for the District of New Jersey, claiming Teva's generic Korlym application violated Corcept's Korlym patents (the "Teva Patent Litigation").

58. While Defendants tried to slow generic competition for Korlym, they continued to assure investors they were committed to what became Plan A—relacorilant. During Corcept's November 1, 2018 earnings call, Defendant Belanoff again described relacorilant as the "planned successor to Korlym."

59. Relacorilant's role as Korlym's replacement became a recurring theme leading up to the Class Period. Defendant Belanoff repeated his description of relacorilant as the "planned successor" to Korlym at ***every single*** earnings call between November 2018 and November 2022, including stating in a February 2020 earnings call relacorilant would "entirely replace Korlym."

60. Leading up to the Class Period, analysts relied on Defendants' repeated statements that relacorilant was Corcept's financial future, particularly considering the risk that generic competitors would enter the market. For example, in a September 2019 report, H.C. Wainwright analysts noted that, of the medications in Corcept's "pipeline," analysts were "most excited about relacorilant," which would be "the primary driver of Corcept's long-term value." In early 2023, Jefferies analysts estimated Corcept stock would fall $8 to $9 per share if Teva's generic Korlym entered the market, and a November 2023 Seeking Alpha Report noted the "transition" to relacorilant was especially "critical in light of the ongoing patent dispute … over Korlym."

2. June 2018-July 2020: Defendants Announce the Start of Relacorilant's Phase 3 Trials, With "GRACE" Trial Results as the Sole Basis for the Drug's Planned FDA Application for Approval

61. In or about June 2018, Corcept discussed its forthcoming Phase 3 trial for relacorilant with FDA. According to FE-3, a member of the clinical development team who was employed at Corcept in 2018, Corcept, and specifically Defendant Belanoff, initially wanted GRACE to be structured solely as an open label study, but FDA insisted that Corcept needed a

placebo-controlled study. An open label study is one that is not blinded, randomized, or placebo-controlled. According to FE-3, Corcept initially fought adding a randomized placebo-controlled withdrawal study to GRACE, but subsequently conceded and added it to the study design.

62. On August 9, 2018, Corcept announced that, "[b]ased on FDA feedback," it had "developed response criteria for relacorilant's Phase 3 trial." Ladenburg Thalmann analysts reported that they were "impressed with the … FDA feedback about the Phase 3 study endpoints," as it was reported by Corcept.

63. In November 2018, Corcept announced in a press release it had begun dosing patients in a Phase 3 trial Corcept called "Glucocorticoid Receptor Antagonism in the Treatment of Cushing Syndrome" or "GRACE." During Corcept's November 2018 earnings call, Defendant Belanoff stated that Corcept expected this Phase 3 trial to be complete in "about" January 2021 and, during Corcept's May 2019 earnings call, stated it would be "reasonable to assume" Corcept would submit an NDA "three to six months" thereafter.

64. GRACE sought to enroll patients with endogenous Cushing's syndrome (where the excessive cortisol levels are caused by a tumor in the pituitary or in the adrenal glands) who were also exhibiting certain signs of hypertension or hyperglycemia, and then study whether relacorilant effectively helped control the patients' signs of hypertension or hyperglycemia.

65. Following Defendant Belanoff's initial resistance, GRACE was designed with two discrete phases. As Corcept described them during its November 7, 2019 earnings call (the "November 2019 Earnings Call"): "In the initial open-label phase, patients received relacorilant for 22 weeks. Those who exhibit prespecified improvements in glucose metabolism or hypertension are randomized to a double-blind placebo-controlled phase in which half continue receiving relacorilant and the rest are switched to placebo" for twelve additional weeks, i.e., the "randomized withdrawal phase," as opposed to the first, 22 week "open-label phase."

66. GRACE's original two "primary endpoints"—the main effects the study was designed to measure and the measure of the trial's success—were "improvement in glucose metabolism" and "hypertension." Defendants would later announce, in August 2023, that they had removed improvements in glucose metabolism as a primary endpoint. *See* ¶80.

67. The GRACE primary endpoint related to "hypertension" was measured at the end of the second, randomized withdrawal, twelve-week phase. The endpoint was the difference between the proportion of the placebo patients with loss of response (i.e., number with loss of response divided by the total number of placebo patients), and the proportion of the relacorilant patients with loss of response (i.e., number with loss of response divided by the total number of relacorilant patients). If that difference was statistically significant, then GRACE would be considered to "meet" its primary endpoint (which typically means the study was a "success").

68. GRACE's primary endpoints were prespecified in its "study protocol" (or "protocol") and its "statistical analysis plan" (or "SAP"). Clinical trials are guided by these two documents. The study protocol serves as the trial's operating manual, describing the trial's objectives, design, methodology, statistical considerations, organizational structure, background, rationale, and research questions. FDA guidance from September 1998 available on the agency's website explains that a SAP complements the study protocol by "provid[ing] a detailed elaboration of the principal features of the analysis described in the protocol," and it "include[s] detailed procedures for executing the statistical analysis of the primary and secondary [endpoints]." Together, the study protocol and SAP are designed to ensure that a trial's methodology and planned analyses are defined prospectively—i.e., before data collection is complete and analyzed—so that the results are transparent, objective, and reproducible. Both documents are eventually posted on the website *www.clinicaltrials.gov*. For example, "Amendment 7" of the GRACE study protocol and "version 2.0" of the SAP appeared on the website on May 17, 2024.

69. During the November 2019 Earnings Call, Defendant Belanoff stated Corcept expected GRACE would serve as "support [for] an NDA" and then pushed back the expected NDA submission date from the first half of 2021 to the "fourth quarter of 2021."

70. Defendant Belanoff further told investors that Corcept also "plan[ned] to open an additional Phase 3 trial" for relacorilant, designed specifically to study the drug's efficacy only in the subset of patients whose "Cushing's syndrome is caused by cortisol secretion from an [sic] adrenal adenoma." Defendant Belanoff told investors that "FDA has not required us to conduct" this study and that they "plan[ned] to base relacorilant's NDA on the results of GRACE."

71. On July 28, 2020, Corcept announced it had begun enrollment for this additional Phase 3 trial. This new study—which would eventually be named "Glucocorticoid Receptor Antagonism in the Treatment of Hypercortisolism in Patients With Cortisol-Secreting Adrenal Adenomas or Hyperplasia" or "GRADIENT"—had only one phase, which would be double-blind and placebo controlled. Like GRACE, GRADIENT also counted "improvements in glucose metabolism and hypertension" as its original two primary endpoints. Like GRACE's randomized-withdrawal primary endpoint, GRADIENT's primary endpoint related to hypertension and sought to measure whether relacorilant was associated with a statistically significant improvement in patients' hypertension symptoms, defined by prespecified measures.

72. For GRADIENT, "Amendment 3" of the study protocol and "version 2.0" of the SAP later appeared on the clinicaltrials.gov website on October 11, 2024.

3. February 2021-Early 2024: Corcept Repeatedly Delays Submitting the Relacorilant NDA and Cuts Off GRACE Enrollment

73. In the years that followed, Defendants reconfirmed that GRACE would be the sole basis for the relacorilant NDA and that GRADIENT would not be a part of the submission. Defendants also repeatedly delayed the expected date of that submission, even as Corcept's business faced other challenges that made relacorilant's approval even more urgent.

74. In February 2021, Corcept announced in its fourth quarter and full-year 2020 results press release that "pandemic-related public health measures" had "slow[ed] the pace of enrollment" in both trials and announced a delay in relacorilant's NDA submission of "as long as one year, to the second quarter of 2023."

75. Then, in May 2021, Corcept announced a disappointing setback in another glucocorticoid receptor modulator it had been studying, called "miricorilant." Miricorilant, like relacorilant, is intended to modulate cells' glucocorticoid receptors to lower or control the amount of cortisol in the blood. Corcept was studying miricorilant to treat a liver condition caused by high cortisol levels and had begun a Phase 2 study in November 2020.

76. However, in a May 6, 2021 press release, Corcept's then-Chief Medical Officer announced that the miricorilant Phase 2 study was halted almost as soon as it had begun because

four of the first five patients who received this version of the drug had experienced potential liver damage, known as "Drug Induced Liver Injury" or "DILI," as indicated by the elevated levels of a liver enzyme—alanine aminotransferase or "ALT"—in the blood. This served as a warning of the potential for liver damage in similar drugs, like relacorilant.

77. Meanwhile, enrollment of a sufficient number of patients for GRACE proved difficult. Defendants continued to push back the expected date of the NDA submission, while assuring investors they were working in concert with FDA. In a May 2022 earnings call, Corcept moved the date of the submission from the second quarter to the "second half of 2023." In a November 2022 earnings call, Defendant Guyer reiterated: "We are actively working on the [relacorilant] NDA, we're actively working with the FDA." In a February 2023 Form 8-K, Defendants delayed the expected NDA submission again, this time to "the first quarter of 2024."

78. Analysts, such as Truist in February 2023, reported that "[c]oncerns about the GRACE timeline … [were] weigh[ing] on [Corcept] stock," but they still believed, as Jefferies noted in April 2023, that "Phase III relacorilant data" would be Corcept's "[k]ey stock catalyst."

79. In May 2023 Corcept again delayed the NDA date to the first half of 2024. Jefferies analysts noted "the NDA submission has been delayed by almost 3 years" and that the delay was "disappointing" because "the speed to getting relacorilant NDA filed, approved, and on the market is important to blunt the pot[entia]l negative impact from generic Korlym" sold by Corcept's competitors. At the same time, the Jefferies analysts confirmed the market's understanding that relacorilant was essential to the "big bull thesis for [Corcept's] stock."

80. After many years of delays, during Corcept's August 2, 2023 earnings call, Defendant Belanoff finally announced that "enrollment in GRACE [was] complete" and that Defendants expected to submit the relacorilant NDA in "the second quarter of 2024." He also again reminded investors that Defendants "d[id] not expect our NDA in Cushing's syndrome to depend on data from GRADIENT," which instead would just "produce valuable data." Defendant Guyer added that Corcept was "collaboratively work[ing] with the FDA."

81. Days later, on August 7, Corcept also removed improvements in hyperglycemia symptoms in the randomized-withdrawal phase from GRACE's primary endpoints, leaving as the

study's sole primary endpoint loss of response with respect to hypertension in the second phase. This change appeared in the version of the GRACE study details on clinicaltrials.gov, though as late as Corcept's November 1, 2023 earnings call, Defendant Guyer still referred investors to the "response to hypertension ***and/or diabetes control***" as the basis of GRACE's primary endpoints.

82. Internally, and unknown to investors, the August 2023 enrollment cutoff raised serious concerns about the trial's completeness. FE-2 oversaw clinical data management for the GRACE and GRADIENT trials. FE-2 stated that there was a rush to get the NDA in, and that Corcept cut off GRACE enrollment before reaching the trial's original target sample size so that Corcept could announce "completed" enrollment at quarter-end in August 2023.

83. FE-2 noted that Defendants did not announce that GRACE had reached its enrollment target; they announced only that enrollment was now completed. FE-2 estimated that Corcept did not reach 100% of its target enrollment goal before Defendants cut enrollment off. FE-2 explained that, statistically speaking, the study had to get to 100% enrollment because absent efficacy already known to be strong enough to justify a smaller sample, Defendants should not have cut enrollment.

84. FE-2 explained that certain clinical trials are prospectively designed to incorporate a "Bayesian" statistical analysis, which permits enrollment to be closed early—sometimes as early as 30 to 40 percent of planned enrollment—but only where the observed efficacy is "great." GRACE was not designed that way. According to FE-2, GRACE's sample size was structured around the interval to worsening of Cushing's symptoms, not unlike an oncology trial, and the relacorilant trials did not have a Bayesian analysis built in, such that there was no Bayesian analysis to be performed. Defendants therefore had no prospectively specified statistical basis on which to close enrollment early and did so knowing that GRACE required its full planned enrollment to be adequately powered.

85. Confirming this account, the GRACE study protocol states that it planned to enroll 162 patients but the official results reported that 152 patients were ultimately enrolled. Moreover, Defendants had violated their own GRACE study protocol, which stated, "randomization of patients in the [randomized-withdrawal] phase ***will continue*** to ensure enrollment of 46 patients

meeting response criteria within the hypertension subgroup" because "[t]his sample size will provide sufficient power to detect the target differences in the primary endpoint for the hypertension subgroup." In the end, as per the posted GRACE results, only 43 patients were analyzed within the hypertension subgroup.

86. FE-2 stated that when Defendants closed enrollment, they did so by reference to a calendar date rather than a patient count: Corcept picked a date instead of a number of patients, clinical operations was simply given a deadline and told that "whatever you got, you got," and the last day of enrollment was August 1, 2023. FE-2 stated that Defendant Belanoff and the C-suite—specifically Defendants Guyer and Robb—were the only persons with authority to direct that enrollment would end on a specific date, noting that the clinical team could halt enrollment only if a safety issue arose.

87. As soon as Defendants cut off GRACE enrollment, FE-2 began to have doubts about FDA approval. FE-2 told FE-2's supervisor, Corcept's Senior Director of Clinical Data Management—who reported to Corcept's Head of Biometrics, who in turn reported to Defendant Guyer—that FE-2 "would be remiss" if FE-2 told the supervisor it would be acceptable to reduce the sample size, and FE-2 had that conversation with FE-2's supervisor more than once. FE-2 noted that the supervisor agreed that it would be very difficult for GRACE to obtain approval.

88. According to FE-2, both FE-2 and FE-2's supervisor had a good idea that the FDA was not going to approve relacorilant at that point, reasoning that if a sponsor cuts off enrollment its efficacy "better be pretty darn good" and "the efficacy would have to be better." Both FE-2 and FE-2's supervisor had decades of industry experience, and both had access to the trial data, the protocol, and the accumulating efficacy results. Although GRACE was blinded, FE-2 could draw educated inferences from the expected adverse effects and efficacy trends. At FE-2's most optimistic FE-2 regarded relacorilant's approval as "a coin toss," and FE-2's doubt only grew after the sample size was reduced, which occurred in mid-2023. FE-2 raised their objection with their supervisor and told the supervisor not to cut off enrollment. That advice was not followed as evidenced by the August 1, 2023 cutoff. After FE-2 had those discussions, FE-2 was taken off the GRACE and GRADIENT projects. None of this was publicly disclosed.

89. Nevertheless, with GRACE's enrollment complete, Defendants focused on the steps remaining before Corcept could submit the relacorilant NDA and increasingly publicly discussed the implications for Corcept's finances from relacorilant's approval.

90. For example, during the September 2023 H.C. Wainwright Investment Conference, Corcept's CFO Atabak Mokari assured investors that the fact that GRADIENT was still ongoing was not an impediment to submitting the NDA because GRADIENT was "a post-approval marketing study that [they]'re just happening to do pre-approval," so it "won't be the registrational study." Mokari also stated that Korlym's "political baggage" and "side effects" were the "leading cause of drug discontinuation for Korlym" and that, by removing Korlym's side effects, relacorilant would "expand[] the market opportunity for Korlym by 2 to 3 times."

91. During Corcept's November 1, 2023 earnings call, one analyst asked whether Corcept would "want to wait for the GRADIENT study by mid-year to submit a more fuller picture of [relacorilant]" and whether "the FDA [would] want to see it." Defendant Robb responded that "the most important demonstrator of [relacorilant's] safety and efficacy" was the GRACE trial. He added: "We think that's sufficient to support our NDA and so we're going to go with that, because it will be ready and ready first, ready to proceed and just continue to move our business forward as expeditiously as possible."

92. Analysts thus continued to understand that GRACE was the key—in the words of Piper Sandler analyst reports in May and November 2023, that "GRACE is the pivotal study for regulatory purposes" and that "results from GRADIENT are not a condition of FDA approval." Analysts also continued to understand that relacorilant was vital to Corcept's financial future. In November 2023, a Truist analyst called relacorilant the "key growth driver[]" for Corcept.

93. But the relacorilant NDA submission took on yet more urgency when, on December 29, 2023, following a bench trial, a federal judge ruled Corcept had not proved patent infringement and entered judgment in Teva's favor in the Teva Patent Litigation.

94. Piper Sandler analysts, in a January 1, 2024 report, noted that "the legal outcome … is undoubtedly disappointing" but "remain[ed] constructive on CORT shares given our view that next-generation selective cortisol modulator relacorilant … will over time widen CORT's

Cushing's syndrome (CS) franchise." On January 2, 2024, H.C. Wainwright & Co. analysts similarly "remain[ed] bullish on [the] Cushing Syndrome franchise" as "[w]e continue to expect Corcept to file the new drug application (NDA) for relacorilant in 2Q24." Truist analysts noted that "the commercial availability of relacorilant would make the court ruling … a non-event." Bullish on relacorilant's potential despite the legal setback on Korlym, analysts also increased their price targets for Corcept stock. Truist analysts increased their price target by over 30% to $38 per share in November 2023, and then again to $42 per share in April 2024. Ladenburg Thalmann analysts raised their price target to $50 per share and then to $61 per share in a January 2024 report.

4. April-September 2024: Defendants Announce GRACE Results. Pivot to Recharacterizing GRADIENT as Part of the NDA, and Cut Off Its Enrollment

95. In an April 1, 2024 press release, Corcept announced it had "completed" enrollment for GRADIENT.

96. Within Corcept, a well-placed insider and former Senior Director described how the GRADIENT enrollment cutoff was seemingly driven more by the need to submit the NDA by the end of 2024 than by the study's requirements to prove efficacy.

97. According to FE-1, Corcept's Senior Director of Regulatory Affairs and Program Management from March 2024 through April 2025, the relacorilant NDA process was one of the most secretive they had ever seen in their 20 years in program management in the pharmaceutical industry. When FE-1 was first hired at Corcept, FE-1 reported to former Vice President of Corporate Regulatory Affairs Ayse Baker, until she was fired in early December 2024, and then reported to Christopher Golis, who became the Vice President, Quality Assurance & Regulatory Affairs at that time. Baker and Golis reported directly to Defendant Robb. FE-1 described the volume of amendments to the relacorilant trial protocols as an "infinite" number of amendments and completely out of the ordinary compared to any other program they had worked on.

98. FE-1 described how Defendant Belanoff was completely involved in preparing Corcept's NDAs, and stated that the relacorilant Project Management team reported up to Defendant Guyer. Defendants Guyer and Robb therefore sat at the top of the internal body that built the relacorilant NDA. According to FE-1, based on their experience at Corcept, Defendants

Belanoff and Robb attended the August 2024 pre-submission meeting with the FDA and post-submission meetings, and Defendant Guyer most likely also attended because the Medical Directors on the submission reported to him. FE-1 explained that nothing was done at Corcept without Defendant Belanoff's knowledge.

99. FE-1 stated that Corcept cut off GRADIENT enrollment to force the NDA filing timeline to 2024. FE-1 stated that they believed that enrollment was cut off in mid-2024 to force the filing date, which was then moved from an original June 2024 deadline to October 2024, and ultimately to December 31, 2024. According to FE-1, the directive that the NDA submission "had to happen by December 31st" came from Defendant Belanoff through Defendant Robb. None of this was disclosed publicly.

100. Meanwhile, on April 22, 2024, nine months after declaring that GRACE's enrollment was complete, Defendants finally announced the results of GRACE's open-label (but not the randomized-withdrawal) phase, stating in a press release that the "[p]atients in the open-label phase exhibited clinically meaningful and statistically significant improvements in hypertension, hyperglycemia and other key secondary and exploratory endpoints." Defendants also said relacorilant "was well-tolerated, consistent with [its] known safety profile."

101. Analysts reacted positively to this news. In an April 22, 2024 report headlined "GRACE [Open Label] Shows Strong Efficacy With Good Safety," Truist analysts wrote that "efficacy from the open label portion … looks strong with good tolerability, a key differentiator." Piper Sandler analysts, in a report also released on April 22, stated, "[w]e like the efficacy" shown in the open-label results, "particularly in the context of the absence of … adverse events associated with Korlym." A Ladenburg Thalmann report released on April 23 reiterated that firm's "Buy" rating for Corcept stock due to the "Positive P3 GRACE OL Data," noting that "[r]elapse with respect to hypertension" was "the endpoint the FDA has accepted for GRACE."

102. On May 1, 2024, Corcept issued its earnings press release and Form 10-Q for the fiscal first quarter of 2024 and held an earnings call. In this press release, Defendant Belanoff stated that "[t]he results of the open-label phase of our GRACE trial … are compelling," and Defendant Guyer stated that "[p]atients in GRACE's open-label phase exhibited significant

improvements across a broad range of clinically meaningful endpoints, without significant safety burden." On Corcept's earnings call Defendant Belanoff repeated that "[p]atients in the open-label phase of GRACE exhibited clinically meaningful and statistically significant improvements," telling investors that "[r]elacorilant was well tolerated, consistent with its known safety profile."

103. After the earnings call, analysts again celebrated the open label results. For example, Truist analysts in a May 1 report raised their price target for Corcept stock from $42 to $44 per share due to "significant upside … if Ph3 GRACE is unequivocally positive." The next day, an H.C. Wainwright & Co. report stated that "[g]iven the positive data released to date, we expect a positive decision from the FDA" on relacorilant and increased its price target to $40. Ladenburg Thalmann analysts reported that "[i]mportantly, rela[corilant] was well tolerated."

104. On May 28, 2024, Corcept announced GRACE's full results in a press release (the "May 28, 2024 Press Release"), stating that the randomized withdrawal phase had "met its primary endpoint of loss of blood pressure control" and that "patients experienced … [no] significant safety burden." Defendant Guyer said in the May 28, 2024 Press Release that "GRACE's clearly positive results … constitute a significant step toward our new drug application for relacorilant."

105. Analysts lauded GRACE's randomized withdrawal phase results, connecting the results and their understanding that the trial had "support" from FDA to relacorilant's odds of FDA approval and, consequently, to the future of Corcept's business. A May 28, 2024 Canaccord report stated: "we view the Teva patent litigation on Korlym as being less significant given that relacorilant, we believe, has a high likelihood of receiving FDA approval" and that "the design of GRACE was driven by the FDA along with the trial's primary endpoint." Truist analysts saw the GRACE results as "highly positive" and stated "[a]pproval of Relacorilant [was] In Sight." Ladenburg Thalmann analysts increased their Corcept stock price target from $61 to $70.50 per share "based on the top line data showing GRACE study achieved the primary endpoint."

106. In the May 28, 2024 Press Release Defendants also announced that they had again pushed back the submission of the relacorilant NDA, from the second to the third quarter of 2024.

107. Then, by no later than June 2024, Defendants' statements to the market began to further emphasize to investors FDA's views of the relacorilant clinical development program and

the role the agency's views played in shaping the trials and upcoming NDA. For example, based on Defendants' statements and communications, in early June 2024, various analysts reported that GRACE's "sole primary endpoint[] was supported by the FDA" (Canaccord), "agreed upon" and "agreed to" by FDA (Truist), and "agreed upon with FDA" (Ladenburg Thalmann).

108. As these statements to analysts show, Defendants were in active discussions with FDA about GRACE's results and the relacorilant clinical program around this time.

109. Significantly, no later than early June 2024, Defendants also changed their public message to investors about the role GRADIENT would play in the relacorilant NDA—from a "post-approval" study (*e.g.*, ¶90), to providing "support" for or "as part of" the NDA. In explaining this change, Defendants again made it seem as though they were in agreement with FDA on the relacorilant clinical development program, highlighting that the decision to submit GRADIENT data as part of the relacorilant NDA was specifically because of discussions with FDA. However, Defendants never disclosed ***the reason why*** GRADIENT had shifted from not being a part of the NDA to now becoming a part of the expected submission, nor did they disclose ***why the meetings with FDA had resulted in this shift***.

110. On June 11, 2024, Truist analysts released a report summarizing their recent conversations with Corcept management. As reflected in the report, Defendants highlighted FDA's supposed approval of GRACE's design and repeatedly noted their discussions with FDA. The Truist analysts' questions and Corcept's answers, as reported, include the following:

- **Q:** Has [t]he FDA signed off on GRACE 3 as sufficient for NDA submission from efficacy standpoint?
  A: Based on our discussions with the FDA, we expect GRACE to serve as the basis for our NDA submission.

- **Q:** Will you need Ph3 GRADIENT for the FDA approval of relacorilant?
  A: ***Based on our discussions with the FDA, we expect to submit the safety data from the GRADIENT study as part of our NDA*** …

- **Q:** Will you disclose when you have a pre-NDA meeting?
  A: We are in regular discussions with the FDA and don't comment beyond that.

- **Q:** What keeps you up at night?
  A: I get great sleep. We have a drug in hypercortisolism that has a strong efficacy and safety profile, hit its primary endpoint and is on the path to approval next year … and

> has peak sales of north of $3 billion … Drug development is never easy but I think we're in an enviable position.

111. On July 14, 2024, after Truist analysts again "hosted CORT m[anagement]," they published another report stating that "Mgmnt didn't get much, if any, push back on the veracity of Ph3 GRACE data" from FDA and that "mgmnt reiterated that FDA has agreed to Odds Ratio as the analytic method for the primary efficacy analysis."

112. On July 29, 2024, Corcept issued its earnings press release and held an earnings call with investors. The release informed investors that Corcept now planned to submit the relacorilant NDA in the fourth quarter of 2024. During the earnings call, Defendant Belanoff told investors that "GRACE met its primary endpoint" per the study's statistical analysis plan "in place with the FDA." When an analyst asked about "the reason for the delay in [the] relacorilant NDA submission," Defendant Robb responded that after "regular conversation with the FDA" during which "the information [wa]s exchanged[and] things were discussed," Defendants had decided "to include [] data from our GRADIENT trial … in the NDA submission." Once again analysts took note. For example, Truist reported that day that "it appears the FDA may also want inclusion of efficacy from GRADIENT for a fuller picture of relacorilant." Again, Defendants did not disclose the reasons for this shift beyond stating it came after a discussion with FDA.

113. During the July 29 earnings call, Defendants also focused investors on the revenue that relacorilant would generate, with Defendant Maduck stating "relacorilant could be priced at a premium to Korlym, given its favorable efficacy and safety profile."

114. Defendants had at least one additional pre-NDA submission meeting with FDA, in or around August 2024, a meeting that was confirmed by FE-1 and Defendants' own statements to the market.

115. On September 2, 2024, Defendants posted on clinicaltrials.gov a change to GRADIENT's primary endpoints from dual hypertension and hyperglycemia endpoints to a single hypertension endpoint—the same change made to GRACE in August 2023, *see supra* ¶81—and told analysts that this, too, had resulted from consultations with FDA. In a September 19, 2024 report, Truist analysts reported that Corcept management had "confirmed to us that the endpoint

has indeed been updated from a co-primary to single primary in alignment with the FDA." Canaccord analysts similarly reported on September 24, 2024 that Corcept management "indicated that" the change was made "in consultation with the FDA."

116. On September 29, 2024, Truist analysts noted that Corcept's "original plan was to submit" GRACE as a "standalone … study to seek regulatory approval of relacorilant, followed by inclusion of GRADIENT data sometime later," but that "the decision was recently made, in consultation and agreement with the FDA, to include both GRACE and GRADIENT as part of the NDA package." The Truist analysts also reported that GRADIENT had been updated to a single primary hypertension endpoint, given what Corcept "and the FDA were discussing."

C. During the Class Period, Defendants Tell Investors the Phase 3 Trials Show Relacorilant is Effective and Safe, and Assure them Approval is Imminent, All While Selling Their Own Corcept Stock

1. October 2024: Defendants Tell Investors Relacorilant's Phase 3 Results Present an "Easy" Argument for Approval

117. The Class Period begins after the market's close on October 30, 2024, when Corcept issued an earnings release for the third quarter of 2024 and associated Form 8-K (the "October 2024 Press Release") and a Form 10-Q for the third quarter of 2024 ("October Form 10-Q"), and held an earnings call with investors. In these communications, Defendants delivered a single, unified message: the results from both studies were significant evidence of relacorilant's efficacy and safety and would lead to approval, and that FDA was aligned with Defendants.

118. In the October 2024 Press Release, Corcept announced GRADIENT's results. The press release acknowledged that GRADIENT missed its primary endpoint but nevertheless announced, without further discussion, that GRADIENT's results "***support [the] findings from [the] pivotal Phase 3 GRACE study***" and that patients in GRADIENT "***exhibited clinically meaningful and statistically significant improvements***." The release also stated that "***relacorilant was well-tolerated, with a safety profile consistent with the GRACE study***."

119. The October 2024 Press Release also quoted Defendant Guyer as stating that (i) "***GRADIENT's positive results in patients with Cushing's syndrome confirm relacorilant's promise*** as a significant medical advancement"; (ii) "***As was true in the GRACE study***, ***patients***

in GRADIENT who received relacorilant experienced clinically meaningful improvements"; and (iii) "[t]hese data will be a ***powerful addition to relacorilant's NDA***." The release also stated that "[t]he pivotal ***Phase 3 GRACE trial*** … ***met its primary endpoint***," with patients "***exhibit[ing] clinically meaningful and statistically significant improvements***," and further stated that, despite GRADIENT missing its primary endpoint, "[a]s part of relacorilant's NDA in Cushing's syndrome, the 22-week Phase 3 ***GRADIENT study supports the GRACE trial by providing further evidence of relacorilant's efficacy and safety profile***."

120. During Corcept's October 30, 2024 earnings call, Defendant Belanoff stated that the "results from our GRACE and GRADIENT Phase 3 studies ***clear the path for relacorilant's new drug application***," that "[p]atients in the GRACE and GRADIENT studies experience[d] ***meaningful improvements***," and that while the GRACE "***provide[s] powerful evidence for our NDA***," GRACE's results did not "stand on their own" because "GRADIENT's data ***will support our NDA by providing further evidence of relacorilant's efficacy and safety, confirming what we found in GRACE***." Defendants again acknowledged that GRADIENT had failed its primary endpoints, but Defendant Belanoff nevertheless stated patients in GRADIENT showed "***clinically meaningful and statistically significant improvements in hypertension***," without any additional disclosure as to the basis for or true facts underlying that statement. Corcept also displayed an investor presentation containing substantively identical representations, including that "***GRADIENT: Results Support Findings from [GRACE]***" and, as to "***Safety***," that relacorilant was "***well-tolerated***."

121. During this call, analysts zeroed in on GRADIENT's results, Defendants' interactions with FDA with respect to GRACE and GRADIENT, and relacorilant's path to approval. The first question from analysts was whether "GRADIENT [was] needed [for] a full approval" and whether Defendants' "communication with the FDA [had] changed regarding the role of GRADIENT in the NDA?" In response, Defendant Guyer stated that: (i) Defendants' "***agreement with the FDA***" was that "***GRACE was always going to be our pivotal study***"; (ii) Corcept had "***met our primary endpoint for GRACE***"; (iii) "***GRADIENT … supports the successful path to an NDA***, ***because we see clinically significant improvements in all signs and***

symptoms of Cushing's syndrome, including improvements in blood pressure"; (iv) there was "***broad improvement of Cushing's syndrome from the GRADIENT study***"; (v) "***no new safety signals were seen in the GRADIENT trial***" confirming "***what we saw in GRACE***"; and (vi) "***we believe we have a successful path to a positive NDA for relacorilant***."

122. Another analyst similarly asked if the view of "GRACE [as] the pivotal" and "GRADIENT … as a supportive study" was "shared by the FDA?" Defendant Robb said: "***The answer is yes***" because "***this isn't some … dark art where we have to guess what's on the FDA's mind***. I mean, there's published guidance, as well as any conversations the sponsor may have, or the FDA has ***made it clear that a single well-controlled study, which we have in the form of our GRACE and [that] the data from GRACE, along with confirmatory evidence***, ***is sufficient to demonstrate a drug safety and efficacy***." Robb continued: "***I just wanted to underscore, from the perspective of the person who has to go in with the team and present the arguments to the FDA, just what a good position we're in … It's that easy an argument to present to the FDA***." The analyst also asked about Corcept's interactions with FDA, specifically about the forthcoming NDA. Defendant Belanoff said Defendants had "***talked to the FDA plenty about this program***" and that he "***fores[aw] absolutely no impediments to getting our NDA in***." During the call, Defendant Guyer similarly assured investors "***we have a successful path to a positive NDA***."

123. During this call, Defendants also continued to focus investors not only on relacorilant's supposed safety and efficacy, but on how that would translate to significant revenues for Corcept and, therefore, value to its shareholders. Adopting Defendant Guyer's and Belanoff's statements during the earnings call, Defendant Maduck stated relacorilant "***shows efficacy across multiple, and all signs and symptoms of Cushing's syndrome***, ***as [Guyer] just walked through and [Belanoff] walked through in his comments***, and ***has significant safety benefit … So, because of this fact and because of where we see this growth going, we believe we're on track to be a $3 billion business in the next five years***."

124. Analysts responded positively to Defendants' statements and the news they communicated, including Defendants' representations that the trial results cleared the way for regulatory approval and that FDA had agreed with Defendants' studies and approach.

125. In a report published October 30, 2024, Canaccord analysts wrote that they had "had a call with [Corcept] management post the earnings release, and ***the company is as confident now as prior to the GRADIENT trial data that relacorilant is very likely to receive FDA approval***." The Canaccord report continued: "Management reiterates that, per FDA's guidance, the filing should be supported with data from one pivotal study and supporting evidence from an additional study. The company believes that ***the data package in rela[corilant]'s submission will be composed of more than sufficient supporting clinical evidence***, and importantly, the ***efficacy measurements demonstrate a broad clinical benefit*** of rela[corilant] for Cushing's patients." The Canaccord analysts concluded, "Will relacorilant receive FDA approival [sic]? We say, YES."

126. Piper Sandler analysts, also on October 30, stated: "[W]e continue to believe that approval of relacorilant on the existing body of data … is more likely than not." The same day, Truist analysts similarly reported that the "totality of data warrants approval."

2. November 2024: After Reassuring Investors About Relacorilant's Approval, Corcept Insiders Begin Selling Their Corcept Stock to Investors and Prepare to Sell More Stock

127. Within days of the October 30, 2024 earnings call during which Defendant Belanoff told investors that the GRACE and GRADIENT results "clear the path for relacorilant's new drug application"; Defendant Guyer assured investors "we have a successful path to a positive NDA"; and Defendant Maduck relayed that the trials "show[] efficacy across multiple, and all signs and symptoms of Cushing's syndrome" and could lead to manifold increases in Corcept's annual revenue (and, presumably, its stock price), these same Defendants all began selling their Corcept stock in amounts that far exceeded prior sales.

128. Over the next few days—and throughout the remainder of the Class Period—the Individual Defendants all sold their Corcept stock to unsuspecting investors, as did at least three other high-ranking Corcept officials—Chief Accounting and Technology Officer Joseph Lyon ("Lyon"); and Board Members David Mahoney ("Mahoney") and Daniel Swisher, Jr. ("Swisher," together with Lyon, Mahoney, and the Individual Defendants, the "Insider Executives").

129. Defendant Guyer sold 6,606 shares of Corcept stock on November 1, 2024, and 3,394 shares on November 4, for total proceeds of $489,700.

130. Swisher sold 2,200 shares on November 11. Defendant Robb made an unplanned open-market sale of 2,609 shares on November 22. Lyon also sold 1,411 shares the same day.

131. Moreover, while the Individual Defendants were putting the finishing touches on the long-awaited relacorilant NDA, certain Defendants were also putting the finishing touches on brand new Rule 10b5-1 trading plans to further sell their stock to unsuspecting investors before FDA's decision on the NDA.

132. On November 26, 2024, Defendant Belanoff adopted a new Rule 10b5-1 trading plan, responsible for the entirety of his Class Period sales—having just assured investors on October 30 the path for the NDA was "clear." Defendant Belanoff's plan was structured to start selling immediately after the statutorily required 90-day cooling off period, and thereafter liquidated 40,000 shares in each of March, April, May, June, August, September, October, November, and December 2025. Pursuant to this plan, Defendant Belanoff ended up selling over $25 million worth of Corcept stock during the Class Period.

133. On November 27, 2024, Defendant Guyer also adopted a brand-new trading plan and, through that plan, sold 200,000 shares of his Corcept stock for Class Period proceeds of $14,821,761. Defendant Guyer's plan also executed monthly throughout 2025.

134. Defendant Maduck similarly executed a new trading plan on September 5, 2024, shortly after Corcept made an amendment to its clinical protocol following a meeting with FDA, and less than two months prior to the announcement of the GRADIENT results. Pursuant to this plan, Defendant Maduck sold 340,000 Corcept shares for proceeds of over $27 million.

3. December 2024: Defendants Submit the Relacorilant NDA and Continue Misleading Investors

135. On December 30, 2024, Defendants announced in a press release they had submitted the relacorilant NDA to FDA. In the release, Corcept stated that the "***NDA is based on positive results from the pivotal GRACE trial and confirmatory evidence from the Phase 3 GRADIENT*** and long-term extension studies and a Phase 2 study in hypercortisolism" and noted relacorilant's "***acceptable safety burden***." In the press release, Defendant Belanoff emphasized "***[r]elacorilant's combination of efficacy and safety***."

136. Behind the scenes, FE-1 described a chaotic race to submit the NDA by year end. According to FE-1, Ayse Baker, the Vice President of Corporate Regulatory Affairs who had controlled FDA communications and NDA preparation, was fired in approximately November or early December 2024, shortly before the filing deadline. Baker was replaced by a junior employee, Associate Director Cameron Capper, whom FE-1 described as having no experience and having never filed an NDA before. FE-1 described the subsequent NDA preparation as chaos, stating that a minor skeleton crew worked with Christopher Golis, Corcept's Vice President of Quality Assurance who took over Baker's role, over the winter holidays to complete the submission by December 31. According to FE-1, the directive that the NDA submission "had to happen by December 31st" came from Defendant Belanoff through Defendant Robb.

137. FE-1 recounted how Corcept's senior management harbored internal concerns about the handling of the relacorilant trial data. According to FE-1, Golis told FE-1 that Golis "had concerns over how" Corcept's Vice President and Head of Biometrics "handled data" for relacorilant. FE-1 further recalled that Defendant Robb told FE-1 that Corcept executives were disappointed with the Head of Biometrics' performance, "but they had to keep her because of her knowledge." The Head of Biometrics was, per FE-1, very involved in the studies and was the statistician who would have been involved in responding to FDA's inquiries.

138. Investors knew nothing of the chaotic path to the NDA submission or internal concerns with the handling of data, and analysts reacted positively to the news that the NDA was finally with FDA for review. In a January 28, 2025 report, H.C. Wainwright analysts wrote that Corcept's NDA was "based on positive data [from] the two Phase 3 studies, GRACE and Gradient [sic]" and that if approved it would "drive long-term revenue." On January 29, 2025, Canaccord Genuity analysts published a report titled, "The year of relacorilant sees our 12-month PT increase from $78 to $130," writing, "[w]e are pounding the table on CORT now because … Strong likelihood of relacorilant approval in Cushing's 2025."

139. When Corcept submitted the relacorilant NDA on December 30, 2024, the statutorily prescribed date by which FDA had to respond to the relacorilant NDA—known as the "PDUFA date," from the statute which establishes it, the Prescription Drug User Fee Act—was

automatically set as December 30, 2025, as Defendants and investors knew.

4. January 2025-October 2025: Defendants Continue to Insist on Relacorilant's Efficacy and Safety—and Continue to Sell Their Stock

140. Over the next year, as FDA considered the relacorilant NDA and sent a series of inquiries about the Phase 3 trials to Corcept, Defendants pumped up investor excitement over relacorilant's approaching "easy" approval (¶122), continuing to tell investors that GRACE and GRADIENT's results showed relacorilant's efficacy, that it was "well tolerated," that FDA had approved the studies' designs and had raised no concerns, and that relacorilant was "progressing" towards approval by the end of the year.

141. On February 26, 2025, Corcept released its fourth quarter and full year results for 2024, filed its Form 10-K for 2024 with the SEC ("2024 Form 10-K"), and held an earnings call.

142. In the February 26 press release, Corcept again emphasized that GRACE's "***primary endpoint [was] achieved***" and showed that relacorilant was "***well-tolerated, consistent with its known safety profile***." As to GRADIENT, Corcept again emphasized that "***relacorilant was well-tolerated, consistent with its known safety profile***" and the supposed "***clinically meaningful improvements*** in a broad range of hypercortisolism signs" from that trial, which supposedly would be "***[s]upportive data for NDA***."

143. In its 2024 Form 10-K, Corcept similarly stated that in "all of the[] trials" submitted as part of the NDA "***patients exhibited clinically meaningful improvements in a wide range of hypercortisolism signs and symptoms, including hypertension***" and, from a safety perspective, "***[r]elacorilant was well-tolerated***." The 2024 Form 10-K further stated that in both trials, patients "exhibited ***clinically meaningful and statistically significant improvements***."

144. During the February 26 earnings call, Defendant Belanoff stated that "***[j]ust as important as relacorilant's efficacy is its safety***" and that "***[r]elacorilant has been well tolerated in all of its studies***." Once again, Defendant Belanoff also emphasized that the "***clinically meaningful and statistically significant improvements in hypertension***" and other symptoms, measured in GRACE, provided "***compelling results***" for the NDA, as did GRADIENT.

145. During the call, Defendant Robb once again invoked Corcept's communications

with FDA and described them as straightforward and routine. One analyst asked Defendants whether they expected an "Advisory Committee" meeting for relacorilant. Generally, FDA invokes a public Advisory Committee meeting so that external experts may assist FDA in assessing complex, nuanced, or difficult decisions with respect to new drug applications. In response to the analyst's question, Defendant Robb conveyed to investors that the relacorilant NDA had such an easy path to approval that an Advisory Committee would not be needed, stating: "[W]e've been receiving that ***very ordinary course routine correspondence*** and responding to it over the past 60 days. ***So the process has been moving exactly as we understood it to move***" and that "***there's nothing about relacorilant's efficacy or safety that we think would require one***."

146. During the call, analysts also focused on the financial significance of relacorilant to Corcept. In response to an analyst's question about guidance and revenue, Defendant Maduck answered, referring to relacorilant, that Defendants were "***on track to grow [their] hypercortisolism business from $3 billion to $5 billion in annual revenues in three to five years***." This represented a four to eight times increase in Corcept's annual revenue, which had been reported as $675 million in the 2024 Form 10-K and during the same earnings call.

147. On March 3, 2025, Corcept announced that FDA had formally accepted the relacorilant NDA filing. The press release reiterated that the NDA was "***based on positive results from the pivotal GRACE trial and confirmatory evidence from the Phase 3 GRADIENT trial***" in which patients "***experienced improvements in a wide array of hypercortisolism's signs and symptoms***" and stated that, safety-wise, "***[r]elacorilant was well tolerated***." In the release, Defendant Belanoff stated that "FDA's acceptance of our [NDA] takes ***us another step closer to bringing relacorilant to patients with hypercortisolism***."

148. The same day, Canaccord analysts reported that this "acceptance of the NDA submission for filing … moves the NDA one step closer to approval," noting that GRACE "was designed based on guidance and input from the FDA" and GRADIENT "offer[s] strong support for drug approval." Canaccord concluded: "We continue to believe that relacorilant for Cushing's will receive FDA approval." In another report published on March 25, 2025, Canaccord reported that they had "hosted the management of Corcept for two full days of meetings" and stated that (i)

"[n]o surprises have come out of communications with the FDA" and (ii) "Corcept will have continued communications … with the FDA." Two days later, on March 27, Piper Sandler analysts similarly reported that they had "recently hosted meetings with Corcept senior management" and "continue to believe that relacorilant's cleaner risk/benefit profile relative to its predecessor ultimately tips the scales in favor of a timely approval."

149. Meanwhile, shortly after Defendant Robb told investors in the February 26 earnings call that communications with FDA about relacorilant's NDA had been "very ordinary course," and shortly after Corcept told investors in the March 3 release that approval was "another step closer," and while analysts believed "timely approval" was imminent, given there had been "no surprises" in FDA talks, the Insider Executives continued selling Corcept stock.

150. On March 31, 2025—a single trading day—the Insider Executives sold more than $33 million of stock at prices between $94.72 and $102.48 per share: Defendant Maduck sold 100,000 shares for $10,054,010; Lyon sold 200,000 shares for $20,093,511; and Defendant Belanoff sold 35,102 shares for $3,324,861. The following day, April 1, 2025, Defendants Belanoff, Guyer, and Maduck, and Lyon, each sold additional shares at $114.51 to $114.71 per share, the highest prices at which any Insider Executive transacted during the Class Period.

151. FE-1 stated that they and other Corcept personnel started seeing sales of Corcept stock from people in management—including Defendant Belanoff and Defendant Robb—and that they questioned why they were selling a huge amount of stock. FE-1 concluded from these sales that Corcept's management knew about the FDA's issues very clearly, reasoning that "if management were confident in the NDA, why would they sell?"

152. FE-2, who oversaw clinical data management for GRACE and GRADIENT, also volunteered that Defendant Guyer's Class Period stock sales were highly suspicious and well timed, opining that, from FE-2's perspective as a clinical data manager, Defendant Guyer had to be aware of the risk of the FDA rejecting the NDA the moment he reduced the GRACE enrollment sample size in 2023.

153. Defendants sold this unusually high volume of stock at a time when they assured investors FDA had agreed to the relacorilant clinical development program and approval was

forthcoming, approval that would cause the stock to trade materially higher. While these sales caused concern internally, Defendants continued to publicly assure investors that the path to relacorilant's approval was clear, driven by the drug's supposed efficacy as established by GRACE's primary endpoint and GRADIENT's supposedly confirmatory results, and based on relacorilant's supposed safety profile and FDA's buy-in.

154. By early 2025, FDA had begun sending information requests to Corcept in response to the NDA submission. While Defendants were professing confidence in FDA approval to investors, Corcept employees painted a less rosy internal picture. For example, FE-2 confirmed that a substantial number of Corcept's Cushing's-focused employees, including investigators and physicians, departed around the time FDA began sending information requests in 2025. Among those who departed were the endocrinologists who served as Corcept's head clinical scientists and medical monitors on the relacorilant trials. FE-2 watched their confidence in the data disappear and stated that the endocrinologists working on the trial saw enough to leave the Company.

155. FE-2 further described how Corcept handled FDA's information requests internally. Corcept did not let employees see the full list of requests. The full requests went only to Corcept's quality assurance and regulatory divisions, which then parceled out individual items to the responsible functions. FE-2 characterized this as "weird," observing that if Corcept was not doing anything "shady," they could be transparent and give people the full context of the requests, and that receiving the requests piecemeal made them harder to answer, a sentiment shared by FE-2's supervisor. As FE-2 put it, "it did not go unnoticed that Corcept held the FDA requests close to their chest," and they wondered "what they had to hide."

156. After the NDA submission, according to FE-1, the initial FDA correspondence concerned the manufacturing processes for the drug and the format in which FDA required Corcept's data to be presented, but the requests later progressed to clinical questions in February, March, and April 2025. According to FE-1, while they were employed at Corcept, FDA had scheduled two post-NDA meetings with Corcept, one for Summer 2025 and another in September 2025. In accordance with their experience at Corcept and Company practice, FE-1 confirmed that attendees at those meetings included Defendants Belanoff and Robb, as well as other Corcept

senior management, including Defendant Guyer, the Head of Biometrics, the Vice President, Head of Global Patient Safety and Pharmacovigilance, and the Vice President, Clinical Development Operations.

157. On May 5, 2025, Corcept issued its earnings press release and Form 10-Q for the first quarter of 2025 and held an earnings call with investors.

158. In the May 5 press release Defendant Belanoff stated that the NDA "for relacorilant in hypercortisolism is ***progressing towards approval by the end of this year***." Defendant Guyer stated that "[t]he ***positive results*** from" GRACE and GRADIENT "provide ***powerful support for the NDA*** for relacorilant in hypercortisolism," as "[p]atients in these studies experienced ***clinically significant improvements … without the off-target effects and toxicities that accompany currently available treatments***." The May 2025 Form 10-Q included similar statements to those in prior quarters' filings, including that patients in GRACE and GRADIENT "***exhibited clinically meaningful improvements***," that GRACE had "***met its primary endpoint***," and that relacorilant was "***well tolerated***" consistent with "***its known safety profile***."

159. During the May 5 earnings call, Defendant Robb provided a brief update on the Teva Patent Litigation, informing investors that Corcept had appealed the trial court's ruling against it. Defendant Belanoff then told investors that the relacorilant NDA, which was "based on ***positive results from our pivotal Phase 3 GRACE trial***" and "***supported by the results from our GRADIENT***" trial, "***is progressing towards approval by the end of this year***." Defendant Belanoff added, in language that was by then familiar to investors and analysts, that "***[p]atients treated with relacorilant in these studies experienced clinically meaningful and statistically significant improvements across all of the signs and symptoms of hypercortisolism***" and "***[r]elacorilant has been well tolerated in all of its studies***."

160. Also during the May 5 earnings call, Defendant Maduck once again highlighted that relacorilant could bring significant revenue to Corcept and values to its shareholders, because "in the next three to five years, relacorilant will generate $3 billion to $5 billion in annual revenue in hypercortisolism alone."

161. Defendants Belanoff and Maduck repeated similar statements during the next

earnings call, held on July 31, 2025. Specifically, Belanoff told investors that "***relacorilant is approaching approval***" and that the NDA was "***supported by***" GRACE and GRADIENT, in which patients "experienced ***clinically meaningful improvements … [that] were observed consistently and durably***" and relacorilant was "***well-tolerated***." Defendant Maduck again encouraged investors to think of Corcept's revenue as quadrupling or more after relacorilant was approved, stating that "***relacorilant is even better***" than Korlym and that, "in the next three to five years, relacorilant will generate $3 billion to $5 billion in annual revenue [for] hypercortisolism alone." Defendant Belanoff went further, noting that Defendants "think this market is substantially larger" than "$3 [b]illion to $5 [b]illion," and would "have a substantial piece of that substantial market." When an analyst asked how much of that $3 billion to $5 billion "is coming from Korlym," Defendant Belanoff responded that the estimate essentially only included relacorilant, as "***relacorilant is a better medication than Korlym.***" Later Defendant Maduck stated, unequivocally, relacorilant "is going to come at the beginning of next year."

162. Corcept's earnings press release and Form 10-Q for the second quarter of 2025, also issued on July 31, included similar statements. For example, in the press release Defendant Guyer stated that "[i]n our studies, ***patients who received relacorilant exhibited clinically and statistically significant improvements … without [] off-target effects and toxicities***."

163. Analysts once again credited Defendants' statements that the path to relacorilant's approval was clear and would be a bounty of riches for Corcept and its investors. On August 1, 2025, for example, H.C. Wainwright analysts reported that they "remain bullish on the Cushing's franchise because of relacorilant's imminent approval in hypercortisolism." The same day, a Seeking Alpha report focused on Defendant Maduck's description of blockbuster relacorilant annual revenues of "$3B–$5B" upon its approval. Canaccord analysts reported on September 10, 2025 that they "continue to expect a positive outcome," and on September 25, 2025 that they "continue to believe relacorilant will be approved."

5. November-December 2025: With FDA's Relacorilant Decision Due By the End of December, Defendants Make Millions Of Dollars In Insider Sales While Continuing to Mislead Investors

164. In November 2025, with FDA's decision date fast approaching, Defendants

continued to assure investors, while announcing Corcept's earnings for the quarter, that the results from the Phase 3 trials showed relacorilant's efficacy and safety and that the interactions with FDA were routine, all of which would lead to approval.

165. On Corcept's earnings call held on November 4, 2025, Defendant Belanoff once again stated that GRACE and GRADIENT had shown "***clinically meaningful improvements … observed consistently and durably, with improvements emerging early and continuing or deepening over time***," and also told investors, "***[n]ext month***, ***we expect FDA approval of relacorilant***." Answering an analyst's question about whether Corcept "had a late-cycle review [meeting with FDA] for rela[corilant]," Defendant Robb stated that Corcept management had met with FDA at least twice and that everything had "***moved per schedule, very ordinary course***." Defendant Maduck again encouraged investors to think about "$3 billion to $5 billion in annual revenue" from relacorilant, stating: "I eagerly anticipate relacorilant's approval."

166. But Maduck was also eagerly selling Corcept stock. Defendant Maduck sold 20,000 shares for $1,479,816 on November 3, the day before he told investors he "eagerly anticipate[d]" approval. Also on November 3, Defendant Belanoff sold 11,218 shares for $831,014, the day before he told investors they expected approval "next month," and 28,782 shares for $2,152,105 on November 5, the day after. Also on November 3, Lyon sold 5,000 shares for $368,245 and, also on November 5, Defendant Guyer sold 20,000 shares for $1,507,122.

167. On November 25, 2025—four weeks before the PDUFA date—Defendant Guyer executed a single unplanned, discretionary sale of 4,500 shares for $364,070, outside any Rule 10b5-1 plan. On December 1 and 2, 2025 Defendant Belanoff sold 40,000 shares for $3,190,796; Defendant Maduck sold 20,000 shares for $1,590,490; Defendant Guyer sold 20,000 shares for $1,601,526; and Lyon sold 5,000 shares for $397,632. These December sales alone yielded more than $6.78 million at prices of approximately $79.52 to $80.88 per share—roughly $45 per share above the $34.80 closing price four weeks later.

168. But investors remained sold on Defendants' narrative, including that FDA was on board with relacorilant's NDA. On November 4, 2025, Truist analysts reported that Corcept management had "reiterated high conviction on timely approval." H.C. Wainwright analysts,

writing on November 25, 2025, "assign[ed] a 90% probability of launch" because "GRACE and GRADIENT[] both achieved their primary efficacy endpoints with statistical significance and demonstrated superior safety over Korlym," and that "[a]ccording to [Corcept] management, all pre-approval interactions with the FDA have been positive." Canaccord analysts gave even higher odds for relacorilant's approval, writing on December 8, 2025 that "the probability of a successful outcome … is 95%." Wolfe Research analysts, on December 22, agreed "rela[corilant] likely secures approval … from our conversation with management."

169. By the expected approval date, Corcept's stock price had risen significantly, from $46.89 at the start of the Class Period, on October 30, 2024, to a Class Period high of $117.33 per share in March 2025, and a closing price of $70.20 per share on December 30, 2025.

D. Corcept's Stock Price Plummets in Response to FDA's Denial of the Relacorilant NDA

170. The PDUFA date arrived on December 30, 2025. Corcept made no announcements that day, and investors started to show concern from this silence, with Corcept's stock dropping from a close of $79.82 on December 29, 2025 to a close of $70.20 on December 30, 2025.

171. The next day, trading was briefly halted as Defendants shocked investors when they announced in a press release issued before the market opened that FDA had issued the CRL the previous day and had refused to approve relacorilant.[3] Even then, Defendants continued to profess to be "surprised and disappointed" by the decision, claiming the agency had "acknowledged that Corcept's pivotal GRACE trial met its primary endpoint and that data from the company's GRADIENT trial provided confirmatory evidence." Still, Defendants disclosed "the [FDA] concluded it could not arrive at a favorable benefit-risk assessment for relacorilant without Corcept providing additional evidence of effectiveness."

172. Analysts were stunned by the news, given Defendants' repeated Class Period statements about relacorilant's efficacy and safety and FDA's supposed buy-in to the relacorilant

[3] While the initial CRL is not publicly available, a "corrected action letter incorporat[ing] revisions for clarity" was later made public on January 28, 2026. References to the CRL herein are to the publicly available version.

clinical development program. In a December 31, 2025 report Piper Sandler analysts wrote, "[W]e believed the success on the primary endpoint and the cleaner safety profile relative to Korlym would carry relacorilant over the finish line." Oppenheimer analysts reported that "the adverse FDA decision came as a surprise to the market." Truist analysts cut their price target from $135 to $50 per share, described the CRL news as a "[d]isappointing update," and wrote, "FDA has asked for additional evidence of relacorilant's effectiveness significantly." Wolfe Research published a report "downgrading [Corcept's] stock to $30 as rela[corilant] was meant to be a bread winner for the company," and wrote, "[r]elacorilant misses the finish line, and we see more downside near-term ... it is clear that the FDA does not see a favorable risk-benefit profile."

173. In response to the disclosure of FDA's denial of relacorilant, Corcept's stock price fell by half, declining by 50.4%, dropping $35.40 per share, from a closing price of $70.20 per share on December 30, 2025, to a closing price of $34.80 per share on December 31, 2025. This decline in Corcept's stock price was associated with a statistically significant "abnormal" decline, meaning that the decline cannot be explained by broader market or industry price movement. This corrective disclosure therefore wiped out billions of dollars in shareholder value.[4]

174. The market immediately and directly connected the decline in Corcept's stock price to the relacorilant NDA denial. In a December 31, 2025 post, *Bloomberg* reported that "Corcept Therapeutics Inc. shares fell after US regulators rejected the company's drug." Analysts at Oppenheimer also connected the price decline to market surprise at the CRL news, writing that, "Today's sharp selloff in CORT (-51%) indicates that the adverse FDA decision came as a ***surprise to the market***." In an H.C. Wainwright report published on January 2, 2026, analysts questioned the truthfulness of Defendants' Class Period statements, stating they "were surprised to hear that the FDA" wanted "additional confirmatory evidence" because "***management [had] stated that they were in alignment with the agency regarding their regulatory strategy***."

175. On January 2, 2026, *Zacks Equity Research* published a report discussing the

[4] As used in this Complaint and in the caselaw, a "corrective disclosure" is information that "corrects" the issuer's stock price by removing "artificial inflation" that had been created by Defendants' misstatements and half-truths and thereby proximately caused investors' losses.

impact of the CRL and a chart comparing Corcept's share price movements against the medical-drug market as a whole, noting that as a result of the news, "shares of Corcept have plunged 51.8% against the industry's rise of 3.4%" over a six-month period:

176. Because of Defendants' alleged misstatements and half-truths, Corcept's stock traded at prices higher than it would have if investors had known the truth. Lead Plaintiffs and other Class members bought Corcept stock at these inflated or maintained prices, trusting that the market price reflected accurate public information about Corcept. When the corrective information came out on December 31, 2025, and the stock price declined significantly, Lead Plaintiffs and other Class members who purchased at inflated or maintained prices suffered losses. In that disclosure, Defendants revealed that FDA had denied the relacorilant NDA in a CRL.

177. It was entirely foreseeable to Defendants that their materially false and misleading statements regarding relacorilant's efficacy and safety and their interactions with FDA about these matters would artificially inflate or maintain Corcept's common stock price. It was foreseeable to Defendants that the price of Corcept's securities would fall as the artificial inflation caused by

Defendants' misstatements and half-truths was removed. Thus, the economic losses (i.e., damages suffered by Lead Plaintiffs and the Class) were a direct, proximate, and foreseeable result of Defendants' materially false and misleading statements, which artificially inflated or maintained the price of Corcept's common stock, and the subsequent significant decline in the value of Corcept's common stock when the relevant truth was revealed.

E. In Reality, FDA Had Repeatedly Warned Defendants of Its Serious Concerns About the Phase 3 Trials and to Proceed at Their Own Risk, Rendering Defendants' Unequivocal Claims of Efficacy and Safety and of FDA's Approval of the Trials False and Misleading

178. Unknown to investors, Defendants' repeated Class Period statements about the Phase 3 relacorilant trials, safety profiles, and FDA reception were materially false and misleading for multiple reasons, as demonstrated by FDA's documented reasons for rejecting relacorilant's December 2024 NDA, the accounts of three well-placed former employees, and other evidence uncovered by Lead Counsel's investigation.

1. Defendants Deceived Investors About GRADIENT's Efficacy Results, Including by Not Telling Investors Defendants' GRADIENT Efficacy Claims Were from a Post-Hoc, Partial Analysis of GRADIENT's Data

179. Defendants' statements about GRADIENT's results as proof of relacorilant's efficacy were materially false and misleading for multiple reasons set forth herein.

180. ***First***, while insisting that GRADIENT's results showed relacorilant's efficacy, Defendants concealed from investors a critical fact: that these claims were based on a post-hoc, unblinded, and selective re-analysis of a subset of incomplete data—all outside of GRADIENT's prespecified statistical analysis plan (or "SAP") and all conducted ***after*** the study had failed. FDA's scathing CRL later revealed all this, but Defendants knew and did not tell investors during the Class Period that their GRADIENT efficacy claims were based on this problematic post-hoc analysis. Simply put, these carefully curated results were not "powerful," "meaningful," or "significant" "evidence" of relacorilant's efficacy, as Defendants had repeatedly claimed.

181. GRADIENT's trial structure and the data it would analyze for both primary and secondary endpoints were prespecified in its SAP. Its primary endpoint was prespecified to analyze data from 137 patients—68 in the relacorilant arm and 69 in the placebo arm. Moreover, each arm

had been further subdivided into certain subgroups. One subgroup consisted of patients who had exhibited signs of hypertension ***only*** at the start of the trial, and resulted in 41 total patients being analyzed, 20 in the relacorilant arm and 21 in the placebo arm (the "Hypertension Only Subgroup"). Another subgroup was patients that had exhibited ***both*** signs of hypertension ***and*** signs of hyperglycemia at the start of the trial, and resulted in 43 total patients being analyzed, 22 in the relacorilant arm and 21 in the placebo arm (the "Hypertension and Hyperglycemia Subgroup"). A third subgroup was patients that had hyperglycemia ***only*** at the start of the trial, and resulted in 53 total patients being analyzed, 26 patients in the relacorilant arm and 27 in the placebo arm (the "Hyperglycemia Only Subgroup").

182. GRADIENT's primary endpoint was prespecified in its SAP—to measure the mean change in patients' 24-hour systolic blood pressure (SBP), based on "24-hour ambulatory blood pressure measurement," from the start of the trial to week 22, as between ***all*** patients with Hypertension in the relacorilant arm and all patients in the placebo arm—i.e., the patients in the Hypertension Only and in the Hypertension and Hyperglycemia Subgroup. The third subgroup was relevant when measuring improvements in hyperglycemia was a primary endpoint for GRADIENT, but that primary endpoint, as discussed above, was removed in September 2024.

183. Moreover, as is typical in clinical trials, the SAP had included a mechanism to deal with data from patients who left the trial before completion. GRADIENT's SAP prespecified what is known as a "wash-out" imputation method to analyze data from such missing patients—generally speaking, assume that the hypertension of the missing patients would have slowly returned to their baseline using data modeling, and use that data in the analysis of each patient.

184. When Defendants disclosed GRADIENT's results on the first day of the Class Period, they disclosed and acknowledged that GRADIENT ***failed*** to meet the primary endpoint that was prespecified in the study documents—it showed no clinically meaningful or statistically significant improvement in the blood pressure-related measures the study had been prespecified to study when data from all 84 patients had been analyzed (including data from missing patients).

185. Faced with that adverse reality, and rather than delay the NDA and conduct additional studies, Defendants conducted a new analysis, one that was ***not originally prespecified***

in GRADIENT's SAP, and one they conducted ***after they knew the trial had failed and after they received the unblinded results***. The inherently biased analysis proceeded as follows. First, contrary to the SAP, Defendants ***discarded*** the results from the 43 patients in the Hypertension and Hyperglycemia Subgroup. Second, with respect to the remaining data, from patients in the Hypertension Only Subgroup, and also contrary to the SAP, Defendants ***excluded*** patients who did not complete the study—rather than apply the "wash-out" imputation method to missing patients in that subgroup as GRADIENT's SAP prespecified was required. In the end, this selective culling of the data left data from only 21 total patients—8 in the relacorilant arm and 13 in the placebo arm (all from the Hypertension Only Subgroup) out of the original 84 patients that GRADIENT's SAP dictated would form the basis of the primary endpoint analysis.

186. By definition, results of post-hoc analyses do not change the non-significant result of the prespecified, failed primary analysis. Nevertheless, it was from ***that group, constructed after the study's conclusion and failure and outside of the trial's governing documents, when Defendants had the unblinded data***, that Defendants purported to derive the "clinically meaningful and statistically significant" evidence of efficacy they announced GRADIENT's results on the first day of and during the Class Period, and it was that post-hoc analysis that was part of the supposed proof of efficacy Defendants submitted in the NDA.

187. Critically, the fact that these claims of efficacy came from the post-hoc analysis was ***not disclosed to investors anywhere***, not with the trial results or in the SAP (since it was not even contemplated by that document), or in any of Defendants' repeated Class Period statements about GRADIENT's results.

188. ***Second***, the GRADIENT statements were false because even the post-hoc analysis of the incomplete, self-selected data that was not even prespecified in the GRADIENT SAP showed only "***nominal*** statistical significance," as the CRL later documented. As Defendants did not disclose the results from this post-hoc analysis that was not in the SAP, they also did not disclose that even their carefully constructed post-hoc analysis yielded only ***nominal*** "proof" of efficacy and, instead, insisted the GRADIENT results were "powerful," "meaningful," and "significant." As FDA later explained in the CRL, discussed below (¶¶220, 224-29), this

unspecified, post-hoc method of analysis is inherently biased, unreliable, and unable to support a claim of efficacy. When FDA ran its own analysis of the subset of data Defendants analyzed after the fact, FDA did use a wash-out method of imputation to extrapolate missing patient data and found that ***even this ex-post analysis was not statistically significant or otherwise meaningful***.

189. ***Third***, Defendants also did not ***ever disclose*** the critical fact that part of the supposed confirmatory proof of efficacy from GRADIENT they submitted in the NDA came from this post-hoc analysis that was entirely outside of GRADIENT's SAP.

190. ***Fourth***, Defendants also failed to disclose that FDA "[d]uring the pre-submission meetings, informed [Defendants] on several occasions of [the agency's] concerns about the adequacy of the ***clinical development program*** to assess the effect of relacorilant on hypertension in the intended population." GRADIENT was part of the relacorilant clinical development program, but Defendants did not disclose FDA's pre-submission repeated warnings about this program in discussing GRADIENT's results with investors as strong proof for the NDA.

191. In short, Defendants defrauded investors when they repeatedly stated patients in GRADIENT "***exhibited clinically meaningful and statistically significant improvements***," or that GRADIENT's results "***support***" the findings from GRACE or would be a "***powerful addition***" to relacorilant's NDA. For reasons Defendants hid from investors, the "proof" from GRADIENT's results was not powerful, meaningful, or significant—it was post-hoc, biased, incomplete, and not contemplated by the study's SAP, even that result proved "nominal," and FDA had warned Defendants before the Class Period about the agency's concerns with the Phase 3 trials. Nor would these results be a powerful addition to the NDA for the same reasons. At minimum, Defendants misleadingly failed to disclose these critical facts when stating GRADIENT's results were proof of efficacy and would support the relacorilant NDA.

2. Defendants Deceived Investors About GRACE, Including By Not Telling Investors FDA Warned Defendants GRACE's Efficacy Results Were Likely Overstated and, Therefore, Insufficient

192. Defendants' statements that GRACE's efficacy results were supposed proof of efficacy were materially false and misleading for multiple reasons set forth herein.

193. ***First***, Defendants did not disclose to investors a critical fact—that, prior to

submitting the NDA, FDA had privately and repeatedly expressed to Defendants the agency's view that results from GRACE could not reliably show efficacy in the intended hypertension population but, instead, were likely to overstate its efficacy, and had told Defendants to expect significant review issues if Defendants proceeded with an NDA based on the results from such a study.

194. To start, GRACE's primary-endpoint results came from a "highly enriched" population that ***overestimates*** relacorilant's efficacy on the population at large. GRACE had studied one hundred and two (102) patients with hypercortisolism associated with uncontrolled hypertension. All these individuals were given relacorilant during the "open-label" phase for 22 weeks—no placebo was administered and the study was not blind. At week 22, only patients whose hypertension symptoms had been significantly controlled would be permitted to continue into the randomized-withdrawal phase, where they would continue with relacorilant or be switched to a placebo for twelve weeks. Of the 102 patients with hypertension studied in the open-label phase, only 46 entered the randomized withdrawal phase. Another 40 patients with hypertension discontinued the study during the open-label phase, and many others did not respond to relacorilant, since their hypertension symptoms had not meaningfully improved to begin with, so they also did not enter the randomized withdrawal phase.

195. Thus, GRACE's second phase was studying a population not selected at random or blindly. Instead, the patients were selected to show the drug's efficacy ***precisely because they had already shown the drug's efficacy***, and the resulting population was, therefore, what is known as a "highly enriched" population. GRACE's primary endpoint came from this highly enriched population, but the efficacy of relacorilant on such a biased group overestimates the drug's ***actual effect*** on the population at large, selected randomly. This was known to Defendants because FDA privately explained these facts to Defendants before the Class Period and before they submitted the NDA (all as FDA eventually revealed in the CRL), and because Defendants understood these facts from their own clinical experience and the relevant FDA guidance they professed to follow.

196. FDA's position about the insufficiency of the GRACE enriched trial, stated repeatedly in private to Defendants before they submitted the NDA as revealed later in the CRL, was consistent with published, longstanding FDA guidance. In its *Enrichment Strategies for*

Clinical Trials guidance, dated March 2019 and posted on FDA's website ("*Enrichment Strategies* Guidance"), FDA explains that enriched trials—those with an open-label phase where all patients are given the treatment drug followed by a randomized-withdrawal phase full of responding patients—were "initially proposed as a way to establish long-term effectiveness of drugs in settings in which long-term use of a placebo would not be acceptable on either ethical or practical grounds." Relacorilant is not such a drug. In any event, the *Enrichment Strategies* Guidance also states that, in such studies, "the response in … a selected group would ***not describe the response in an unselected population***" and that a "study that uses a marker-positive population only," i.e., a population that already responded positively to the drug as GRACE did, "***will provide no direct information about the marker-negative population***." The guidance also explains, tracking almost precisely the language in the eventual CRL denying the relacorilant NDA, that these studies may "support an effectiveness claim in the enriched population, ***but it would overstate the actual effectiveness for an unselected population***" such that "***the fraction of marker-positive patients would be important***."

197. Not only did Defendants specifically tell investors that they were aware of FDA guidance applicable to their NDA, *see* ¶122, the GRACE study protocol claimed to "account[] for relevant US FDA regulatory guidance" in a section describing the "rationale for study design." The *Enrichment Strategies* Guidance also at least twice highlights the importance of discussing the parameters (and limitations) of enriched studies "with FDA early in development" because "[t]hese issues are critical aspects of a development program," also noting that "[g]iven the potentially complex interpretation of studies using enrichment designs, plans to use them should be discussed with FDA early in development."

198. ***Second***, GRACE's limited sample size further rendered the randomized-withdrawal phase results less meaningful. GRACE was originally structured to attempt to address concerns about enrichment by enrolling a sufficiently large patient population, such that even the overstated treatment effect from the second phase could be of some limited use even if not alone sufficient proof of efficacy. As the *Enrichment Strategies* Guidance explains, because the results from a randomized-withdrawal phase studying an enriched population "would overstate the actual

effectiveness for an unselected population," that "***the fraction of marker-positive patients would be important***"—i.e., it is important to understand if, for example, only 1/100th of the study's patients respond to the drug in the open-label phase and enter the second phase as "marker positive," or if, for example, 90/100ths responded and entered the second phase.

199. GRACE's enriched study population was small—only 21 individuals studied for relacorilant's effect on hypertension completed the randomized-withdrawal phase on relacorilant and 22 on the placebo. This rendered the results from GRACE's highly enriched second phase of even more limited meaning. GRACE's own study protocol called for 162 patients to be enrolled and for "randomization of patients" into the second phase to "continue to ensure enrollment of 46 patients" into the randomized withdrawal phase, but GRACE enrolled only 152 patients and analyzed only 43 patients at the end of the second phase.

200. As set forth above, Defendants had altered their own design at the last minute, in August 2023, by removing one of the study's original endpoints (the one related to symptoms of hyperglycemia) and by cutting off enrollment early, as confirmed by FE-2, who worked directly on the GRACE and GRADIENT trials, and contemporary evidence.

201. As FE-1 explained, as a matter of standard clinical development practice, each modification to a study protocol carries a substantial risk of losing the power of the study, which is why sponsors normally avoid protocol amendments altogether. Despite this, FE-1, who spent approximately twenty years in pharmaceutical program management before joining Corcept, described the volume of amendments to the relacorilant trial protocols as an "infinite" number of amendments and "completely out of the ordinary" compared to any other program they had worked on.

202. Moreover, GRACE's poor efficacy results were identified and discussed internally. One well-placed former Corcept employee, FE-2, explained the behind the scenes of GRACE's enrollment and Corcept's rush to get the NDA in. According to FE-2, Corcept cut off GRACE enrollment before reaching the trial's original target sample size so that Corcept could announce "completed" enrollment at quarter-end in August 2023. FE-2 explained that, statistically speaking, GRACE needed to reach 100% enrollment because, absent efficacy already known to

be strong enough to justify a smaller sample, Defendants should not have cut enrollment. Specifically, FE-2 stated that Defendants had no prospectively specified statistical basis on which to close enrollment early and yet did so knowing that GRACE required its full planned enrollment to be adequately powered. FE-2 stated that Corcept picked a date instead of a number of patients, and that clinical operations was simply given a deadline and told that "whatever you got, you got."

203. As soon as Defendants cut off GRACE enrollment, FE-2 recalled that FE-2 began to have doubts about the FDA approval and that FE-2 told their supervisor, Corcept's Senior Director of Clinical Data Management, that FE-2 "would be remiss" if they told her it would be acceptable to reduce the sample size. According to FE-2, internally, everyone knew to "keep their mouths shut" when it came to any concern they might have had with the enrollment closure announcement, but FE-2 nonetheless raised the objection with their supervisor and told her not to cut off enrollment. In fact, FE-2 had that conversation with their supervisor more than once, and FE-2 and FE-2's supervisor were in agreement that it would be very difficult to obtain FDA approval after the enrollment was cut off. FE-2 clarified that—based on FE-2's decades of experience and access to the trial data, the protocol, and the accumulating efficacy results—both FE-2 and FE-2's supervisor had a good idea that the FDA was not going to approve relacorilant at that point, reasoning that if a sponsor cuts off enrollment its efficacy "better be pretty darn good" and that "the efficacy would have to be better." Specifically, although GRACE was blinded, FE-2 confirmed they could draw educated inferences from the expected adverse effects, and FE-2 concluded that the efficacy was not trending significantly in the right direction. At FE-2's most optimistic, FE-2 regarded relacorilant's approval as "a coin toss," and this doubt only grew after the sample size was reduced.

204. Defendants knew, from FDA's repeated private pre-Class Period warnings, from their own extensive experience with clinical trials, from available FDA guidance, and from the warnings of their employees, that all this meant that the results from GRACE's randomized-withdrawal phase were even less meaningful proof of efficacy and that GRACE's results would alone not support a claim of efficacy in the relacorilant NDA. Instead, GRADIENT's results would be needed as confirmatory evidence—which is why Defendants suddenly began discussing

GRADIENT as part of the NDA by June 2024. *See* ¶¶109-12. In touting that GRACE had met its primary endpoint and that it showed meaningful proof of efficacy, Defendants did not disclose any of these critical facts to investors.

205. ***Third***, Defendants' statements about the results of GRACE's ***open-label*** phase being meaningful proof of efficacy were also materially false and misleading. As noted, GRACE's open-label phase was unblinded and not placebo controlled and had studied one-hundred and two (102) patients with hypercortisolism associated with uncontrolled hypertension at the start of the study, but 40 (or 39%) discontinued the trial during the open-label phase. Given the unblinded, uncontrolled nature of this phase and the large number of patients who had dropped out, analysis of data from the open-label phase was also not significant.

206. The *Enrichment Strategies* Guidance also explains that the open-label phase data for an enriched study like GRACE "***provide[s] no new clinical evidence with respect to the marker-negative population***." FDA also specifically cautions that there are serious "concerns" with the "[u]se of an initial open-label phase without a control group." The guidance further notes the importance of a large enough data set in the open-label phase because "a critical question is almost always how much data will be needed in the off-target (nonenriched) population."

207. Defendants knew the truth about the insignificance of the GRACE open-label results, including from FDA's warnings and guidance and their own experience, but disclosed none of this to investors in discussing GRACE's open-label results.

208. ***Fourth***, as FDA later went out of its way to document in the CRL, before the Class Period FDA had privately warned Defendants, "[d]uring the pre-submission meetings, … on several occasions of [the agency's] concerns about the adequacy of the clinical development program to assess the effect of relacorilant on hypertension in the intended population." These "concerns" "***includ[ed]*** … the design of [GRACE]." The agency also emphasized that it told Defendants on "several occasions" to "***expect significant review issues if [they] were to submit [their] application***." Defendants disclosed none of these critical qualifying facts in repeatedly insisting that GRACE's results were additional proof of efficacy.

209. In short, Defendants misled investors when they repeatedly stated that GRACE's

results proved relacorilant's efficacy—including stating that GRACE's open-label phase results were "***clinically meaningful and statistically significant***" and that the achievement of the primary endpoint in the study's highly-enriched second phase demonstrated "***clinically meaningful improvements***" that would be "***[s]upportive data for NDA***"—because FDA had warned Defendants that the results from GRACE would likely ***overestimate the effect of relacorilant*** on the entire population and that GRACE alone would be insufficient. At minimum, Defendants misleadingly failed to disclose the critical, and ultimately determinative fact, that FDA had already told Defendants to expect significant review issues for relacorilant based on this clinical development program and the reasons the GRACE results would not be enough.

3. Relacorilant Was Not "Well Tolerated"

210. Contrary to Defendants' Class Period statements that relacorilant was "***well-tolerated***" or that the trial results showed its "***safety***," during the Phase 3 trials relacorilant had been associated with significant safety issues in the form of drug-induced liver injury (or "DILI") requiring patients to stop taking the drug. Specifically, the Phase 3 trials' investigators had observed at least four cases of probable DILI, including at least one case featuring elevated ALT as much as fifty times higher than normal, which is indicative of serious liver damage, *see also* ¶76, and is associated with an increased risk of jaundice and death. Relacorilant, therefore, was ***not*** "well-tolerated" or "safe."

211. According to FDA commentary in its CRL, relacorilant's Phase 3 investigators observed at least four cases of probable DILI, including one subject with an ALT elevation of 1,952 U/L—more than fifty times the upper limit of normal. According to FDA, the DILI cases observed during the Phase 3 trials were "probabl[y]" and "likely" "due to relacorilant," because of the close "temporal relationship of the adverse event to study drug initiation, and the lack of alternative etiology [explanation] identified despite extensive work-up." Moreover, the number of patients exhibiting DILI—four out of 303 patients who took relacorilant across both Phase 3 trials—is high. As FDA later explained, this ratio is "concerning" as it "remains possible that more DILI cases may occur in the larger population with longer exposure."

212. These serious adverse effects are a critical part of the benefit-risk analysis FDA

employs in considering an NDA. In this case, "[a]fter conducting a thorough safety review, [FDA] concluded that relacorilant is associated with drug inducted liver injury (DILI)," as FDA later disclosed in the CRL denying the relacorilant NDA.

213. These serious adverse effects also matter to patients and they matter to investors because, in evaluating the scope of even an approved drug, FDA balances any new drug's proven benefits against toxicity or other risk of patient harm. FDA specifically recognizes liver damage (or "hepatotoxicity") as a serious event that triggers sponsor monitoring and reporting obligations. Even if a drug is ultimately approved, liver toxicity signals can and frequently do lead FDA to require a liver toxicity warning on the drug's label and/or to require additional, post-approval monitoring to ensure patient safety. This, in turn, can significantly limit the scope of patients to whom a drug may be properly prescribed, meaning the total market for the drug is narrower—and, therefore, less valuable—than if the drug did not have such liver warnings on its label.

214. Moreover, Defendants possessed the liver enzyme elevation data well before their Class Period safety statements—based on their prior experience with liver-related events and their class of drugs, Defendants were monitoring for this issue and received the data while the studies were ongoing or, at a minimum, at their conclusion by early 2024.

215. Both GRACE and GRADIENT's SAPs specifically contemplate that, based on information gathered during the relacorilant pre-clinical and clinical development program, investigators should monitor, among other things, signs of "Hepatoxicity," defined to include "Alanine aminotransferase [ALT] increase[s]."

216. In fact, Defendants also knew from prior experiences with miricorilant that their class of drugs had immediately caused DILI cases during another trial and that they therefore had to monitor and report these negative findings. *See* ¶¶75-76.

217. GRACE's protocol additionally requires study investigators to "***promptly***" report to Corcept any adverse events "that may reasonably be regarded as caused by, or probably caused by, the study drug." GRADIENT's protocol similarly requires study investigators to report "[a]ll [serious adverse events]" to Corcept and requires Corcept to "***promptly*** evaluate all reported safety information"—including "adverse events"—"against cumulative product experience to identify

and ***expeditiously communicate possible new safety findings to*** Investigators and ***applicable regulatory authorities***." Both protocols further define "adverse events" as "any untoward medical occurrence in a study patient administered a pharmaceutical product" regardless of whether it is related to the drug, and define a "***serious*** adverse event" as one that is "life-threatening" or involves "other medically important conditions."

218. Not only were the trials' investigators specifically monitoring liver issues and required to report them to Corcept during the trials, FDA flagged to Defendants during its review that it was concerned about relacorilant's safety due to the notable liver enzyme elevations. In a conversation with analysts from Piper Sandler after the Class Period, Corcept "[m]anagement did note that liver enzyme elevations (albeit mild) ***came up as a late review item***."

219. In short, Defendants knowingly misled investors when repeatedly assuring them that relacorilant was "***well tolerated***" and that its "***safety profile***" was favorable. Relacorilant was in fact ***not*** well tolerated or safe. At minimum, Defendants misleadingly failed to disclose that they had observed a highly concerning liver toxicity signal associated with relacorilant.

4. Defendants Misled Investors About Defendants' Interactions with FDA about the Relacorilant NDA

220. According to the CRL, prior to the Class Period FDA had, "[d]uring the pre-submission meetings, informed [Defendants] on several occasions of [the agency's] concerns about the adequacy of the clinical development program to assess the effect of relacorilant on hypertension in the intended population." These "concerns" "***includ[ed]*** … the design of [GRACE]." The agency also emphasized that it told Defendants on "several occasions" to "***expect significant review issues if [they] were to submit [their] application***."

221. Defendants did not disclose any of this to investors, which directly conflicted with Defendants' unequivocal statements that communications with FDA had been "routine" or "ordinary course," or that FDA had agreed with the clinical development program for relacorilant.

222. Thus, Defendants knowingly misled investors when they repeatedly characterized their interactions with FDA about relacorilant as positive, routine, or ordinary course, and when they told investors FDA had "agreed" to GRACE's endpoints or relacorilant's clinical

development program. In fact, Defendants' meetings with FDA were full of concerns and review issues, and were thus not positive, routine, or ordinary course. At minimum, it was misleading to discuss FDA's supposed views about the relacorilant NDA without also disclosing the agency had expressed numerous concerns on repeated occasions and had warned Defendants to proceed at their own risk under the circumstances Defendants hid from investors.

F. After the Class Period, FDA's Scathing Complete Response Letter Confirms Defendants Deceived Investors

223. On January 28, 2026, FDA publicly released an "updated" CRL. *See supra* n.3.

224. In the CRL, FDA went out of its way to make clear that even before Defendants submitted the relacorilant NDA, the agency had repeatedly warned Corcept and its executives that the Company faced a difficult path to approval—warnings that Defendants concealed from investors—stating: "During the pre-submission meetings, ***we informed you on several occasions of our concerns about the adequacy of the clinical development program to assess the effect of relacorilant on hypertension in the intended population including the design of [GRACE], and to expect significant review issues if you were to submit***."

225. The CRL detailed the many reasons that GRACE and GRADIENT were "not sufficient to demonstrate the effectiveness of relacorilant." While GRACE had "met its primary endpoint," the CRL said, "the analysis was conducted in a highly enriched population" and, "[a]s such, ***the observed treatment effect in the randomized withdrawal phase likely overestimates the treatment effect of relacorilant in the intended population***." The CRL continued, explaining that despite the apparently positive results of GRACE's open-label portion, these results were "unreliable given the large amount of missing data." Further, the CRL stated, "there was no control group with which to interpret the change in blood pressure" in the open-label portion.

226. As to GRADIENT, the CRL noted that Defendants' "post-hoc analysis of the primary endpoint in the 33 subjects with hypertension and Cushing's Syndrome … showed [only] a ***nominally significant*** decrease in [SBP] compared to placebo," but "***was not pre-specified in the statistical analysis plan***, and ***in general, post-hoc analyses of a failed trial can be unreliable***." The post-hoc analysis was also insufficient, the CRL stated, because it "was ***based on a small***

number of subjects and there was a ***large amount of missing data***," as "only 8/16 subjects in the relacorilant arm and 13/17 subjects in the placebo arm were included." The CRL went on: "A wash-out imputation method that [FDA] conducted during review of your application ***failed to demonstrate even nominal statistical significance for the estimated treatment effect of relacorilant*** compared to placebo in this subgroup."

227. In a section on "Benefit Risk Assessment," the CRL stated that FDA was "unable to conduct a final benefit risk assessment" because "***substantial evidence of effectiveness was not demonstrated***." The drug's proven lack of effectiveness was then weighed against clear safety concerns because the CRL noted that, "***[a]fter conducting a thorough safety review [FDA] concluded that relacorilant is associated with drug induced liver injury (DILI)***." It also explained that "four cases [study patients] were assessed as probable DILI ***due to relacorilant***." One of these patients, the CRL said, had "significant" elevation of ALT that "represent[ed] more than 50 times the upper limit of normal," which put this patient at "***a higher liver related fatality risk***" and was "***likely related to relacorilant***." The presence of four cases of "probabl[y] DILI" was "concerning," the CRL stated, "[b]ecause there were only 303 subjects exposed" to the drug.

228. With respect to a "path forward," the CRL noted that, if Defendants chose to resubmit an NDA, they would "need to provide new clinical data to demonstrate that relacorilant treatment results in a clinically meaningful … [REDACTED] benefits … [that] must outweigh its risks." The agency also "recommend[ed] [Defendants] submit a proposal for adequate DILI risk mitigation strategies, including appropriate labeling warnings, routine monitoring requirements, enhanced pharmacovigilance, and post-market evaluation." Finally, the agency required Defendants, should they choose to resubmit, to "include a safety update as described" by FDA regulations, including but not limited to extensive information about the reasons patients discontinued taking the drug during the studies and other safety-related information.

229. Analysts and the media took note of the contents of the CRL and further questioned the truthfulness of Defendants' Class Period statements to investors. For example, in an article published on January 30, 2026, *Reuters* wrote that "FDA had explicitly told Corcept to 'expect significant review issues' if it proceeded with the submission," and quoted a UBS analyst as stating

that it is "rare for FDA to use such language." Pharmaceutical industry publication *Fierce Biotech* stated things plainly: "***The FDA warned Corcept Therapeutics that it would face significant hurdles if it submitted its lead rare disease asset for approval, contradicting the biotech's claims that the candidate's eventual rejection came as a shock***." *Capitol Forum* wrote: "When the FDA issued its CRL in December, Corcept CEO [Belanoff] said the company was 'surprised and disappointed'—but the recently published CRL suggests that the company may have been aware of the FDA's concerns with its clinical trials." *BioSpace* published an article on February 2, 2026 titled "FDA Warned Corcept of 'Significant Review Issues' for Rejected Drug in Early Meetings." The article noted that when FDA denied Corcept's NDA, Corcept "said at the time" that the "verdict…was surprising," but the "complete response letter" showed that FDA "had flagged issues with the application package early on."

V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS TO INVESTORS

230. During the Class Period, Defendants made statements about relacorilant and its NDA that were either outright false by misrepresenting material facts or were misleading "half-truths" that omitted material information necessary to make the statements not misleading.

231. Defendants misrepresented material facts concerning relacorilant's efficacy and safety, including misrepresenting the GRACE and GRADIENT trials underlying relacorilant's NDA as strong evidence of relacorilant's efficacy and safety; about Defendants' communications with FDA regarding these matters; and about existing material risks to Corcept's business that Defendants misleadingly cast as merely hypothetical.

A. Defendants Misled Investors About Relacorilant's Efficacy

1. False and Misleading Statements About GRACE

232. On October 30, 2024, Corcept issued its earnings press release for the third quarter of 2024, which was reviewed and approved by Defendants Belanoff and Guyer, who were quoted in the release, and which Corcept posted on the Company's website that day and incorporated into a Form 8-K filed with the SEC (the "October 2024 Press Release"); filed with the SEC a Form 10-Q for the third quarter of 2024 signed by Defendant Belanoff (the "October 2024 10-Q"); and held

an earnings call with investors in which it showed investors a slide deck presentation.

233. Statement 1: In the October 2024 Press Release, Corcept stated that "***GRACE met its primary endpoint***," and that patients in GRACE's "***open-label phase exhibited clinically meaningful and statistically significant improvements in hypertension***."

234. Statement 2: During the Company's earnings call on October 30, 2024, Defendant Belanoff told investors that GRACE "***outcomes would, on their own, provide powerful evidence for our NDA***," and that GRACE patients in the open-label phase "***exhibited clinically meaningful and statistically significant improvements***." During the same call, Defendant Maduck adopted this statement as his own, telling analysts that relacorilant "***shows efficacy across multiple, and all signs and symptoms of Cushing's syndrome***, ***as … Joe [Belanoff] walked through in his comments***."

235. Statement 3: During the October 30, 2024 earnings call, an analyst asked: "[W]hat gives you the confidence that you will be able to, not only file, but be able to get approval here with the GRADIENT data in hand[?]" In his response, Defendant Guyer stated, "***we met our primary endpoint for GRACE***." During the same call, Defendant Maduck adopted this statement as his own, telling analysts that relacorilant "***shows efficacy across multiple, and all signs and symptoms of Cushing's syndrome, as Bill [Guyer] just walked through***."

236. Statement 4: In the October 30, 2024 slide deck shown to investors during that day's earnings call, Corcept stated that GRACE's "***[p]rimary endpoint [was] met***," GRACE's "***open-label phase results***" showed "***[c]linically meaningful and statistically significant improvements in hypertension***" and that GRACE's "***[r]andomized withdrawal phase results … [m]et [its] primary endpoint***."

237. Statement 5: In its October 2024 10-Q, Corcept stated that in GRACE's "***open-label phase, patients experienced clinically meaningful and statistically significant improvements in a wide-array of Cushing's syndrome signs and symptoms, including hypertension***."

238. On February 26, 2025, Corcept issued its earnings press release for the fourth quarter of 2024, which was reviewed and approved by Defendants Belanoff and Guyer, who were

quoted in the release, and which Corcept posted on Corcept's website that day and incorporated into a Form 8-K filed with the SEC (the "February 2025 Press Release"); filed its 2024 Form 10-K, signed by Defendant Belanoff (*see* ¶141); and held an earnings call with investors in which it showed investors a slide deck presentation.

239. Statement 6: In the February 2025 Press Release, Corcept stated that GRACE's "***primary endpoint [was] achieved***" and that patients in GRACE's "***open-label phase demonstrated clinically meaningful improvements in a broad range of hypercortisolism signs and symptoms***."

240. Statement 7: In the February 26, 2025 slide deck shown to investors during that day's earnings call, Corcept represented that GRACE's "***[p]rimary endpoint [was] met***," GRACE's "***open-label phase results***" showed "***[c]linically meaningful and statistically significant improvements in hypertension***," and that GRACE's "***[r]andomized withdrawal phase results … [m]et [its] primary endpoint***."

241. On May 5, 2025, Corcept issued its earnings press release for the first quarter of 2025, which was reviewed and approved by Defendants Belanoff and Guyer, who were quoted in the release, and which Corcept posted on Corcept's website that day and incorporated into a Form 8-K filed with the SEC ("the May 2025 Press Release"); filed with the SEC a Form 10-Q for the first quarter of 2025 signed by Defendant Belanoff ("the May 2025 10-Q"); and held an earnings call with investors in which it showed investors a slide deck presentation.

242. Statement 8: In its May 2025 10-Q, Corcept stated that "***GRACE met its primary endpoint***," and that in GRACE's "***open-label phase, patients experienced clinically meaningful and statistically significant improvements in a wide-array of hypercortisolism signs and symptoms, including hypertension***."

243. Statement 9: In the May 5, 2025 slide deck shown to investors during that day's earnings call, Corcept said that GRACE's "***[o]pen-label phase results***" showed "***[c]linically meaningful and statistically significant improvements in hypertension***" and that GRACE's "***[r]andomized withdrawal phase results … [m]et [its] primary endpoint***."

244. Statement 10: On June 26, 2025, analysts at Truist Securities published a report

stating that they "***caught up with [Corcept's] mgmnt***" after a medical association conference. The report stated that "***[r]egarding high drop out rates seen in Ph3 GRACE***, which is a common concern for investors heading into PDUFA, ***mgmnt shared that it's consistent with 1) dropouts seen in Korlym study, 2) that of other trials in Cushings [sic] and 3) with real-world experience with Korlym***," and that "***[t]hese are all driven by the severity of the disease, per mgmnt***."

245. On July 31, 2025, Corcept issued its earnings press release for the second quarter of 2025, which was reviewed and approved by Defendants Belanoff and Guyer, who were quoted in the release, and which Corcept posted on Corcept's website that day and incorporated into a Form 8-K filed with the SEC (the "July 2025 Press Release"); filed with the SEC a Form 10-Q for the second quarter of 2025 signed by Defendant Belanoff ("July 2025 10-Q"); and held an earnings call with investors in which it showed investors a slide deck presentation.

246. Statement 11: In its July 2025 10-Q, Corcept stated that "***GRACE met its primary endpoint***" and that in GRACE's "***open-label phase***, ***patients experienced clinically meaningful and statistically significant improvements in a wide-array of hypercortisolism signs and symptoms, including hypertension***."

247. Statement 12: In the July 31, 2025 slide deck shown to investors during that day's earnings call, Corcept stated that GRACE's "***[o]pen-label phase results***" showed "***[c]linically meaningful and statistically significant improvements in hypertension***" and that GRACE's "***[r]andomized withdrawal phase results … [m]et [its] primary endpoint***."

248. **Reasons for falsity.** For the following reasons, Statements 1-12 were materially false and misleading and misrepresented and failed to disclose facts necessary to make the statements not misleading.

249. ***First***, Defendants' statements that results from GRACE's randomized-withdrawal phase showed relacorilant's efficacy (i.e., that they "met their primary endpoint") were materially false and misleading because Defendants failed to disclose critical facts including that: (i) prior to submitting the NDA, FDA had privately and repeatedly warned Defendants that GRACE would not be adequate to assess relacorilant's efficacy because data from the randomized-withdrawal phase, even if it met its primary endpoint, was likely to overstate relacorilant's efficacy, and had

also warned Defendants that efficacy results from GRACE alone would likely not, and did not, support Corcept's claims about relacorilant's efficacy in an NDA, *see* ¶¶193, 195, 208, 220, 224; (ii) GRACE's randomized-withdrawal phase could not reliably show relacorilant's efficacy in the intended hypertension population because they came from a highly enriched population and thus overstated relacorilant's true effect, consistent with FDA's warnings and guidance on these matters, *see* ¶¶193-97; (iii) GRACE's randomized-withdrawal phase's limited sample size made its enriched population results even less meaningful as Defendants understood from FDA's warnings and industry guidance, their employees' warnings, and their own experience with clinical trials, *see* ¶¶198-204; and (iv) FDA had also expressed to Defendants the agency's concerns with the overall design of GRACE and to expect significant review issues if Defendants proceeded with an NDA based on such a study. *See* ¶¶193, 195, 208.

250. Thus, it was materially false and misleading for Defendants to state that: GRACE's randomized-withdrawal phase "***met its primary endpoint***," (Statements 1, 8, 11), that "***we met our primary endpoint for GRACE***" (Statement 3), and that the study "***achieved***" or "***[m]et [its] primary endpoint***" (Statements 4, 6, 7, 9, 12). In reality, but as Defendants failed to disclose, FDA had repeatedly warned Defendants that the results from GRACE's randomized-withdrawal phase alone could not support a finding of efficacy because the results ***overestimated the treatment effect*** of relacorilant in the population, particularly since it came from a relatively small sample size, so the fact that the phase "met its primary endpoint" was of limited significance and was not "meaningful," "significant," or "powerful" evidence of improvements, and FDA had privately repeatedly expressed concerns to Defendants about the design of GRACE and its adequacy to assess the efficacy of relacorilant and to expect significant review issues if they proceeded with an NDA based on such a program.

251. ***Second***, Defendants' statements that results from GRACE's open-label phase were proof of efficacy (i.e., that they showed "clinically meaningful and statistically significant improvements in hypertension") were materially false and misleading. As Defendants knew, GRACE's open-label phase was unblinded and not placebo controlled, and a large number of patients dropped from the study during that phase, all of which rendered the open-label phase

results unreliable, not "significant." *See* ¶¶205-07; *see also* ¶225. Defendants understood this, including because FDA had privately warned Defendants prior to the Class Period about the "design" of GRACE, but did not disclose it to investors during the Class Period.

252. Thus, it was materially false and misleading for Defendants to state that patients in GRACE's open-label phase exhibited "***clinically meaningful and statistically significant improvements***" (Statements 1, 2, 4, 5, 7, 8, 9, 11, 12), or "***clinically meaningful improvements***" (Statement 6). In reality, but as Defendants failed to disclose, the results from that phase were unblinded, uncontrolled, and unreliable due to the large number of dropouts—not "meaningful" or "significant," and FDA had privately repeatedly expressed concerns to Defendants about the adequacy of their relacorilant clinical development program to assess the efficacy of relacorilant and to expect significant review issues if they proceeded with an NDA based on such a program. For the same reasons, it was false and misleading for Defendants to minimize concerns about GRACE's "***high drop out rates***" (Statement 10) without disclosing the problems for GRACE's ability to show efficacy that Defendants knew arose from the missing data these dropouts caused.

253. ***Third***, Defendants' statements that GRACE was powerful evidence for the relacorilant NDA were materially false and misleading. As noted, but as Defendants did not disclose, FDA had warned Defendants that GRACE's results alone would likely *not* show relacorilant's efficacy and that, critically, additional confirmatory evidence would be needed. *E.g.*, ¶¶13, 204, 220-21, 224. Defendants thus misled investors when they failed to disclose FDA's stated view about GRACE's insufficiency, while stating that GRACE results "***would, on their own, provide powerful evidence for our NDA***" (Statement 2). Moreover, FDA's warnings about the deficiencies in GRACE's design, including about the sufficiency of GRACE to support an NDA, and FDA's warning to expect "significant review issues" from an application based on such a trial, *see* ¶¶17, 21, 193, 208-09, 220, 224, 229, 249-52, further rendered statements that GRACE was "powerful evidence" for the NDA materially false and misleading.

2. False and Misleading Statements About GRADIENT

254. Statement 13: In the October 2024 Press Release, Corcept stated that (i) patients in GRADIENT "***exhibited clinically meaningful and statistically significant improvements in***

hypertension," (ii) GRADIENT's results "***support [the] findings from [the] pivotal Phase 3 GRACE study***," (iii) GRADIENT was "***[s]upportive trial data for NDA***," and (iv) "***GRADIENT … supports the GRACE trial by providing further evidence of relacorilant's efficacy and safety profile***."

255. Statement 14: In the October 2024 Press Release Defendant Guyer stated that "***GRADIENT's positive results*** in patients with Cushing's syndrome ***confirm relacorilant's promise***" and that GRADIENT's data "***will be a powerful addition to relacorilant's NDA***."

256. Statement 15: In its October 2024 10-Q, Corcept stated that GRADIENT patients showed "***clinically meaningful and statistically significant improvements in hypertension***" and that GRADIENT "***supports the GRACE trial by providing further evidence of relacorilant's efficacy*** and safety."

257. Statement 16: During the October 30, 2024 earnings call, Defendant Belanoff stated that GRADIENT showed "***clinically meaningful and statistically significant improvements in hypertension***" and other measures, and that "***GRADIENT's data will support our NDA by providing further evidence of relacorilant['s] efficacy and safety, confirming what we found in GRACE***." During the same call, Defendant Maduck adopted this statement as his own, stating relacorilant "***shows efficacy across multiple, and all signs and symptoms of Cushing's syndrome, as … Joe [Belanoff] walked through in his comments***."

258. Statement 17: During the October 30, 2024 earnings call, an analyst asked: "[W]hat gives you the confidence that you will be able to, not only file, but be able to get approval here with the GRADIENT data in hand[?]" In his response, Defendant Guyer stated, "***when you look at the results from GRADIENT, it supports the successful path to an NDA, because we see clinically significant improvements in all signs and symptoms of Cushing's syndrome, including improvements in blood pressure***," and that there was "***broad improvement of Cushing's syndrome from the GRADIENT study***." During the same call, Defendant Maduck adopted this statement as his own, telling analysts that relacorilant "***shows efficacy across multiple, and all signs and symptoms of Cushing's syndrome, as Bill [Guyer] just walked through***."

259. Statement 18: In the October 30, 2024 slide deck shown to investors during that

day's earnings call, Corcept stated that GRADIENT "***[r]esults [s]upport [f]indings from [] GRACE***" and that GRADIENT showed "***clinically meaningful and statistically significant improvements in hypertension***."

260. Statement 19: In the February 2025 Press Release, Corcept stated that GRADIENT was "***[s]upportive data for [the] NDA***" and that GRADIENT "***[p]atients treated with relacorilant exhibited clinically meaningful improvements in a broad range of hypercortisolism signs and symptoms***."

261. Statement 20: In its 2024 Form 10-K, Corcept stated that "***[p]atients in GRADIENT who received relacorilant exhibited clinically meaningful and statistically significant improvements in hypertension***."

262. Statement 21: In its May 2025 10-Q, Corcept stated that "***[p]atients in GRADIENT who received relacorilant exhibited clinically meaningful and statistically significant improvements in hypertension***."

263. Statement 22: In its July 2025 10-Q Corcept stated that "***[p]atients in GRADIENT who received relacorilant exhibited clinically meaningful improvements in a wide array of hypercortisolism's signs and symptoms, including hypertension***."

264. Statement 23: In the July 31, 2025 slide deck shown to investors during that day's earnings call (*see* ¶245), Corcept stated that "***GRADIENT [r]esults [s]upport [f]indings from [] GRACE***."

265. On November 4, 2025, Corcept issued its earnings press release for the third quarter of 2025, which was reviewed and approved by Defendants Belanoff and Guyer, who were quoted in the release, and which Corcept posted on Corcept's website that day and incorporated into a Form 8-K filed with the SEC (the "November 2025 Press Release"); filed with the SEC a Form 10-Q for the third quarter of 2025 signed by Defendant Belanoff (the "November 2025 10-Q"); and held an earnings call with investors during which it showed investors a slide deck presentation.

266. Statement 24: In its November 2025 10-Q, Corcept stated that "***[p]atients in GRADIENT who received relacorilant exhibited clinically meaningful improvements in a wide***

array of hypercortisolism's signs and symptoms, including hypertension."

267. **Reasons for falsity.** For the following reasons, Statements 13-24 were materially false and misleading and misrepresented and failed to disclose facts necessary to make the statements not misleading.

268. ***First***, statements that GRADIENT's results were proof of relacorilant's efficacy (i.e., because the study supposedly showed "clinically meaningful and statistically significant improvements") were materially false and misleading because Defendants failed to disclose critical facts. In reality, Defendants' efficacy claims based on GRADIENT were based on a post-hoc, unblinded, and selective re-analysis of a subset of incomplete data—all outside of GRADIENT's prespecified SAP and all conducted ***after*** the study had failed. As set forth above, after GRADIENT failed to meet its prespecified primary endpoint and after Defendants had access to all the trial's unblinded data, they conducted a post-hoc analysis in violation of GRADIENT's study documents, which started by discarding data from the Hypertension and Hyperglycemia Subgroup and, from the remaining data consisting of only patients in the Hypertension Subgroup, further eliminating data from patients who had not completed the trial rather than use the "wash-out" imputation method prespecified in GRADIENT's SAP. *See* ¶¶181-88. Further, even this post-hoc, biased, incomplete analysis not contemplated by GRADIENT's SAP showed only "nominal" statistical significance. *See* ¶¶188, 191. Defendants did not disclose any of these facts to investors, and they did not disclose that part of the efficacy "evidence" Defendants submitted in the NDA was this post-hoc analysis. As FDA later explained in the CRL, this unspecified, post-hoc method of analysis is biased and unable to support a claim of efficacy and, when FDA ran its own analysis of the subset of data Defendants analyzed using a wash-out imputation method, FDA found that ***even this ex-post analysis was not statistically significant or otherwise meaningful***. *See* ¶¶188, 226. Finally, before the Class Period but as Defendants did not disclose, FDA had repeatedly expressed concerns to Defendants about the adequacy of their relacorilant clinical development program to assess the efficacy of relacorilant and to expect significant review issues if they proceeded with an NDA based on such a program. *See* ¶¶190, 208, 220-21, 224-28.

269. Thus, it was materially false and misleading for Defendants to state (i) that patients

on relacorilant in the GRADIENT trial exhibited "***clinically meaningful and statistically significant improvements***" (Statements 13, 15, 16, 18, 20, 21), that they "***exhibited clinically meaningful improvements***" (Statements 19, 22, 24), or that they experienced "***clinically significant improvements***" (Statement 17); and (ii) that GRADIENT "***supports the successful path to an NDA***, ***because we see clinically significant improvements in all signs and symptoms of Cushing's syndrome***," and that there was "***broad improvement of Cushing's syndrome from the GRADIENT study***" (Statement 17). In reality, but as Defendants failed to disclose, the GRADIENT results Defendants based their NDA on were from a post-hoc, conveniently-selected, unblinded, and incomplete subset of GRADIENT's data that was ***not*** prespecified in GRADIENT's SAP and was therefore inherently biased, and even these results were "***nominal***" (i.e., small)—so they were ***not*** "meaningful" or "significant" proof of efficacy, nor did they show "improvements" of any meaningful kind. Nor did the analysis show improvements in GRADIENT "patients" without qualification—the results of the data as to ***all*** relevant patients failed to show efficacy, and whatever the post-hoc results showed applied only to a ***subset*** of the patients in the GRADIENT trial, a total of only 21 patients, all of whom were from the Hypertension Only Subgroup. *See* ¶¶180-88, 226.

270. ***Second***, statements that GRADIENT served as support for GRACE or as furthering the evidence found in GRACE were materially false and misleading. In reality, Defendants' efficacy claims based on GRADIENT and submitted in the NDA were based on a post-hoc, biased, and incomplete review of unblinded data that was not contemplated by the study's SAP and was conducted ***after*** the study had failed—and had even then only shown "***nominal***" proof of efficacy. *See* ¶¶181-88. In addition, because Defendants' statements about GRACE's results were false and misleading for the reasons set forth above—including for failing to disclose to investors that FDA had warned Defendants GRACE's results alone would likely be insufficient but instead that reliable confirmatory evidence would be needed, *see* ¶¶193, 195, 204, 208, 220-21, 224—it was materially false and misleading to state that GRADIENT was support or further evidence of GRACE in the first place. These statements were false and misleading also because before the Class Period, but as Defendants did not disclose, FDA had repeatedly expressed

concerns to Defendants about the adequacy of their relacorilant clinical development program to assess the efficacy of relacorilant and warned Defendants to expect significant review issues if they proceeded with an NDA based on such a program. *See* ¶¶190, 208, 220-21, 224. Defendants' statements about GRADIENT as support for GRACE or as furthering the evidence found in GRACE left investors with the misimpression that Defendants had filed an NDA containing what FDA wanted to see to approve relacorilant—an adequate and well-controlled primary study with strong proof of efficacy and reliable confirmatory evidence—when, in fact, Defendants had submitted neither.

271. Thus, it was materially false and misleading for Defendants to state that (i) GRADIENT's "***positive***" results "***support [the] findings from [the] pivotal Phase 3 GRACE study***" or "***support findings***" from GRACE, provide "***[s]upportive data***" or "***[s]upportive trial data for [the] NDA***," or "***support[] the GRACE trial***," including "***by providing further evidence of relacorilant's efficacy***" (Statements 13, 14, 15, 16, 19, 23); (ii) GRADIENT's results "***confirm relacorilant's promise***" or "***confirm[] what we found in GRACE***" (Statements 14, 16); and (iii) GRADIENT's results "***will be a powerful addition to relacorilant's NDA***" (Statement 14). In reality, GRADIENT's data was not "powerful" or "evidence of relacorilant's efficacy," and GRACE resulted in no meaningful results to "support" or to "further" in the first place; FDA had expressed concerns to Defendants about the adequacy of their relacorilant clinical development program to assess the efficacy of relacorilant (because the studies likely ***would not*** "show efficacy across multiple, and all signs and symptoms of Cushing's syndrome"), and to expect significant review issues if Defendants proceeded with an NDA based on such a program.

3. False and Misleading Statements About the Overall Efficacy Shown by the Clinical Development Program for Relacorilant

272. Statement 25: In the October 2024 Press Release, Defendant Guyer stated: "***As was true in the GRACE study, patients in GRADIENT who received relacorilant experienced clinically meaningful improvements in a broad range of hypercortisolism signs and symptoms***."

273. Statement 26: In its October 2024 Form 10-Q, Corcept stated that "***[i]n both trials [GRACE and GRADIENT], patients exhibited clinically meaningful improvements in***

hypertension."

274. Statement 27: During the October 30, 2024 earnings call, Defendant Belanoff stated: "***Patients in the GRACE and GRADIENT studies experience[d] meaningful improvements in hypertension***."

275. Statement 28: During the October 30, 2024 earnings call, Defendant Maduck said: "***Korlym is a great product, but relacorilant is going to be even better. It shows efficacy across multiple, and all signs and symptoms of Cushing's syndrome***."

276. Statement 29: During the October 30, 2024 earnings call, Defendant Robb answered an analyst's question about whether Corcept's view of GRACE and GRADIENT was "shared by the FDA," stating, "***the data from GRACE, along with confirmatory evidence, is sufficient to demonstrate [relacorilant's] safety and efficacy***."

277. Statement 30: A Canaccord analyst report published on October 30, 2024 printed statements made by Corcept "management" on "a call" after that day's earnings call, including that the relacorilant studies' "***efficacy measurements demonstrate a broad clinical benefit of rela[corilant] for Cushing's patients***" and that "***the data package in rela[corilant]'s submission will be composed of more than sufficient supporting clinical evidence***."

278. On December 30, 2024, Corcept issued a press release announcing it had submitted its NDA for relacorilant as a treatment for hypercortisolism, which was reviewed and approved by Defendant Belanoff who was quoted in the release, and which it posted on Corcept's website and incorporated into a Form 8-K filed with the SEC (the "December 2024 Press Release").

279. Statement 31: In the December 2024 Press Release, Corcept stated that the relacorilant "***NDA is based on positive results from the pivotal GRACE trial and confirmatory evidence from the Phase 3 GRADIENT***" trial. The December 2024 Press Release also quoted Defendant Belanoff as stating that "***[r]elacorilant's combination of efficacy and safety give it the potential to become the standard of care for the medical treatment of patients with hypercortisolism***."

280. Statement 32: In the February 2025 Press Release, Defendant Guyer stated that

"***[t]he positive results from [the] pivotal GRACE study, and confirmatory evidence from [] GRADIENT … provide powerful support for relacorilant's NDA in hypercortisolism***," that GRACE and GRADIENT "***[p]atients … experienced clinically significant improvements in a wide array of hypercortisolism's signs and symptoms***," and that "***[r]elacorilant's strong efficacy and safety profile positions it to become the new standard of care for patients with hypercortisolism***."

281. Statement 33: In its 2024 Form 10-K, Corcept stated that the relacorilant "***NDA is based on positive results from our pivotal trial 'GRACE', as well as confirmatory evidence from our Phase 3 'GRADIENT' trial***," that in "***all of the[] trials***" submitted as part of the relacorilant NDA, "***patients exhibited clinically meaningful improvements in a wide range of hypercortisolism signs and symptoms, including hypertension***," and that in both GRACE and GRADIENT, patients exhibited "***clinically meaningful and statistically significant improvements***" in measures including "***hypertension***."

282. Statement 34: During the February 26, 2025 earnings call, Defendant Belanoff stated that (i) "***[r]elacorilant's strong efficacy and safety profile positions it to become the new standard of care for patients with hypercortisolism***," (ii) "***[t]he positive results from***" GRACE and GRADIENT "***provide powerful support for successful relacorilant NDA in hypercortisolism***," (iii) the relacorilant "***NDA is based on compelling results from***" GRACE and GRADIENT, and (iv) "***[r]elacorilant's efficacy and safety … is clearly evident***" from GRACE and GRADIENT.

283. On March 3, 2025, Corcept issued a press release announcing the FDA's acceptance of the relacorilant NDA, which was reviewed and approved by Defendant Belanoff, who was quoted in the release, and which Corcept posted on Corcept's website and incorporated into a Form 8-K filed with the SEC (the "March 2025 Press Release").

284. Statement 35: In the March 2025 Press Release, Corcept stated that the "***NDA is based on positive results from the pivotal GRACE trial and confirmatory evidence from the Phase 3 GRADIENT trial***," and that in both trials, patients "***experienced improvements in a wide array of hypercortisolism's signs and symptoms***." The March 2025 Press Release also quoted

Defendant Belanoff as stating, "***[r]elacorilant's combination of efficacy and safety gives it the potential to become the new standard of care***."

285. Statement 36: In Corcept's 2024 Proxy Statement filed with the SEC and dated April 25, 2025 (the "2024 Proxy Statement"), Corcept stated that the relacorilant "***NDA is based on positive results from our pivotal GRACE trial, [and] Phase 3 GRADIENT trial***."

286. Statement 37: In the May 2025 Press Release, Defendant Guyer stated that "***[t]he positive results from our pivotal GRACE, and GRADIENT … studies provide powerful support for the NDA for relacorilant***," as "***[p]atients in these studies experienced clinically significant improvements in a wide array of the signs and symptoms of hypercortisolism***."

287. Statement 38: In its May 2025 10-Q Corcept stated that the relacorilant "***NDA is based on positive results from our pivotal GRACE trial, as well as confirmatory evidence from our Phase 3 GRADIENT trial***," and that "***[p]atients in these trials exhibited clinically meaningful improvements in a wide range of hypercortisolism signs and symptoms, including hypertension***."

288. Statement 39: During the May 5, 2025 earnings call, Defendant Belanoff stated that "***[r]elacorilant's strong efficacy and safety profile gives us the potential to become the new standard of care for patients with hypercortisolism***," and that "***[p]atients treated with relacorilant in***" GRACE and GRADIENT "***experienced clinically meaningful and statistically significant improvements across all of the signs and symptoms of hypercortisolism***," including "***in hypertension***," with "***a high level of consistency and durability***."

289. Statement 40: In the July 2025 Press Release, Defendant Guyer stated: "***In our studies, patients who received relacorilant exhibited clinically and statistically significant improvements in a wide array of hypercortisolism's signs and symptoms***."

290. Statement 41: In its July 2025 10-Q, Corcept stated that "***[t]he NDA is based on positive results from our pivotal GRACE trial, with confirmatory evidence from our Phase 3 GRADIENT trial***," as "***[p]atients in these trials exhibited clinically meaningful improvements in a wide range of hypercortisolism signs and symptoms, including hypertension***."

291. Statement 42: During the July 31, 2025 earnings call, Defendant Belanoff stated

that (i) "***Relacorilant's NDA is supported by***" GRACE and GRADIENT, in which patients "***experienced clinically meaningful improvements across all of the signs and symptoms of hypercortisolism, including hypertension***," which "***were observed consistently and durably***," (ii) "While Korlym's effectiveness … is well-established, ***relacorilant is a substantial advance. Its strong efficacy and safety positions it to become a new standard of care***," and (iii) "***[R]elacorilant is a better medication than Korlym***. Korlym works extremely well but ***relacorilant has very, very tangible advantages***."

292. Statement 43: During the July 31, 2025 earnings call, Defendant Maduck stated, "***[w]hile Korlym is a great medication, relacorilant is even better***."

293. Statement 44: In the November 2025 Press Release, Defendant Guyer stated that patients in GRACE and GRADIENT "***showed clinically meaningful and statistically significant improvements in a wide range of hypercortisolism's signs and symptoms***" and that "***[r]elacorilant has the potential to become the new standard of care for patients with hypercortisolism***."

294. Statement 45: In its November 2025 10-Q, Corcept stated that "***[t]he NDA is based on positive results from our pivotal GRACE trial, with confirmatory evidence from our Phase 3 GRADIENT trial***," and that "***[p]atients in these trials exhibited clinically meaningful improvements in a wide range of hypercortisolism signs and symptoms, including hypertension***."

295. Statement 46: During the November 4, 2025 earnings call, Defendant Belanoff stated that "***[r]elacorilant's NDA is supported by***" GRACE and GRADIENT, which had shown "***clinically meaningful improvements in all the measures of hypercortisolism, including hypertension … observed consistently and durably, with improvements emerging early and continuing or deepening over time***."

296. **Reasons for falsity.** For the following reasons, Statements 25-46 were materially false and misleading and misrepresented and failed to disclose facts necessary to make the statements not misleading.

297. ***First***, Defendants' statements that GRACE's results (together with

GRADIENT's) supported the NDA or showed efficacy were materially false and misleading for the reasons set forth above, including that Defendants failed to disclose critical facts, such as that: (i) prior to submitting the NDA, FDA had privately and repeatedly warned Defendants that GRACE would likely overstate relacorilant's efficacy, had warned Defendants that efficacy results from GRACE alone would likely not, and did not, support Corcept's claims about relacorilant's efficacy in an NDA, had also expressed concerns with the overall design of GRACE, and had told Defendants to expect significant review issues if Defendants proceeded with an NDA based on such a study, all consistent with FDA's warnings and guidance on these matters; (ii) GRACE's randomized-withdrawal phase's limited sample size made its enriched population results even less meaningful; and (iii) GRACE's open-label phase results were unreliable because they were based on unblinded, uncontrolled data that was, moreover, incomplete due to a high number of dropouts. *See* ¶¶193-208, 220-21, 224-28, 249-53.

298. ***Second***, Defendants' statements that GRADIENT's results (together with GRACE's) showed relacorilant's efficacy were materially false and misleading for the reasons set forth above, *see* ¶¶180-91, 220-22, 224-29, 267-71, including that Defendants failed to disclose that their claims were based on a post-hoc, unblinded, and selective re-analysis of a subset of incomplete data—all outside of GRADIENT's prespecified SAP—a result that only yielded "nominal" significance.

299. ***Third***, Defendants' statements that GRACE and GRADIENT together showed efficacy or were support for the NDA left investors with a fundamental misimpression about the relacorilant NDA—that Corcept had filed an NDA containing what FDA wanted to see to approve relacorilant, i.e., an adequate and well-controlled primary study with strong proof of efficacy and reliable confirmatory evidence—when, in fact, Defendants had submitted neither. They further concealed the critical fact that FDA had warned Defendants that GRACE's results alone would likely *not* be sufficient, *see* ¶¶13, 204, heightening the importance of the significance and reliability of GRADIENT's results.

300. ***Fourth***, nor did the analysis show improvements in "patients" in the GRADIENT trial. Whatever the post-hoc results Defendants were referring to showed, it applied only to a small

subset of the patients in the GRADIENT trial—21 patients in total, all of whom were from the Hypertension Only Subgroup. *See* ¶¶181-88, 226. Without that critical qualification, it was materially false and misleading to state the results showed improvements in GRADIENT's "patients" writ large.

301. It was thus materially false and misleading for Defendants to state that (i) GRACE and GRADIENT patients "***experienced … improvements***" that were "***meaningful***," "***clinically meaningful***," "***clinically significant***," "***statistically significant***," and "***observed consistently and durably***" or with "***a high level of consistency and durability***," and thus that these studies provided "***powerful support***" and "***compelling results***" for the relacorilant NDA (Statements 25, 26, 27, 32, 33, 34, 35, 37, 38, 39, 40, 41, 42, 44, 45, 46); (ii) the "***NDA is based on positive results from***" GRACE "***and confirmatory evidence from***" GRADIENT and that the clinical evidence supporting the NDA was "***sufficient to demonstrate [relacorilant's] safety and efficacy***" and "***more than sufficient***" (Statements 29, 30, 31, 33, 35, 36, 38, 41, 45); (iii) relacorilant is "***even better***" and "***a better medication***" than Korlym, and has "***very, very tangible advantages***" over Korlym (Statement 28, 42, 43); (iv) relacorilant "***shows efficacy across multiple, and all signs and symptoms of Cushing's syndrome***," "***all the measures of hypercortisolism***," and "***all***" or "***a wide array of hypercortisolism's signs and symptoms***," and its "***efficacy measurements demonstrate a broad clinical benefit***" (Statements 28, 30, 35, 39, 40, 42, 46); and (v) relacorilant's "***efficacy and safety … is clearly evident***," and it "***has the potential to***" become or its "***strong efficacy and safety profile positions it to become the new standard of care***" or "***the standard of care***" "***for patients with hypercortisolism***" (Statements 31, 32, 34, 35, 39, 42, 44). Neither trial's results showed relacorilant's efficacy, nor did the trials' results together show efficacy, as set forth herein.

4. False and Misleading Statements About the "Path" to Approval

302. Statement 47: During the October 30, 2024 earnings call, Defendant Belanoff said that "***[t]he results from our GRACE and GRADIENT Phase 3 studies clear the path for relacorilant's new drug application in Cushing's syndrome***."

303. Statement 48: During the October 30, 2024 earnings call, an analyst asked: "[W]hat gives you [the] confidence that you will be able to, not only file, but be able to get approval

here with the GRADIENT data in hand[?]" In response, Defendant Guyer stated: "***When you look at the results from GRADIENT, it supports the successful path to an NDA***," and that "***when you look at the totality of evidence that we see from all of these studies, we believe we have a successful path to a positive NDA for relacorilant that will happen in the coming weeks***."

304. Statement 49: A Canaccord analyst report published on October 30, 2024 printed statements made by Corcept "management" on "a call" after that day's earnings call, including that "***the company is as confident now as prior to the GRADIENT trial data that relacorilant is very likely to receive FDA approval***."

305. Statement 50: In the May 2025 Press Release, Defendant Belanoff stated that relacorilant "***is progressing towards approval by the end of this year***."

306. Statement 51: During the May 5, 2025 earnings call, Defendant Belanoff told investors, "***Our new drug application for relacorilant in hypercortisolism is progressing towards approval by the end of this year***."

307. Statement 52: During the July 31, 2025 earnings call Defendant Belanoff told investors, "***relacorilant is approaching approval***" and "***[w]e expect its approval in hypercortisolism by the end of this year***."

308. Statement 53: During the November 4, 2025 earnings call Defendant Belanoff told investors, "***[n]ext month, we expect FDA approval of relacorilant*** for the treatment of hypercortisolism."

309. **Reasons for falsity.** For the following reasons, Statements 47-53 were materially false and misleading and misrepresented and failed to disclose facts necessary to make the statements not misleading.

310. Defendants' statements about the upcoming success and approval of the relacorilant NDA were materially false and misleading because Defendants failed to disclose that, on several occasions during the pre-submission meetings, FDA had informed Defendants of its concerns with the adequacy of the clinical development program and the relacorilant Phase 3 trials to assess the efficacy of the drug in the intended population. Because of these serious concerns, FDA had warned Defendants that they should "expect significant review issues if [Defendants]

were to submit [their NDA]." *See* ¶¶193, 208, 220, 224, 249-50, 252, 268, 270-71, 297. Defendants understood the agency would require GRADIENT's confirmatory data because GRACE's results alone would likely *not* support approval, given the agency's concerns with that trial, *see* ¶¶13, 204, a critical qualification of what the agency would require for approval that Defendants did not disclose.

311. Thus, it was materially false and misleading for Defendants to state that (i) results from GRACE and GRADIENT "***clear the path for relacorilant's new drug application in Cushing's syndrome***" (Statement 47); (ii) Defendants had "***a successful path to a positive NDA for relacorilant***" (Statement 48); (iii) "***the company is as confident now as prior to the GRADIENT trial data that relacorilant is very likely to receive FDA approval***" (Statement 49); (iv) the relacorilant NDA was "***progressing towards approval*** by the end of" 2025 and "***approaching approval***" (Statements 50, 51, 52); and (v) Defendants "***expect***" FDA to approve the relacorilant NDA (Statements 52, 53). GRACE's results alone were insufficient, GRADIENT had failed, and Defendants' post-hoc analysis of GRADIENT was unreliable, so they could ***not*** "clear the path for" or result in a "successful path" to approval.

B. Defendants Misled Investors About Their Interactions with FDA and the Agency's Feedback About Relacorilant

312. Statement 54: During the October 30, 2024 earnings call, an analyst asked Defendant Belanoff whether Corcept's view of "GRACE [as] the pivotal" and "GRADIENT … as a supportive study" was "shared by the FDA?" Defendant Belanoff responded, "***Yes***." Later, when that same analyst questioned whether Corcept had already held a pre-NDA meeting with FDA, Defendant Belanoff stated: "***we've talked to the FDA plenty about this program, about all of our programs, and I foresee absolutely no impediments to getting our NDA in***."

313. Statement 55: During the October 30, 2024 earnings call, Defendant Robb also answered the same analyst question about whether Corcept's view of "GRACE [as] the pivotal" and "GRADIENT … as a supportive study" was "shared by the FDA," stating that "***[t]he answer is yes***," because "this isn't some … dark art where we have to guess what's on the FDA's mind. I mean, there's published guidance, as well as any conversations the sponsor may have," and "***the***

FDA has made it clear that a single well-controlled study, which we have in the form of our GRACE and the data from GRACE, along with confirmatory evidence, is sufficient to demonstrate a drug safety and efficacy." Defendant Robb continued, stating, "***I just wanted to underscore, from the perspective of the person who has to go in with the team and present the arguments to the FDA, just what a good position we're in***," and "***[i]t's that easy an argument to present to the FDA***."

314. Statement 56: During the October 30, 2024 earnings call, an analyst asked, "Has your communication with the FDA changed regarding the role of GRADIENT in the NDA?" In response, Defendant Guyer stated that "GRADIENT, from its inception, was always designed to be supportive of GRACE and GRACE was always going to be our pivotal study and ***that's our agreement with the FDA.***"

315. Statement 57: During the February 26, 2025 earnings call, an analyst asked Defendants about the timing of the NDA's acceptance and the potential for an FDA Advisory Committee ("AdCom") meeting, which is typically held to discuss controversial or difficult questions regarding a drug's safety and efficacy. In response, Defendant Robb stated that "we've been receiving that ***very ordinary course routine correspondence*** and responding to it over the past 60 days," that "***the process has been moving exactly as we understood it to move***," and that "***we are not expecting an AdCom … there's nothing about relacorilant's efficacy or safety that we think would require one***."

316. Statement 58: A Canaccord analyst report published on March 25, 2025 printed statements made by "the management of Corcept" during "two full days of meetings" Canaccord had hosted, including that "***[n]o surprises have come out of communications with the FDA***."

317. Statement 59: On June 26, 2025, Truist analysts reported that they "caught up with [Corcept's] ***mgmnt***" and that "***[m]gmnt shared*** that they recently had a mid-cycle review on relacorilant NDA during which ***the FDA continued to communicate that an AdCom won't be needed***."

318. Statement 60: During the November 4, 2025 earnings call, in response to an analyst's question regarding any updates on the "upcoming PDUFA for relacorilant" and the late-

cycle review meeting with FDA, Defendant Robb stated: "***Things have moved per schedule, very ordinary course***."

319. **Reasons for falsity:** Statements 54-60 were materially false and misleading and failed to disclose facts necessary to make Defendants' statements not misleading.

320. Prior to the Class Period FDA had privately and "[d]uring the pre-submission meetings, informed [Defendants] on several occasions of [the agency's] concerns about the adequacy of the clinical development program to assess the effect of relacorilant on hypertension in the intended population," as it later documented in the CRL. *See* ¶¶190, 208, 220-21, 224-29. These "concerns" "***includ[ed]*** … the design of [GRACE]" as the CRL stated. *See* ¶¶193, 195, 208, 220-21, 224. The agency had also privately warned Defendants that GRACE alone would likely not support claims of efficacy—as evidenced by Defendants' decision to pivot to including GRADIENT as part of the NDA following a meeting with FDA, after years of stating GRADIENT would not be needed for the NDA and even though GRADIENT was not by then completed and was in any event studying a smaller subset of the Cushing's population with a particular etiology of the disease. *See* ¶¶13, 204. Defendants acknowledged to market analysts that they had decided to pivot away from years of telling investors that GRADIENT would not be a part of the NDA, after consultation with FDA, *see* ¶¶109-12, but did not disclose the critical reason for the change—that by then they understood GRACE's results alone would likely not prove sufficient, which would have disclosed to investors the heightened importance of GRADIENT's results and the relatively less significant meaning and power of GRACE's. Thus, GRACE was ***not*** the "single-well controlled study" that Defendants claimed to "have in the form of … GRACE and the data from GRACE." Prior to the Class Period and as documented in the CRL, the agency also emphasized that it told Defendants on "several occasions" to "***expect significant review issues if [they] were to submit [their] application***." *See* ¶¶220-21, 224-28.

321. Given these undisclosed facts, it was materially false and misleading for Defendants to state that (i) FDA's feedback had been "***ordinary course***" and "***routine***" (Statements 57, 60); (ii) there had been "***no surprises … [in] communications with the FDA***" (Statement 58); (iii) there was an "***easy … argument to present***" to FDA (Statement 55); (iv) there were

"***absolutely no impediments to getting [the] NDA in***" (Statement 54); (v) FDA had "***agree[d]***" to the roles of GRACE and GRADIENT in the NDA (Statement 56); (vi) FDA "***made it clear that***" GRACE was "***sufficient to demonstrate***" relacorilant's "***safety and efficacy***" (Statement 55); (vii) "***we have [a single well-controlled study] in the form of our GRACE and the data from GRACE***" (Statement 55); and (viii) FDA shared Corcept's view of GRACE as "***the pivotal***" study and GRADIENT as "***a supportive stud***y" (Statements 54, 55), when, in fact, FDA had expressed repeated concerns about these studies and told Defendants to expect significant review issues if they proceeded with their application, including telling them that GRACE's results alone would not support the application. At a minimum, it was misleading for Defendants to repeatedly discuss their interactions with FDA and convey only supposedly positive aspects about those discussions without also disclosing the foregoing, contrary facts. Similarly, in conveying supposed FDA feedback that an AdCom "***won't be needed***" and that "***there's nothing about relacorilant's efficacy or safety that we think would require***" an AdCom (Statements 57, 59), Defendants left investors with the misimpression that FDA had conveyed approval would be so straightforward that no issues would need to be analyzed, when, in fact, FDA had conveyed the exact opposite—to "expect significant review issues."

C. Defendants Misled Investors About Relacorilant's Safety

322. Statement 61: In the October 2024 Press Release Corcept stated that the results from GRADIENT showed "***relacorilant was well-tolerated, with a safety profile consistent with the GRACE study***" and that "***[c]onsistent with its known safety profile, relacorilant was well-tolerated in both phases of GRACE***."

323. Statement 62: In its October 2024 10-Q, Corcept stated that "***[r]elacorilant was well-tolerated***" and that "***[r]elacorilant was well tolerated in GRADIENT***."

324. Statement 63: During the October 30, 2024 earnings call, Defendant Belanoff told investors that "***[r]elacorilant was very well tolerated and do[es] not cause some of the serious adverse events that can be caused by other medications used to treat Cushing's syndrome***," and that "***[a]n important feature of relacorilant is how well it was tolerated in both GRACE and GRADIENT***."

325. Statement 64: During the October 30, 2024 earnings call, Defendant Guyer stated, "***when you look at [relacorilant's] safety profile, it confirms what we saw in GRACE … it's consistent with a known safety profile of relacorilant, and no new safety signals were seen in the GRADIENT trial***."

326. Statement 65: During the October 30, 2024 earnings call, Defendant Maduck stated that "***relacorilant is going to be even better***" than Korlym, as it "***has significant safety benefit[s]***."

327. Statement 66: In the October 30, 2024 slide deck presentation shown to investors during that day's earnings call, Corcept described "***Relacorilant Safety Results***," stating that "***[i]n both GRACE and GRADIENT trials, relacorilant was well-tolerated, consistent with its known safety profile***."

328. Statement 67: In the December 2024 Press Release, Corcept stated that patients in GRACE and GRADIENT "***who received relacorilant*** experienced improvements in a wide array of hypercortisolism's signs and symptoms, ***with an acceptable safety burden***."

329. Statement 68: In the December 2024 Press Release, Defendant Belanoff stated that "***[r]elacorilant's combination of efficacy and safety*** give it the potential to become the standard of care for the medical treatment of patients with hypercortisolism."

330. Statement 69: In the February 2025 Press Release, Corcept stated that in both GRACE and GRADIENT, "***relacorilant was well-tolerated, consistent with its known safety profile***."

331. Statement 70: In its 2024 Form 10-K, Corcept stated that, from a safety perspective, "***[r]elacorilant was well-tolerated in all of the trials***."

332. Statement 71: During the February 26, 2025 earnings call, Defendant Belanoff stated: "***Just as important as relacorilant's efficacy is its safety. Relacorilant has been well tolerated in all of its studies***."

333. Statement 72: In the February 26, 2025 slide deck presentation shown to investors during that day's earnings call, Corcept described "***Relacorilant Safety Results***," stating that "***[i]n all its studies, relacorilant has been well-tolerated, consistent with its known safety profile***."

334. Statement 73: In the March 2025 Press Release, Corcept stated that "***[r]elacorilant was well tolerated***."

335. Statement 74: In the May 2025 Press Release, Defendant Guyer stated that GRACE and GRADIENT patients "experienced clinically significant improvements … ***without the off-target effects and toxicities that accompany currently available treatments***."

336. Statement 75: In its May 2025 10-Q, Corcept stated that "***[r]elacorilant has been well-tolerated in all of its trials***" and that, "***[c]onsistent with its known safety profile***, ***relacorilant was well-tolerated***."

337. Statement 76: During the May 5, 2025 earnings call, Defendant Belanoff stated: "***Relacorilant has been well tolerated in all of its studies***."

338. Statement 77: In the May 5, 2025 slide deck presentation shown to investors during that day's earnings call, Corcept stated: "***In all its studies, relacorilant has been well-tolerated, consistent with its known safety profile***."

339. Statement 78: In the July 2025 Press Release, Defendant Guyer stated: "***In our studies, patients who received relacorilant*** exhibited clinically and statistically significant improvements in a wide array of hypercortisolism's signs and symptoms ***without the off-target effects and toxicities that accompany currently available treatments***."

340. Statement 79: In its July 2025 10-Q, Corcept stated that "***[r]elacorilant has been well-tolerated in all of its trials***" and that, "***[c]onsistent with its known safety profile***, ***relacorilant was well-tolerated***."

341. Statement 80: During the July 31, 2025 earnings call, Defendant Belanoff described "relacorilant's safety characteristics" as "noteworthy," and stated that "***[r]elacorilant has been well-tolerated in all of its studies***."

342. Statement 81: In the July 31, 2025 slide deck presentation shown to investors during that day's earnings call, Corcept stated: "***In all its studies, relacorilant has been well-tolerated, consistent with its known safety profile***."

343. Statement 82: In the November 2025 Press Release, Defendant Guyer stated that patients in GRACE and GRADIENT "showed clinically meaningful and statistically significant

improvements … ***without off-target effects and toxicities associated with currently available treatments***."

344. Statement 83: In its November 2025 10-Q, Corcept stated that "***[r]elacorilant has been well-tolerated in all of its clinical trials***" and that, "***[c]onsistent with its known safety profile***, ***relacorilant was well-tolerated***."

345. **Reasons for falsity**: For the following reasons, Statements 61-83 were materially false and misleading and failed to disclose facts necessary to make Defendants' statements not misleading.

346. Relacorilant carried an undisclosed risk of DILI. As FDA documented in the CRL, relacorilant's Phase 3 investigators observed at least four cases of probable DILI, which posed "a higher liver related fatality risk," and the DILI cases were so severe that even after patients were discontinued from the drug, there was a "continued rise in liver enzyme levels." These cases were "probabl[y]" and "likely" "due to relacorilant," because of the close "temporal relationship of the adverse event to study drug initiation, and the lack of alternative etiology [explanation] identified despite extensive work-up," as FDA later confirmed following a thorough review of the safety data. And, because only 303 patients had been exposed to relacorilant, having four DILI cases was so "concerning" that FDA could not conclude relacorilant had a favorable benefit-risk profile and required Defendants to submit extensive additional data about relacorilant's safety on patients if they decided to submit a new NDA. *See* ¶¶210-18, 227-28.

347. Thus, it was materially false and misleading for Defendants to state that relacorilant was "***well-tolerated***" or "***well tolerated***" (Statements 61, 62, 66, 69, 70, 71, 72, 73, 75, 76, 77, 79, 80, 81, 83), that relacorilant was "***very well tolerated***" (Statement 63), and that it had an "***acceptable safety burden***" (Statement 67). In truth, the DILI cases had demonstrated that the drug was life-threateningly toxic. It was similarly materially false and misleading for Defendants to state that "***no new safety signals were seen***" (Statement 64), when in fact, new and critical safety signals ***had*** been identified—specifically, DILI "probabl[y]" and "likely" due to relacorilant. For the same reasons, it was materially false and misleading for Defendants to state that relacorilant "***has significant safety benefit[s]***" (Statement 65). Similarly, it was materially false and

misleading for Defendants to tout relacorilant's supposed lack of serious side effects and state only that it acted without "***off-target effects and toxicities***," including those "***that can be caused by other medications used to treat Cushing's syndrome***" or are "***associated with currently available treatments***," such that relacorilant's "***combination of efficacy and safety***" could make it "the standard of care" (Statements 63, 68, 74, 78, 82). In reality, the observed DILI cases were significant off-target side effects.

D. Defendants Misleadingly Presented as Hypothetical Existing Risks to Corcept's Business

348. During the Class Period, Defendants knowingly or recklessly made materially false and misleading statements concerning the business risks facing Corcept. Defendants misleadingly presented these risks as hypothetical and contingent, when in fact the risks had already come to pass.

349. Statement 84: In the October 2024 10-Q Corcept stated:

(a) "Our ***current clinical trials may prove inadequate*** to support marketing approvals. Even trials ***that generate positive results may have to be confirmed in much larger, more expensive and lengthier trials before we could seek regulatory approval***. ***Clinical trials may … fail for many reasons, including: failure to show efficacy or acceptable safety***."

(b) "At any time prior to the regulatory approval of a product candidate, we may decide, or the ***FDA or other regulatory authorities may require us***, ***to conduct more pre-clinical or clinical studies, provide additional analysis of existing data*** or change the size or design of a trial already underway."

(c) "Our Products and product candidates ***may cause undesirable side effects*** that halt their clinical development, ***prevent their regulatory approval, limit their commercial potential*** or cause us significant liability."

350. Statement 85: In the 2024 Form 10-K Corcept repeated verbatim the hypothetical risk factors above. *Supra* ¶349.

351. Statement 86: In the May 2025 10-Q Corcept repeated verbatim the hypothetical

risk factors above. *Supra* ¶349.

352. Statement 87: In the July 2025 10-Q Corcept repeated verbatim the hypothetical risk factors above. *Supra* ¶349.

353. Statement 88: In the November 2025 10-Q Corcept repeated verbatim the hypothetical risk factors above. *Supra* ¶349.

354. **Reasons for falsity:** Statements 84-88 were materially false and misleading and failed to disclose facts necessary to make Defendants' statements not misleading.

355. ***First***, it was materially misleading for Defendants to warn investors that Corcept's "current clinical trials ***may*** prove inadequate to support marketing approvals" (Statements 84, 85, 86, 87, 88) as though this were merely a speculative possibility, because, as FDA later confirmed in the CRL, the agency had already told Corcept, during pre-submission meetings that preceded each of the Risk Disclosures, that it had "concerns about the adequacy of the clinical development program to assess the effect of relacorilant on hypertension in the intended population including the design of [GRACE], and to expect significant review issues if [Corcept] were to submit [its] application." *See* ¶¶208, 220-21, 224-28. FDA had also told Defendants that GRACE's results alone would likely be inadequate to support relacorilant's approval. *See* ¶¶13, 204. These were not a contingent risk that "may" occur in the future—FDA had already directly communicated these precise inadequacies and materially significant risks to Corcept.

356. It was further materially misleading for Defendants to state that "[c]linical trials ***may***" fail for reasons including "***failure to show efficacy or acceptable safety***" (Statements 84, 85, 86, 87, 88) because this too was no mere speculative possibility. GRADIENT had already "fail[ed] to show efficacy," and Corcept's analysis of cherry-picked study data meant to salvage the GRADIENT results showed only "nominal," i.e., small, efficacy at best—and was conducted in post-hoc fashion, so it could not rescue GRADIENT's failure to show efficacy, unbeknownst to investors. *See* ¶¶181-87, 188, 191, 226, 268-60. Moreover, relacorilant's Phase 3 trials had ***already*** failed to show acceptable safety. *See* ¶¶218-19, 227-28.

357. ***Second***, the statement that "the FDA or other regulatory authorities ***may*** require [Corcept] … to conduct more pre-clinical or clinical studies, provide additional analysis of existing

data or change the size or design of a trial already underway" (Statements 84, 85, 86, 87, 88) was materially misleading because FDA had already imposed such a requirement. During the pre-submission meetings that preceded each of the Risk Disclosures, FDA specifically raised concerns regarding the design of GRACE and informed Corcept, on several occasions, that additional data and analysis would be necessary to assess relacorilant's effect on hypertension in the intended patient population. *See* ¶¶193, 195, 208, 220-21, 224-28. FDA had also told Defendants that GRACE's results alone would likely be inadequate to support relacorilant's approval and had thus already requested if not outright required additional analysis of data. *See* ¶¶13, 204.

358. ***Third***, it was materially misleading for Defendants to state that Corcept's "product candidates ***may*** cause undesirable side effects" that "prevent their regulatory approval" or "limit their commercial potential" (Statements 84, 85, 86, 87, 88), because this had already happened with relacorilant, which caused the undesirable side effect of liver hepatotoxicity. *See* ¶¶218-19, 227-28.

359. To the extent any of Statements 1-88 are opinions, they are materially false and misleading under the federal securities laws. Defendants did not subjectively believe their statements, including that the Phase 3 trials proved relacorilant's efficacy and safety and that relacorilant's approval was coming by the end of the year, as evidenced by all of the facts alleged herein, including their extensive Class Period sales of Corcept's stock, which continued up until the moment of FDA's decision date. Nor did the information in Defendants' possession fairly align with their statements, given the undisclosed repeated FDA warnings about relacorilant's clinical development program, the undisclosed facts about the nature of the GRACE and GRADIENT results analyses, and the undisclosed facts about liver injury. Those omitted facts substantially undermine the basis for the statements and a reasonable investor's belief in them. And Defendants' statements contain false embedded and objectively verifiable facts (including, for example, that a study was "well-controlled") about the relacorilant NDA.

VI. ADDITIONAL INDICIA OF SCIENTER

360. The allegations set forth above and summarized below, when viewed holistically and together with all the other allegations in the Complaint, establish a strong inference that each

Defendant acted with scienter, including because they knew or were reckless in not knowing that each of the misrepresentations and half-truths alleged herein were materially false and misleading when made.

361. ***First***, Defendants knew the specific facts that rendered their misstatements and half-truths false and misleading, including because FDA directly warned Defendants in private meetings about its serious concerns that the relacorilant clinical development program would not adequately support the drug's efficacy, and also raised concerns about relacorilant's safety.

362. ***Second***, Defendants had access to specific information contradicting their misstatements and half-truths. This information included the minutes of private FDA meetings in which the agency expressed to Corcept its concerns with the relacorilant clinical development program; their own analysis from the Phase 3 trials submitted in the NDA together with their sophisticated understanding of what FDA guidance said about that data, including that trials like GRACE do not show a drug's efficacy in the population at large, and also had access to the non-public GRADIENT post-hoc analysis that was not contemplated in the study's SAP; and the Phase 3 trials' data about relacorilant's liver effects, which they did not disclose.

363. ***Third***, the Individual Defendants had significant motive to make their false and misleading misstatements and half-truths. As they misleadingly assured investors that relacorilant was effective and safe, and that FDA had not told them anything to the contrary, the Insider Executives sold nearly $100 million worth of their personally held Corcept stock at artificially inflated prices. Defendants' compensation structure also incentivized them to rush the submission of the relacorilant NDA in 2024, regardless of FDA's concerns with the clinical trials.

364. ***Fourth***, relacorilant was the most critical aspect of Corcept's business during the Class Period. As the intended successor to Korlym—the Company's only material source of revenue and a drug whose future was increasingly at risk due to competitors' impending generic equivalents—relacorilant was the key to Corcept's future and Defendants' core business concern. Thus, the drug and its NDA became the subject of intense market scrutiny, and Defendants made repeated, specific statements about relacorilant's clinical development program and their related interactions with FDA, including in response to analyst questions.

365. ***Fifth***, for related reasons, Defendants prematurely halted enrollment for both Phase 3 trials, despite knowing this rendered the results further insufficient to establish efficacy.

A. FDA Privately Told Defendants the Trials Would Not Establish Relacorilant's Efficacy and that the NDA Faced Significant Issues

366. The Individual Defendants possessed direct, first-hand knowledge of the facts that made their Class Period statements to investors materially false and misleading because, before and during the Class Period, FDA repeatedly in private meetings warned Defendants that relacorilant's Phase 3 trials would not show relacorilant's efficacy, raised concerns about relacorilant's efficacy, and told Defendants to expect significant issues on the road to approval, as FDA later publicly revealed in the CRL. *See* ¶¶193, 195, 204, 208, 220-21, 224-228.

367. The Individual Defendants, during their respective tenures, on multiple occasions attended and participated in Corcept's relacorilant-related FDA meetings, including the pre-NDA submission and pre-Class Period meetings where FDA privately expressed its concerns and issued its warnings, and were otherwise in regular, direct communication with FDA about the relacorilant Phase 3 trials and NDA. The Individual Defendants themselves repeatedly told investors of their direct communications with FDA, and Lead Counsel's investigation independently confirms this.

368. Thus, because the Individual Defendants attended the meetings at which FDA issued these warnings, they knew or recklessly disregarded that relacorilant's Phase 3 trial results did not support their claims of relacorilant's efficacy or provide "clinically meaningful or statistically significant" or "further" evidence of efficacy; that relacorilant was ***not*** "well-tolerated" but was, instead, potentially fatal; and that their interactions with FDA had ***not been*** "routine" or "ordinary course" and that they did not have an "easy" argument to present to FDA, but that there were, instead, serious impediments to the relacorilant application.

1. The Individual Defendants Attended Multiple Meetings with FDA, Both Leading Up to and Continuing Through the Class Period, as They Repeatedly Publicly Emphasized

369. Corcept's first meeting with FDA regarding relacorilant occurred no later than August 2018. After telling investors in a November 2, 2017 press release that Corcept was planning an "FDA meeting … [for] the third quarter of next year," on August 9, 2018, Corcept announced

that it had developed "response criteria for relacorilant's Phase 3 trial" (only GRACE existed then) "***[b]ased on FDA feedback***." *See* ¶¶55, 62.

370. During an earnings call on November 3, 2022, an analyst asked Defendants whether GRACE patient enrollment "ha[d] been hitting [Corcept's] targets." Defendant Guyer responded that while they "don't typically talk about enrollment," their focus was completing the NDA and that Corcept had taken "***an all-hands on deck approach*** … ***[W]e're actively working with the FDA***." *See* ¶77. On May 3, 2023, during an earnings call, Defendant Guyer gave the same answer in response to another question: "***we're actively working with the FDA***."

371. On June 11, 2024, Truist released a report summarizing conversations with Corcept management. Truist analysts asked management whether "FDA signed off on GRACE 3 as sufficient for NDA submission from [an] efficacy standpoint" and whether GRADIENT would be necessary for approval. Management responded that "***[b]ased on our discussions with the FDA***" GRACE would serve as the basis for the NDA submission. Management also told Truist: "***We are in regular discussions with the FDA***." *See* ¶110.

372. During the July 29, 2024 earnings call, Defendant Robb again stated that "any ***company including ours***, as you're preparing to submit an NDA is in ***regular conversation with the FDA***, while the information is exchanged, things were discussed. ***And it was after that back and forth*** we decided to include data from our GRADIENT trial." *See* ¶112.

373. In September 2024, after Corcept changed GRADIENT's primary endpoint from dual hypertension and hyperglycemia endpoints to a single hypertension endpoint, Corcept management told investors that this had occurred "in consultation with" or "in alignment with" FDA, as reported by equity analysts. *See* ¶¶115-16.

374. During the Class Period, Defendants reconfirmed they were in frequent contact with FDA. For example, during the October 2024 Earnings Call, in response to an analyst's question about whether FDA shared Corcept's characterization of GRACE as the pivotal study and GRADIENT as supportive, Defendant Robb assured investors that Corcept's dealings with FDA were not "***some ... dark art where [Corcept] ha[s] to guess what's on the FDA's mind***," but were instead grounded in "published guidance" and in "***conversations***" between FDA and Corcept.

During the same earnings call, an analyst asked about Corcept's "last interaction with the FDA" and whether the Company had "already h[eld] a pre-NDA meeting with the FDA." Defendant Belanoff responded: "***I can say that we've talked to the FDA plenty about this program, about all of our programs***." *See* ¶¶122, 312.

375. During Corcept's February 26, 2025 earnings call (*see* ¶238), Defendant Robb told investors that, during FDA's 60-day filing review, Corcept received "various information requests" from the agency and responded to them. *See* ¶¶154-55, 400-01.

376. On March 25, 2025, Canaccord analysts reported that they "hosted the management of Corcept for two full days of meetings" during which management stated that "[n]o surprises have come out of communications with the FDA" and that "***Corcept will have continued communications … with the FDA***" regarding the indication on relacorilant's label.

377. During Corcept's November 4, 2025 Earnings Call (*see* ¶265), Defendants further admitted they met with FDA at least two times in 2025, referring to having had both a mid-cycle and a late-cycle meeting with FDA. *See also* ¶¶317-18. Because the PDUFA date for the relacorilant NDA was December 30, 2025, this means Defendants met with FDA at least once sometime in mid-2025 and at least once in late 2025.

378. Additionally, in a "chat" with Piper Sandler analysts on December 31, 2025, Corcept acknowledged an additional meeting with FDA, where "liver enzyme elevations (albeit mild) came up as a late review item." *See* ¶218.

379. Individual Defendant Belanoff personally attended the meetings where FDA expressed its concerns and warned Defendants to expect significant review issues. Defendant Belanoff is Corcept's founder and its sole CEO. As documents Corcept filed in the Teva Patent Litigation show, Defendant Belanoff personally attended FDA meetings on Korlym's approval. In addition, Belanoff was a co-author of a published study on relacorilant's Phase 1 trial. He was one of only a handful of Corcept employees with a medical degree—as of 2017, Corcept had only 137 employees, of which only six had a medical degree and, as of 2018, it had 166 employees, and only five had a medical degree. Defendant Belanoff repeatedly described relacorilant as Corcept's future, the product that would replace its only product, and repeatedly spoke to investors about the

Phase 3 trials generally and about the Company's interactions with FDA, and spoke to investors in the first-person plural, about what "we" had discussed with FDA. *E.g.*, ¶¶165, 312.

380. Individual Defendant Guyer (starting in August 2021, the beginning of his tenure as CDO) also personally attended the relevant meetings where FDA expressed its concerns and warned Defendants to expect significant review issues. During the February 26, 2025 earnings call, Defendant Belanoff held Defendant Guyer out to investors as the person "***in charge of everything related to relacorilant's development[]***." As Corcept's CDO, he was personally responsible for Corcept's relacorilant clinical development program, was a clinical pharmacist by training and, along with Defendant Belanoff, was one of just a handful of Corcept employees with a medical degree, and spoke to investors in the first-person plural about what "we" had discussed with FDA or "we" had decided to do based on meetings with FDA. *E.g.*, ¶¶77, 370.

381. Individual Defendant Robb (starting in 2021, the beginning of his tenure as CBO) also personally attended the relevant meetings where FDA expressed its concerns and warned Defendants to expect significant review issues. Defendant Robb was personally responsible for Corcept's business and was described as the person in charge of interactions with FDA. For example, during the October 30, 2024 Earnings Call, Defendant Robb underscored that he was providing "the perspective of the person ***who has to go in with the team and present the arguments to the FDA***." On the same call, when one analyst asked Defendants about GRADIENT and FDA's view on GRADIENT, Defendant Belanoff told analysts that Defendant Robb was the officer "***who handles all of our regulatory affairs***." Similarly, during the July 31, 2025 earnings call, Defendant Belanoff held Defendant Robb out to investors as the "Chief Business Officer," who "***oversees all of our regulatory interactions***." Thus, Defendant Robb also spoke to investors in the first-person plural, about what "we" had discussed with FDA or "we" had decided to do based on meetings with FDA. *E.g.*, ¶¶122, 145.

382. Individual Defendant Maduck (starting in April 2022, the beginning of his tenure as President of Corcept's Endocrinology Division) also either personally attended the relevant meetings where FDA expressed its concerns and warned Defendants to expect significant review issues, or was fully apprised of their contents. Defendant Maduck was personally responsible for

the division about endocrinology, which oversaw Corcept's Korlym franchise and would oversee Corcept's relacorilant franchise. Defendant Maduck repeatedly spoke to investors about the present circumstances and future expectations for both products—Korlym and relacorilant. *E.g.*, ¶¶113, 123, 127, 146, 160-61, 165, 275.

383. The Individual Defendants' attendance at other relacorilant-related FDA meetings additionally supports an inference that the Individual Defendants attended the meetings with FDA about the relacorilant Phase 3 trials and NDA. On May 27, 2025, Defendants Belanoff, Guyer, and Robb, as well as Corcept's "Head of Clinical Development, Oncology and Neurology," attended a pre-NDA meeting with FDA concerning relacorilant for ovarian cancer. *See supra* n.2. During the Class Period, Defendants and investors had assigned relacorilant for ovarian cancer only about one-fifth of the value they assigned to relacorilant for Cushing's syndrome. For example, during the July 31, 2025 Earnings Call, Corcept stated relacorilant for ovarian cancer has the "potential to deliver over $1 billion in long-term revenues," compared to the *$3 to $5 billion annual* revenue for relacorilant for Cushing's that Defendant Maduck repeatedly spoke about. Thus, Defendants' attendance at an FDA meeting for a smaller drug that would provide $1 billion in revenue to Corcept, strongly supports the inference that the Individual Defendants also attended FDA meetings for relacorilant for Cushing's—Corcept's most significant drug candidate which Corcept projected could generate "$3 to $5 billion" in annual revenue. And the attendance at that meeting, about a drug to treat cancer, by Corcept's head of oncology, further supports the inference that Defendant Maduck, the head of endocrinology, attended FDA meetings about relacorilant, a drug to treat an endocrinal condition.

2. Former Corcept Employees Confirm Certain Individual Defendants Repeatedly Communicated with FDA About Relacorilant

384. Three former Corcept employees interviewed by Lead Counsel corroborate the foregoing and provide additional evidence that Defendants Belanoff, Guyer, and Robb personally attended Corcept's meetings with FDA about relacorilant, pre- and post-NDA submission.

385. FE-1 stated that Corcept and FDA held pre-NDA submission meetings, including a pre-NDA submission meeting which FE-1 stated occurred in or around August 2024.

386. According to FE-1, Defendants Belanoff and Robb attended this pre-submission meeting with FDA, and Defendant Guyer most likely also attended because the Medical Directors on the submission reported to him.

387. FE-1 stated that Defendants Belanoff and Robb were always present for interactions regarding FDA. FE-1 explained that this was Corcept's first NDA filing in approximately 20 years and was an attempt to replace a previous product. FE-1 continued to say that this filing was a "big deal."

388. FE-1 further stated that Corcept amended the study protocol for one of the relacorilant trials as a result of this meeting, as contemporaneous evidence confirms. *See* ¶¶114-16.

389. FE-1 further stated there were at least five protocol amendments before FE-1's tenure began in March 2024, with at least one or two more occurring afterward. FE-1, who spent approximately twenty years in pharmaceutical program management before joining Corcept, described the volume of amendments to the relacorilant trial protocols as out of the ordinary compared to any other program they had worked on.

390. FE-1 identified the Corcept personnel responsible for designing and executing the relacorilant Phase 3 trials and for assembling the NDA. According to FE-1, Corcept's Senior Medical Director was the "science person" who developed the relacorilant protocols for both the GRACE and GRADIENT studies, and Corcept's Senior Director of Clinical Development Operations was responsible for the operational execution of the trials and understood the impact the amendments had on trials. FE-1 also stated that the relacorilant Project Management team reported up to Defendant Guyer. Defendants Guyer and Robb therefore sat at the top of the internal body that built the relacorilant NDA.

391. FE-1 was also involved in assisting the Individual Defendants' response to FDA questions about the NDA after it was submitted.

392. FE-1 recalled that Defendant Belanoff was completely involved in preparing Corcept's NDAs and FDA responses.

393. FE-1 described Golis, Corcept's Vice President of Quality Assurance and

Regulatory Affairs starting in December 2024 and to whom FE-1 then reported, as the point of contact who received incoming FDA questions following the December 2024 submission, and who then sent them to FE-1 and a colleague, who were responsible for creating response timelines, collecting internal answers, and routing responses up through Golis and Defendants Belanoff and Robb for approval before receiving a final sign-off from Defendant Robb before submission to FDA.

394. FE-1 stated that Defendants Belanoff and Robb approved every response Corcept made to FDA about the relacorilant NDA and that nothing went to FDA without the approval of Robb and Belanoff.

395. FE-1 stated that the initial FDA correspondence concerned the manufacturing processes for the drug and the format in which FDA required Corcept's data to be presented, but the requests later progressed to clinical questions in February, March, and April 2025.

396. FE-1 also stated that FDA's post-submission questions were routed through Corcept's regulatory team and that FE-1 and the Senior Manager of Regulatory Affairs were responsible for obtaining timely responses and signatures from the relevant personnel. These responses were approved by Defendants Belanoff and Robb and were signed by FE-1's supervisor.

397. According to FE-1, while FE-1 was still employed at Corcept, FDA had scheduled two post-NDA meetings with Corcept, for Summer 2025 and another for September 2025. FE-1 confirmed that attendees at those meetings included Defendants Belanoff and Robb, as well as other Corcept senior management, including likely Defendant Guyer. FE-1 explained that dates were proposed by FDA for these standard meetings and then work was done to confirm the availability of the relevant employees from Corcept.

398. FE-2 similarly stated that Defendant Guyer, as Corcept's Chief Development Officer, was "completely in the loop" regarding any FDA communications and the status of the GRACE and GRADIENT trials. FE-2 explained that Defendant Guyer was the head of clinical development and it was his job to know the status of every study, how close to enrollment they were, when enrollment and when the submission was ready.

399. FE-2 further stated that the regulatory department and C-suite executives saw

everything from FDA and routed requests to the appropriate personnel, and that it was commonly known within the Company that Defendant Guyer attended FDA meetings.

400. Through the summer and/or fall of 2025, FDA then sent another wave of information requests concerning the relacorilant NDA or related trial data. FE-2 recalled that it was typical to get one or two waves of requests like the ones FDA sent Corcept, but that Corcept received *three* waves of requests for the relacorilant submission. FE-2 received these requests, which sought reports of specific data, from Corcept's regulatory group. Per FE-2, the regulatory department and C-suite executives saw everything that came from FDA, and disseminated the FDA requests to the appropriate people.

401. In December 2025, Corcept received yet another FDA information request. FE-2 stated that there was a planned December 2025 meeting between Corcept and FDA, but that this meeting never happened. Corcept instead received an FDA information request in its place seeking a list of things FDA needed.

402. Additionally, FE-3 stated that Corcept discussed the design of GRACE with FDA in or about June 2018. FE-3 was informed of these discussions by Julia Varshavsky, the Director of Biometrics at Corcept at the time, who worked on GRACE's study design and likely attended FDA meetings. Varshavsky told FE-3 that Corcept, and specifically Defendant Belanoff, initially wanted GRACE to be structured with only an open label study, similar to the studies that had been used for Korlym's NDA, but FDA insisted that Corcept needed a placebo-controlled study.

B. Defendants Had Access to the Facts Contradicting their Class Period Statements

403. In addition to direct evidence that the Individual Defendants attended FDA meetings and/or signed off on all FDA responses, even if any Individual Defendant did not personally attend a given FDA meeting where FDA expressed its views and concerns about relacorilant (a wholly implausible inference), Defendants nevertheless had access to the facts contradicting their statements to investors about relacorilant's safety and efficacy and about Defendants' supposedly non-eventful interactions with FDA. This information included the private minutes of the meetings with FDA; the results from the Phase 3 trials themselves, coupled

with Defendants' own extensive sophisticated experience with and understanding of clinical trials and medications for controlling excessive cortisol levels; and non-public information concerning the association between relacorilant and similar Corcept drugs and DILI.

404. ***Access to Minutes of Corcept's Critical Pre-NDA FDA Meetings.*** FDA's 2009 guidance, *Formal Meetings Between the FDA and Sponsors or Applicants*, explains that "documentation of meeting outcomes, agreements, disagreements, and action items is critical to ensuring that this information is preserved for meeting attendees and future reference," and that "FDA minutes are the official record of the meeting." The same guidance further provides that "[t]he official, finalized minutes will be issued to all FDA attendees (with copies to appropriate files) and to the sponsor or applicant within 30 days of the meeting."

405. Thus, no later than 30 days after the critical pre-submission meetings with FDA, Defendants had access to the minutes from any meeting they may not have attended, which would have documented FDA's concerns about the relacorilant clinical development program. This includes minutes of the pre-NDA submission meeting with FDA that occurred on or around August 2024, after which they made a change to the GRADIENT protocol on September 2, 2024. *See* ¶¶114-16, 385, 388. Under FDA guidance, the Individual Defendants had access to the minutes from that meeting by the end of September 2024 or by early October 2024 at the latest, well before the October 30, 2024 start of the Class Period. The same is true for the minutes of Corcept's other pre-submission meetings with FDA, including those that Defendants acknowledged occurred starting in 2018. *E.g.*, ¶¶55, 62, 77, 110, 112, 115-16; *see also* ¶402.

406. Defendants, who spoke frequently to investors about FDA's views about relacorilant's clinical development program, either in fact reviewed the minutes from these meetings or were reckless in not doing so while repeatedly discussing these topics with investors.

407. ***Access to and Understanding of FDA Guidance and the Phase 3 Trials' Analysis.*** FDA's warnings were consistent with FDA's published guidance of which Defendants were aware, and which Defendants stated they used to interpret the Phase 3 trial results.

408. The Individual Defendants—the Corcept executives in charge of relacorilant's development, approval, and marketing—had access to the results from GRACE and GRADIENT,

Corcept's analysis of the results, and the contents of the NDA. The Individual Defendants, in the course of their ordinary duties, reviewed that data. Alternatively, they were reckless in not doing so while speaking to investors about relacorilant's supposed efficacy and safety and about the Phase 3 trials as supporting approval.

409. Defendants also told investors that Corcept understood and followed FDA guidance. During the October 30, 2024 Earnings Call at the start of the Class Period, Defendant Robb stated: "this isn't … a dark art where we have to guess what's on the FDA's mind. I mean, ***there's published guidance***, as well as any conversations the sponsor may have, ***or the FDA has made it clear that a single well-controlled study, which we have in the form of our GRACE and the data from GRACE, along with confirmatory evidence***, is sufficient to demonstrate a drug safety and efficacy." *See* ¶¶122, 313.

410. In a report published on October 30, 2024, Canaccord analysts wrote that they had "had a call with [Corcept] management post the earnings release," where "[m]anagement reiterate[d] that, ***per FDA's guidance***, the filing should be supported with data from one pivotal study and supporting evidence from an additional study."

411. Corcept likewise stated in each of its Class Period Form 10-Qs, signed by Defendant Belanoff, that it was "subject to oversight by the FDA ... with respect to our research, testing, manufacturing, labeling, [and] distribution, … activities," and that these requirements included "***continued compliance with FDA regulations, including [Current Good Manufacturing Practices], good laboratory practices and good clinical practices***."

412. The very guidance Defendant Robb publicly cited as the basis for his confidence in relacorilant's approval and that Corcept invoked in its SEC filings makes clear that the analysis of the Phase 3 trials Defendants submitted in the NDA did not meet the evidentiary standards for demonstrating relacorilant's effectiveness. For example, the *Enrichment Strategies* Guidance warned, among other things, that the "[u]se of an initial open-label phase without a control group" raises "concerns," and further explained that "the response in … a selected group would not describe the response in an unselected population." *See* ¶¶196-98; *see also* ¶206.

413. Moreover, the Individual Defendants were experienced in all the foregoing

matters—FDA guidance, clinical trial data, and relacorilant for Cushing's syndrome—they understood or recklessly disregarded that post-hoc analysis of a failed study's data, such as the analysis they submitted as to GRADIENT in the NDA, does not meet FDA's evidentiary standards.

414. Defendant Belanoff is an experienced physician-scientist who co-founded Corcept and has spent decades leading Corcept's drug development efforts. Defendant Belanoff is also a clinical faculty member and has held various positions, including as an Adjunct Professor, in the Department of Psychiatry and Behavioral Sciences at Stanford University since 1992. As a physician and co-founder of Corcept who had overseen the Company's cortisol-modulator franchise for decades, Defendant Belanoff possessed the scientific sophistication to appreciate that GRACE was a highly-enriched study that overestimated efficacy in the intended population; that GRACE's open-label phase had no control group against which to properly measure efficacy; that the post-hoc analysis of GRADIENT data, an already failed study, could not support claims about relacorilant's efficacy; and that GRACE's enriched population and high dropout rate and GRADIENT's outright failure to meet its primary endpoint, all posed a serious threat to relacorilant's approval prospects, even as he told investors the opposite.

415. Defendant Belanoff demonstrated a specific understanding of these issues during earnings calls with investors. For example, during a November 1, 2023 earnings call, in answer to an analyst's question about the GRACE trial data, Defendant Belanoff stated that the trial had "90% power to detect a loss of response of about a 50% difference between staying on relacorilant and maintaining that response or switching to placebo and losing a response," even though GRACE's protocol had called for enrolling 46 patients with hypertension in the randomized-withdrawal phase and had only studied 43 patients who met the hypertension response criteria.

416. As FE-1 explained, as a matter of standard clinical development practice, each modification to a study protocol carries a substantial risk of losing the power of the study, which is why sponsors normally avoid protocol amendments. Despite this, FE-1, who spent approximately twenty years in pharmaceutical program management before joining Corcept, described the volume of amendments to the relacorilant trial protocols as an "infinite" number of amendments and completely out of the ordinary compared to any other program FE-1 had worked

on.

417. Defendant Robb was hailed as the person who handles "all of [Corcept's] regulatory affairs." Defendant Robb repeatedly demonstrated detailed technical fluency with the details of relacorilant's mechanism of action, the key design and analysis of GRACE and GRADIENT, and the Company's private interactions with FDA as part of the relacorilant development program, including FDA guidance that he publicly discussed with investors and of which Defendants were aware. *E.g.*, ¶¶38, 91, 145, 159, 165, 313. As the person stated to be in charge of Corcept's regulatory affairs, Defendant Robb had access to the guidance and the trial results, and possessed the regulatory sophistication to understand that FDA's own published guidance undermined the Phase 3 trials' ability to support Defendants' claims of relacorilant's efficacy and that GRACE's enriched population and high dropout rate and GRADIENT's outright failure to meet its primary endpoint all posed a serious threat to relacorilant's approval prospects, even as he told investors the opposite.

418. Defendant Guyer was Corcept's CDO throughout the Class Period with nearly 30 years of medical and clinical experience. Guyer is a clinical pharmacist and holds a Pharm.D. Defendant Guyer repeatedly demonstrated detailed technical fluency with the details of relacorilant's mechanism of action, the key design and non-public analysis of GRACE and GRADIENT data, and the Company's private interactions with FDA as part of the relacorilant development program. As such, Defendant Guyer possessed the scientific sophistication to appreciate that GRACE was a highly-enriched study that likely overestimated efficacy in the intended population, that GRACE's open-label phase had no control group against which to properly measure efficacy, that the post-hoc analysis of GRADIENT data, an already failed study, could not support claims about relacorilant's efficacy, and that GRACE's enriched population and high dropout rate, and GRADIENT's outright failure to meet its primary endpoint, all posed a serious threat to relacorilant's approval prospects, even as he told investors the opposite.

419. Defendant Maduck was Corcept's President of Endocrinology throughout the Class Period with over 12 years of pharmaceutical, biotechnology, and management experience. Defendant Maduck holds a BE in Biomedical Engineering from the Thayer School of Engineering

at Dartmouth College. As Corcept's President of Endocrinology and given his extensive experience, Defendant Maduck possessed the scientific sophistication to appreciate that GRACE was a highly-enriched study that likely overestimated efficacy in the intended population, that GRACE's open-label phase had no control group against which to properly measure efficacy, that the post-hoc analysis of GRADIENT data, an already failed study, could not support claims about relacorilant's efficacy, and that GRACE's enriched population and high dropout rate and GRADIENT's outright failure to meet its primary endpoint, all posed a serious threat to relacorilant's approval prospects, even as he told investors the opposite.

420. The Individual Defendants' access to the non-public clinical trial data and analysis, their access to FDA guidance about the type of trials they employed, together with their extensive specialized experience, gives rise to a strong inference that the Individual Defendants on their own understood relacorilant's Phase 3 trials did not meaningfully or significantly demonstrate its efficacy and had demonstrated significant liver safety concerns, the very facts they concealed from investors—even if, contrary to all plausible inference, they had not heard these facts directly from FDA.

421. ***Access to Data About Relacorilant's Toxic Liver Signal.*** Defendants also had access to and knew or recklessly disregarded data about relacorilant's potential toxic effect on a patient's liver, information that was concealed from investors throughout the Class Period.

422. For one, this information was available to them as part of the relacorilant Phase 3 trial results—if not much earlier—which included information about four patients experiencing DILI, with ALT levels in one patient more than 50 times normal levels. *See* ¶227.

423. But Defendants also had access to ***real time data*** of relacorilant's liver safety issues while the trials were ongoing, before the Class Period, as required by their own study documents. The GRACE and GRADIENT SAPs specifically defined a special set of safety topics, based on evidence observed during the relacorilant pre-clinical and clinical development programs, to "identify and characterize events possibly associated with the use of relacorilant," including specifically signs of liver damage as manifested by elevated ALT levels. The study's protocols also required investigators to report this type of information to Corcept. *See* ¶¶215, 217.

424. Defendants also knew that another glucocorticoid receptor modulator compound Corcept had studied—miricorilant—had likely caused DILI in four of the first five patients to be put on the drug during its 2021 trial, requiring an abrupt end to the trial. *See* ¶¶75-76.

425. FE-3 confirmed what Defendants publicly acknowledged in 2021: that Corcept first observed liver enzyme elevations for glucocorticoid receptor antagonists during Corcept's separate miricorilant study, and that Corcept had stopped the study after observing these elevations to change the dosing structure. FE-3 explained that, after the study was stopped, Corcept ran a liver scan to look at the liver composition, confirmed the fat loss spikes, and determined that the glucocorticoid receptor antagonist dose used in the miricorilant study required dose modification.

426. FE-3 further stated that, from a safety standpoint, Corcept should have done fiber scans—i.e., liver scans—to monitor for liver injury during the GRACE and GRADIENT trials. According to FE-3, Corcept knew about the liver enzyme elevations and fat loss while GRACE and GRADIENT were ongoing, and that if Corcept knew liver enzymes were a problem when they submitted the NDA filing and they lauded the results but failed to show the fiber scans, that was problematic. FE-3 also explained that if a company hides data in a NDA, that is a big red flag for FDA. Corcept's failure to disclose the serious safety signal—the very signal that FDA later identified in the CRL as a basis for denying the NDA—was done with knowledge, or at least reckless disregard for the truth.

427. Moreover, during the Class Period, Defendants also frequently discussed miricorilant with investors, further demonstrating their knowledge of that drug's liver issues. For example, during the October 2024 Earnings Call where Defendants first announced GRADIENT's results, Defendant Belanoff also told investors that they were continuing to enroll in their "Phase 2b" trial of miricorilant. During the May 2025 Earnings Call, Defendant Belanoff again discussed miricorilant, stating that it "has very potent activity in the liver." In the July 2025 Press Release, Defendant Guyer discussed miricorilant and its effects on the liver.

428. In addition, as detailed by FDA in the CRL, FDA specifically brought up the liver toxicity issue during the "late-cycle" review meeting with Defendants, a meeting that Defendant Robb confirmed occurred in November 2025, *see* ¶165, and which Defendants admitted to analysts

after the Class Period had involved discussions about relacorilant's safety. *See* ¶218.

429. Thus, Defendants were either tracking the liver safety signals from the Phase 3 trials and knew that patients exhibited DILI, or they were reckless in not doing so while repeatedly telling investors relacorilant was "well-tolerated" (and reckless to the patients in the trials, too).

C. Defendants Profited Greatly From Their Fraud

430. While Lead Plaintiffs need not plead any motive to allege scienter, Defendants had powerful, personal financial motives to mislead investors about relacorilant's efficacy and safety and to misrepresent their interactions with FDA.

1. The Insider Executives' Sales of Nearly $100 Million of Corcept Stock Raise a Strong Inference of Scienter

431. ***Amount of Sales.*** The Individual Defendants were motivated to make materially false and misleading statements to investors in order to maintain Corcept's stock price inflation, as it allowed them (and the other Insider Executives) to dispose of large amounts of personally held Corcept shares at these artificially inflated stock prices.

432. During the Class Period, the Individual Defendants together sold 896,864 shares of Corcept stock for proceeds of $69,047,221. These amounts are dramatically out of proportion to their sales during the period of equal length immediately preceding the Class Period, i.e., August 29, 2023 to October 29, 2024 (the "Control Period"). During the Control Period, the Individual Defendants together sold 363,694 shares of Corcept stock for proceeds of $10,943,594. In other words, the Individual Defendants pocketed nearly ***seven times*** the amount of proceeds from their sales of Corcept stock during the Class Period as compared to the Control Period.

433. Defendant Belanoff sold 320,965 of his personally held Corcept shares during the Class Period, for proceeds of $25,078,150, after having sold ***nothing at all*** during the Control Period.

434. Defendant Maduck sold 340,000 Corcept shares during the Class Period, for proceeds of $27,027,324, over four times his $6,136,953 Control Period proceeds, when he sold 225,000 shares.

435. Defendant Guyer sold 214,500 shares during the Class Period, for proceeds of

$15,675,531, five times his $3,127,400 Control Period proceeds, when he sold 90,000 shares.

436. Defendant Robb sold 21,399 Corcept shares in November 2024 (right before Corcept submitted the relacorilant NDA), in January 2025, and in May and June 2025 (as Defendants assured investors approval was coming "by the end of this year"), for proceeds of $1,266,216. These highly clustered sales were worth almost as much as Defendant Robb's sales in the ***entire*** fourteen months preceding the fourteen-month Class Period, when he sold 48,694 shares (at lower prices) for proceeds of $1,679,241.

437. Three other Insider Executives—Lyon, Mahoney, and Swisher Jr.—sold $28,249,503 during the Class Period, over twelve times their $2,234,349 in Control Period sales, bringing the total across the Insider Executives to $97,296,724, as summarized in Table 1 below.

Insider	Class Period Proceeds	Class Period Shares	Control Period Proceeds	Control Period Shares
Joseph K. Belanoff	$25,078,150	320,965	$0	0
Sean Maduck	$27,027,324	340,000	$6,136,953	225,000
William Guyer	$15,675,531	214,500	$3,127,400	90,000
Gary Charles Robb	$1,266,216	21,399	$1,679,241	48,694
SUBTOTAL — INDIVIDUAL DEFENDANTS	**$69,047,221**	**896,864**	**$10,943,594**	**363,694**
Joseph Douglas Lyon (Officer)	$24,441,852	261,411	$1,533,770	55,000
David L. Mahoney (Director)	$2,030,452	27,352	$0	0
Daniel N. Swisher, Jr. (Director)	$1,777,198	26,400	$700,579	25,900
SUBTOTAL — NON-DEFENDANT INSIDERS	**$28,249,502**	**315,163**	**$2,234,349**	**80,900**
TOTAL — ALL INSIDERS	**$97,296,724**	**1,212,027**	**$13,177,943**	**444,594**

Table 1: Insider Sales of Corcept Stock

438. Defendant Belanoff's Class Period sales are particularly salient. The gross proceeds of $25,078,150 that Belanoff profited are the largest dollar-value liquidation of Corcept stock Belanoff has undertaken in his more than quarter-century as the Company's co-founder, Chairman, and CEO—larger than his sales in 2022 ($8,798,952), 2018 ($4,126,509), 2016 ($8,643,297), 2006 ($379,003), 2005 ($549,022), and 2004 ($119,016) ***combined***, as set forth

below:

	DOLLAR VALUE	# SHARES
2025	$ 25,078,150	320,965
2022	$ 8,798,952	335,019
2018	$ 4,126,509	217,115
2016	$ 8,643,297	1,000,000
2006	$ 379,003	110,000
2005	$ 549,022	112,006
2004	$ 119,016	20,000

Table 2: Defendant Belanoff's History of Corcept Stock Sales

439. ***Timing of Sales.*** The timing of the Insider Executives' sales furthers the inference of scienter. Each sold a large number of shares at artificially inflated prices after learning the materially adverse information FDA had conveyed about the relacorilant development program, but before it was public. Multiple sales occurred on or shortly after the issuance of false or misleading statements, and the Insider Executives sold nearly $7 million of Corcept shares in the thirty days prior to the corrective disclosure that crashed Corcept's stock price.

440. Within days of the October 30, 2024 earnings call on which Defendant Belanoff told investors that the GRACE and GRADIENT results "clear the path for relacorilant's new drug application," and on which Defendant Guyer assured investors "we have a successful path to a positive NDA," and Defendant Robb described the argument to FDA as "that easy an argument to present," insiders were selling. Guyer sold 6,606 shares on November 1, 2024, and 3,394 shares on November 4. Swisher sold 2,200 shares on November 11. Robb made an unplanned open-market sale of 2,609 shares on November 22. Lyon also sold 1,411 shares the same day.

441. On February 26, 2025, Belanoff told investors that the GRACE, GRADIENT, long-term extension, and Phase 2 results "provide powerful support for successful relacorilant NDA in hypercortisolism." Within weeks, on March 31, 2025, the Insider Executives sold more than $33 million worth of stock at prices between $94.72 and $102.48 per share: Belanoff sold 35,102 shares for $3,324,861; Maduck sold 100,000 shares for $10,054,010; and Lyon sold 200,000 shares for $20,093,511. The following day, April 1, 2025, Defendants Belanoff, Guyer, and Maduck, and Lyon each sold additional shares at $114.51 to $114.71 per share, the highest

prices at which any Insider Executive transacted during the Class Period.

442. On November 4, 2025, Maduck told investors: "I eagerly anticipate relacorilant's approval," and Defendant Belanoff assured them that "[n]ext month, we expect FDA approval of relacorilant for the treatment of hypercortisolism." Defendant Belanoff had sold 11,218 shares for $831,014 on November 3, 2025—the trading day immediately before that statement—and then sold 28,782 shares for $2,152,105 on November 5, 2025, the trading day immediately after his statement. Defendant Maduck similarly sold 20,000 shares for $1,479,816 on November 3, 2025. Defendant Guyer sold 20,000 shares for $1,507,122 on November 5, 2025. Lyon sold 5,000 shares for $368,245 on November 3, 2025. Thus, in the space of three trading days bracketing a statement that FDA approval was expected "[n]ext month," the Insider Executives extracted more than $6.3 million from Insider Executive sales to investors.

443. The Insider Executives continued selling into the final month before the revelation that FDA had rejected the NDA on December 31, 2025. The PDUFA date was public—it is set by statute and Defendant Belanoff told investors on May 5, 2025 that the NDA was "under review with an FDA action date of December 30, 2025." The Insider Executives therefore knew precisely when FDA's decision would land. They sold in the final weeks before that known date, at prices reflecting the market's confidence in a path to approval Defendants had been told (but concealed from investors) would be fraught with "significant review issues."

444. On November 25, 2025—five weeks before the corrective disclosure—Defendant Guyer sold 4,500 shares for $364,070 outside any Rule 10b5-1 plan. On December 1 and 2, 2025 Defendant Belanoff sold 40,000 shares for $3,190,796; Defendant Maduck sold 20,000 shares for $1,590,490; Defendant Guyer sold 20,000 shares for $1,601,526; and Lyon sold 5,000 shares for $397,632. Those December sales alone yielded more than $6.78 million at prices of approximately $79.52 to $80.88 per share—roughly $45 per share above the $34.80 closing price four weeks later, and fundamentally at odds with Defendants' professed confidence in approval.

445. ***Losses Avoided.*** On December 31, 2025, Corcept was forced to acknowledge that FDA had denied the relacorilant NDA. Corcept's stock price fell $35.40 per share, or 50.4%, from a closing price of $70.20 on December 30 to $34.80 on December 31. By selling before that

disclosure, the Individual Defendants avoided approximately $31.7 million in losses on shares they disposed of during the Class Period, conservatively calculated by multiplying the number of shares each sold by the $35.40 per-share decline—even though the Individual Defendants' sales frequently occurred at prices far above the December 30 $70.20 closing price, meaning they avoided larger losses by selling at Class Period high prices—as set forth below.

Defendant	Class Period Shares Sold	Minimum Loss Avoided (shares × $35.40) (rounded to nearest dollar)
Maduck	340,000	Approximately $12,036,000
Belanoff	320,965	Approximately $11,362,161
Guyer	214,500	Approximately $7,593,300
Robb	21,399	Approximately $757,525
TOTAL	**896,864**	**Approximately $31,748,986**

Table 3: Losses Avoided by Individual Defendants

446. ***Manner of Sales.*** Under SEC rules, trades by corporate insiders may be insulated from insider trading liability if made pursuant to a non-discretionary trading plan adopted pursuant to and in compliance with SEC Rule 10b5-1. *See generally* 17 C.F.R. § 240.10b5-1. Trades pursuant to such plans are immunized only if the plan is entered into by an insider "[b]efore becoming aware" of material non-public information and is established "in good faith and not as part of a plan or scheme to evade the prohibitions" of the rules. *Id.* § 240.10b5-1(c)(1)(ii)(A). Rule 10b5-1 requires an insider to, among other things, include a representation in the plan certifying that, on the date of adoption of the plan, he is not in possession of material non-public information about the issuer at the time the plan is adopted. *Id.* § 240.10b5-1(c)(1)(ii)(C)(*1*). Otherwise, insider trades that do not comply with these provisions and are made on the basis of material nonpublic information about the issuer or its securities, in breach of a duty of confidence owed to the issuer of the security and its shareholders, are a "manipulative or deceptive device" prohibited by Section 10(b) of the Exchange Act and Rule 10b-5 thereunder. *Id.* § 240.10b5-1(a).

447. In this case, the vast majority of the Individual Defendants' sales occurred pursuant to Rule 10b5-1 trading plans adopted by the Individual Defendants close to or during the Class Period, when they were already in possession of material, non-public information about Corcept's relacorilant clinical development program and a significant number of the Insider

Executives' remaining sales occurred pursuant to no Rule 10b5-1 trading plan at all.

448. Defendant Belanoff adopted the Rule 10b5-1 trading plan responsible for the entirety of his $25,078,150 in Class Period sales on November 26, 2024—approximately thirty days after the first false statement on October 30, 2024. Either Defendant Belanoff failed to provide the certification required by SEC Rule 10b5-1, in which case his trades are not immunized from liability, or he falsely stated in the certification that he was not aware of any material non-public information about Corcept and its securities when, in fact, he was. Regardless of the certification itself, the timing of adoption of the trading plan itself—less than one month into the Class Period—furthers the strong inference of Defendant Belanoff's scienter.

449. Defendant Belanoff's plan was structured to start selling immediately after the regulatorily required 90-day cooling off period (*see* 17 C.F.R. § 240.10b5-1(c)(1)(ii)(B)(1)(i)), and thereafter liquidated 40,000 shares nearly every month from March through December 2025.

450. Defendant Guyer adopted a plan the day after that Defendant Belanoff did so, on November 27, 2024, and that plan is responsible for 200,000 shares and $14,821,761 of Guyer's Class Period proceeds—the overwhelming majority of his selling. Either Defendant Guyer failed to provide the certification required by SEC Rule 10b5-1, in which case his trades are not immunized from liability, or he falsely stated in the certification that he was not aware of any material non-public information about Corcept and its securities when, in fact, he was. Regardless of the certification itself, the timing of adoption of the trading plan itself—less than one month into the Class Period—furthers the strong inference of Defendant Guyer's scienter.

451. In addition, Defendant Guyer executed a wholly unplanned, discretionary sale of 4,500 shares for $364,070 on November 25, 2025, thirty-six days before the corrective disclosure.

452. Defendant Robb executed a trading plan in February 2024. On January 2, 2025, Defendant Robb made $555,552 of Class Period sales.[5] Defendant Robb's approximately $700,000 in other Class Period sales of Corcept stock did not occur pursuant to any trading plan.

[5] Defendant Robb's publicly available Form 144 regarding the January 2, 2025 sale of $555,552 in Corcept stock does not indicate that this Class Period sale was made pursuant to a Rule 10b5-1 trading plan, but the Form 4 for the same sale does.

These sales included a discretionary open-market sale on November 22, 2024, less than a month into the Class Period and around the time Defendants Belanoff and Guyer adopted their new trading plans. Defendant Robb also made discretionary sales on May 20 and June 16, 2025, immediately following his statement during the May 2025 earnings call that the NDA "is progressing towards approval by the end of this year."

453. Defendant Maduck's plan was adopted on September 5, 2024, fifty-five days before the first identified false statement, when he was already in possession of material non-public information about FDA's concerns with the relacorilant clinical development program as well as about GRADIENT's results. Indeed, the plan's adoption came only two days after Corcept had to amend its trial protocol. Either Defendant Maduck failed to provide the certification required by SEC Rule 10b5-1 when he adopted that plan, in which case his trades are not immunized from liability, or he falsely stated in the certification that he was not aware of any material non-public information about Corcept and its securities when, in fact, he was. Regardless of the certification itself, the timing of adoption of the trading plan itself—approximately two months before the Class Period—furthers the strong inference of Defendant Maduck's scienter.

454. Corcept's employees found the foregoing pattern of sales suspicious. FE-1 stated that FE-1 and other Corcept personnel started seeing sales of Corcept stock from people in management—including Defendants Belanoff and Robb—and that they questioned "why they were selling a huge amount of stock." FE-1 concluded from these sales that Corcept's management knew about these issues very clearly, reasoning that "if management were confident in the NDA, why would they sell?" FE-2, who oversaw clinical data management for GRACE and GRADIENT, also volunteered that Guyer's Class Period stock sales were highly suspicious and well timed, opining that, from FE-2's perspective as a clinical data manager, Defendant Guyer had to be aware of the risk the moment he reduced the GRACE enrollment sample size.

2. Defendants' Executive Compensation Further Contributes to a Strong Inference of Scienter

455. Defendants also knew they would make—and did make—millions of dollars of additional cash payments pursuant to compensation plans that uniquely incentivized the fraud.

456. Corcept's 2023 Proxy Statement, dated April 10, 2024 ("2023 Proxy Statement"), stated that Corcept "pay[s] discretionary bonuses annually based on the Compensation Committee's assessment of [its] prior year's progress toward achieving significant long-term goals and the contribution to such achievements by each named executive officer" and that the Company "maintain[s] the discretion to pay bonuses when significant goals are met." The first such goal listed was "successful completion of a clinical trial."

457. The 2023 Proxy Statement further stated that, in February 2024, Corcept's executive compensation committee had "evaluated the contributions of each of our named executive officers with respect to progress towards the achievement of our long-term goals" and listed as two of the first three most important goals "completing enrollment of patients in GRACE" and "enrolling patients in GRADIENT" (the third was "increasing revenue"). According to the 2023 Proxy Statement, the compensation committee had concluded that "[i]n light of these accomplishments and the team's individual contributions" a significant bonus, 120% of the target bonus, was warranted for Defendants Belanoff, Guyer, and Robb, and a 140% bonus was warranted for Defendant Maduck, the head of endocrinology.

458. The Individual Defendants were four of the five "executive officers" listed by name in the 2023 Proxy Statement (the fifth was Corcept's CFO Atabak Mokari). Pursuant to this award, Belanoff received an additional $1,320,000, Guyer an additional $379,800, Maduck an additional $422,800, and Robb an additional $397,200.

459. Thus, by no later than February 2024 when they received their 2023 bonuses, the Individual Defendants understood that, just like completing enrollment in GRACE and GRADIENT had led to significant bonuses for them personally for calendar year 2023, successful completion of the long-extant GRACE and GRADIENT Phase 3 trials and submission of the relacorilant NDA was highly likely to personally financially benefit them—regardless of whether the NDA eventually resulted in FDA approval.

460. This is what ultimately happened. Corcept's 2024 Proxy Statement again listed "successful completion of a clinical trial" as a key Corcept goal. The 2024 Proxy Statement further explained that in determining the Individual Defendants' compensation Corcept's compensation

committee considered that the Individual Defendants had submitted "an NDA to the FDA for relacorilant to treat patients with hypercortisolism," which the Committee described as meeting "aggressive goals." The 2024 Proxy Statement further said that "in light of these accomplishments," the Individual Defendants received bonuses totaling $3.2 million—with more than $1.7 million being awarded to Defendant Belanoff alone.

461. Thus, the Individual Defendants were incentivized to push the GRACE and GRADIENT trials through completion and submit the relacorilant NDA by the end of 2024, despite any pushback from FDA and regardless of whether the NDA was ultimately approved.

462. Former Corcept employees interviewed by Lead Counsel confirm that the Individual Defendants acted pursuant to this personal financial incentive. FE-2, Corcept's Associate Director of Clinical Data Management from October 2021 through March 2026, confirmed that the NDA submission was on everyone's annual review goals and that there was a compensation-related goal that trickled down to everyone. FE-2 stated that this was specifically communicated to FE-2, as an Associate Director, Clinical Data Management.

463. FE-1 confirmed that the directive that the NDA submission "had to happen by December 31st" came from Defendant Belanoff through Defendant Robb.

D. Defendants' Fraud Concerned Corcept's Most Significant Studies Related to Its Most Significant Drug, Which Became the Subject of Repeated Statements to Investors and of Intense Market and Regulatory Scrutiny

464. That Defendants' misstatements concerned the most critical studies related to Corcept's single most significant drug, at a time when it was the subject of intense regulatory scrutiny by way of the pending NDA, furthers the strong inference of scienter, particularly as Corcept was a relatively small company whose management was focused on relacorilant's success throughout the Class Period. Relacorilant was so essential to the Company's future that Defendants cast it as the drug that would be the "successor" to Corcept's longstanding, only revenue generating product, and discussed it on ***every*** investor conference call throughout the Class Period and on ***every*** quarterly call for the six years preceding it. *See also* ¶59.

465. In addition, relacorilant's Phase 3 trials were an extensive, yearslong project for Corcept and its relatively small number of employees. The studies took over six years to complete

and required numerous amendments and changes. A project of this extensive scope and importance does not occur without the significant involvement of Corcept's executive leadership—the Individual Defendants—nor does it occur while escaping their attention.

466. Moreover, before and during the Class Period, investors were intensely focused on relacorilant's efficacy and safety and on FDA's views of the drug and its application, all as investors sought to properly assess whether Corcept would be able to replace its sunsetting Korlym franchise with a new, profitable product.

467. For the entire time before and throughout the Class Period, Corcept's portfolio included just one drug, Korlym, from which Corcept had derived essentially all of its revenue. However, in the years before the Class Period, generic competitors threatened that lucrative position. In December 2023, this threat became starker after a federal court found that Teva's generic alternative to Korlym did not infringe on Corcept's patents. Under these circumstances, relacorilant's role as a successor to Korlym made its approval an existential imperative for Corcept.

468. From the outset, Defendants described relacorilant as the "planned successor to Korlym" that would "entirely replace Korlym" and "expands the market opportunity by 2 to 3 times." Defendants repeated their description of relacorilant as the "planned successor" at every single earnings call between November 2018 and November 2022 and discussed relacorilant and its Phase 3 trials with investors during ***every single*** earnings call since at least 2018 through the end of the Class Period. As just one example, during the July 31, 2025 earnings call Defendant Belanoff told investors that relacorilant would "ultimately … entirely replace Korlym," as "almost all patients [] receiving Korlym" were expected to "transition to relacorilant."

469. Former Corcept employees confirm that Defendants internally viewed the Teva Patent Litigation ruling and the Korlym marketing exclusivity loss as intensifying the urgency to obtain relacorilant's approval.

470. FE-1 stated that Defendant Robb told them during their pre-employment interview in early 2024 that the Teva patent lawsuit was "not going to be relevant because Korlym would be replaced by relacorilant."

471. FE-1 described the directive on the need to meet the December 31st deadline as

the message that came from Belanoff through Defendant Robb. Corcept's strategy, according to FE-1, was to replace Korlym with the new molecule under a very different cost structure, leveraging Corcept's existing specialty pharmacy infrastructure and patient relationships to transition patients to relacorilant immediately upon approval.

472. Defendants Maduck and Belanoff also repeatedly told investors that relacorilant would generate $3 billion to $5 billion annual revenue within three to five years, *e.g.*, ¶¶110, 123, 146, 160-61, 165—a figure that dwarfed the approximately $761.4 million in revenue Corcept generated from Korlym in 2025. Further, on July 31, 2025, Defendant Maduck told investors that "[w]hile Korlym is a great medication, relacorilant is even better … I expect that almost all patients who are receiving Korlym will choose to transition to relacorilant and our growth will accelerate when it becomes available."

473. Investment analysts, in turn, specifically predicated their ratings and price targets for Corcept stock on the view, based on Defendants' statements, that relacorilant would replace Korlym, generate significant revenues for Corcept, and was all but certain to obtain approval. For example, on September 17, 2024, analysts at Piper Sandler upped their estimates for Corcept from $38.47 to $67 per share to "more fully reflect[] the commercial impact of relacorilant," assuming the product gained FDA approval before the end of 2025. H.C. Wainwright & Co. stated in a February 11, 2025 report: "If successful, we project risk-adjusted Cushing's syndrome related relacorilant revenues to grow to nearly $824M by 2030 from $175M in 2026." On March 3, 2025, analysts at Canaccord rated Corcept "buy" because they "continue to believe that relacorilant for Cushing's will receive FDA approval on or before the 12-30-25 PDUFA date." Also on March 3, Truist analysts noted relacorilant's approval would "neutralize any threat from [competitor's] generics," as "patients on Korlym or any generic mifepristone" would presumably switch to relacorilant. On October 9, 2025 Truist stated, "[m]ore importantly, we continue to view CORT vs TEVA … decision … and relacorilant PDUFA (Dec 30) as key catalysts for CORT."

474. Defendants were aware that relacorilant had become the focus of intense investor scrutiny, not only because Defendants themselves encouraged investors to focus on it, but because market analysts repeatedly asked Defendants questions about these subjects. Between the

November 2018 earnings call and the end of the Class Period, which the Individual Defendants routinely attended throughout their respective tenures, analysts asked questions about relacorilant ***fifty-three*** (53) times. During the Class Period alone, Defendants sat down for interviews, provided quotes, or engaged in question-and-answer sessions with no fewer than seven analysts, who reported to the market on their conversations with Defendants. These interviews included the one Corcept "management" had with Truist analysts, reported by Truist on June 11, 2024, where management stated the Phase 3 trial analysis was "agreed to with the FDA," that they were "in regular discussions with the FDA," and that they had "a drug in hypercortisolism that has a strong efficacy and safety profile, hit its primary endpoint, and is on the path to approval next year, has exclusivity till 2040, and has peak sales of north of $3 billion." *See also* ¶¶244, 277, 304, 316-17.

475. At the same time, relacorilant and its Phase 3 trials occupied significant attention inside Corcept, including significant attention from the Individual Defendants themselves. As noted, since the Phase 3 trials started in 2018 and throughout the Class Period, Corcept has been a relatively small company with a few hundred employees and only one revenue-generating product. Corcept has been operating without a Chief Medical Officer since at least 2021.

476. The relacorilant clinical trials were expansive, expensive, years-long corporate endeavors. The trials lasted a decade (the Phase 1 trial began as early as 2014) and enrolled patients across over 100 study sites and 30 countries. They involved seven amendments to the GRACE study protocol and three to GRADIENT's. They involved multiple rounds of in person meetings and written correspondence with FDA, Corcept's principal regulator. Given the central importance of relacorilant to Corcept, this is the kind of corporate endeavor that does not occur without management involvement or, at minimum, management awareness and approval. In fact, further confirming the obvious—that the Individual Defendants were intimately involved in all aspects of the relacorilant Phase 3 trials and its NDA—Corcept's 2023 and 2024 Proxy Statement specifically mention the Individual Defendants' personal involvement in those projects as the basis for millions of dollars in additional compensation. *See* ¶¶457-59, 461.

477. That the subjects of Defendants' misstatements were also the focus of intense, ongoing regulatory scrutiny and concern during the Class Period further supports an inference that

the true facts concerning those subjects could not have escaped Corcept management's notice. Given that FDA's views on relacorilant would have an outsized impact on the Company's business and profitability, the Individual Defendants could not reasonably have been unaware of the substance of these discussions, including FDA's warnings to expect significant review issues and that relacorilant's clinical development program would not support claims about efficacy.

478. In sum, relacorilant's singular importance to Corcept's survival and the intensity of Defendants' and investors' focus on FDA's review of the NDA indicate that Defendants knew about FDA's repeated, substantive warnings about the inability of relacorilant's Phase 3 trials to support claims of efficacy, of the true nature of GRADIENT's post-hoc analysis, of the liver safety signal discovered during the trials, and of the falsity of Defendants' statements concerning these subjects. Yet, despite the overriding importance of relacorilant and GRACE and GRADIENT to investors, Defendants failed to disclose FDA's repeated warnings about the trials' ability to support efficacy and safety claims and misled the market about the tenor of their conversations with FDA. Defendants either knew or were reckless in failing to know that these critically important facts were publicly misstated or concealed.

E. Defendants Prematurely Stopped the Relacorilant Trials To Force an NDA Submission By 2024, Knowing This Rendered Their Results Further Insufficient To Support Approval

479. Defendants' statements, public documents, and former Corcept employees interviewed by Lead Counsel establish that Defendants arbitrarily cut short their relacorilant Phase 3 trials—in significant part to obtain personal financial benefits—despite knowing this decision endangered the application altogether, a critical fact they withheld from investors.

480. Between 2018 and 2024, Defendants had to push back the stated expected date of the relacorilant NDA repeatedly and no fewer than nine times, from early 2021 to the eventual submission date in the last days of 2024. Not only did this damage Corcept and its executives' credibility in the market, but by no later than 2023 investors were losing patience, and the delays had begun to weigh on Corcept's stock. *E.g.*, ¶¶78-79.

481. In 2023, with the imminent end of Corcept's Korlym franchise approaching, no other viable candidate on the horizon, and amid mounting pressure from the market, the Individual

Defendants decided they could not delay any longer and had to submit the NDA as soon as possible. Moreover, as set forth above, the Individual Defendants understood that their personal financial compensation for 2024 would increase if they submitted the NDA in 2024. *See* §VI.C.2.

482. Consistent with the foregoing, FE-2 stated that there was a rush to get the NDA in. Specifically, Corcept cut off GRACE enrollment in August 2023 (as confirmed by Defendants' public statement in August 2023 that GRACE had "completed" enrollment, *see* ¶80) before reaching the trial's original target sample size and leaving only 43 patients. FE-2 explained that GRACE was not designed in a way that could permit early enrollment closure because Defendants had no prospectively specified statistical basis on which to close enrollment early and yet did so knowing that GRACE required its full planned enrollment to be adequately powered.

483. FE-2 told their supervisor that FE-2 "would be remiss" if FE-2 told their supervisor it would be acceptable to reduce the sample size, and FE-2 had that conversation with the supervisor more than once. FE-2 stated that, both FE-2 and FE-2's supervisor had a good idea that FDA was not going to approve relacorilant after enrollment was cut off, reasoning that if a sponsor cuts off enrollment, its efficacy "better be pretty darn good." After raising these objections with their supervisor, FE-2 added that FE-2 was moved into another group, stating that the Company "parked" FE-2 and put FE-2 on busy work. FE-2 was laid off in March 2026 along with several other employees. Corcept did not provide a reason for the layoff, but FE-2 believed it resulted from expressing concerns over the relacorilant process.

484. FE-2 also stated that FDA's concerns about the adequacy of relacorilant's clinical development program were communicated to Corcept well before submission, and that FDA said all along that Corcept needed to have a good sample size unless the safety profile of relacorilant was a lot better, and that Corcept needed more data.

485. FE-2 stated that Defendant Guyer, along with the C-suite—specifically Defendants Guyer and Robb—were the only persons with authority to order enrollment closure. FE-2 further stated that clinical operations was simply given a deadline and told the last day of GRACE enrollment was August 1, 2023.

486. FE-1 similarly stated that Corcept cut off GRADIENT enrollment to force the

NDA filing timeline. FE-1 stated that FE-1 believed that enrollment was cut off in mid-2024 to force the filing date, which was then moved from an original deadline to October 2024, and ultimately to December 31, 2024. According to FE-1, the directive that the NDA submission "had to happen by December 31st" came from Defendant Belanoff through Defendant Robb.

487. Defendants knowingly or recklessly prioritized an artificial NDA filing deadline to personally financially benefit, regardless of whether the Phase 3 trials had produced the efficacy data FDA had privately asked for (consistent with its published guidance), while concealing from investors the resulting insufficiency of GRACE and GRADIENT to support Defendants' claims of efficacy. Defendants took this risk not only because they stood to personally benefit but because even a smaller GRACE trial could in theory support approval if GRACE's data was robust and powerful evidence of efficacy ***and*** there was other strong confirmatory evidence of efficacy, too—which Defendants risked would come from GRADIENT.

488. But in the fall of 2024, when GRADIENT results came in and failed to show relacorilant's efficacy in any prespecified, statistically significant way, and by then FDA had expressed to Defendants the agency's concerns about the relacorilant clinical development program and that GRACE would likely not be enough, it became clear Defendants had gambled with Corcept's future by ending the studies early and lost.

489. Defendants then faced a stark choice. They could concede defeat and start over with another Phase 3 trial for relacorilant, one that would provide the supporting evidence that GRACE needed, but that could take up to another decade given the rarity of the condition and difficulties enrolling patients, well past the end of Korlym's exclusivity period and any remaining investor patience with Defendants' repeated delays. Or they could forge ahead with the data they had, and hope that, contrary to its past feedback, FDA—soon to be under new leadership in 2025—would change its mind. Regardless of the NDA's outcome, Defendants would receive their own bonuses and profit handsomely by selling their shares to unsuspecting investors. So, Defendants decided to forge ahead, but they disclosed none of this multitude of devastating facts to investors, choosing instead to mislead them about the true facts underlying the NDA they submitted.

VII. THE INDIVIDUAL DEFENDANTS SOLD OVER $69 MILLION IN STOCK, CONTEMPORANEOUSLY WITH LEAD PLAINTIFFS' PURCHASES

490. By no later than October 30, 2024, the start of the Class Period, the Individual Defendants were in possession of material, non-public information about Corcept and its securities that they did not disclose, including FDA's specific warnings. During the Class Period, and while in possession of that material non-public information they did not disclose, the Individual Defendants sold over $69 million of Corcept stock.

491. Over $16 million of these sales were contemporaneous with Lead Plaintiffs' purchases of Corcept common stock.

492. Defendant Belanoff sold the following shares of Corcept common stock for more than $4.1 million, contemporaneously with Lead Plaintiffs' purchases:

Date of Individual Defendant Sales	Shares Sold	Proceeds from Sales	Date of Lead Plaintiffs' Purchases[6]	Days After Insider Sales	Shares Purchased	Purchase Amount
03/31/2025	35,102	$3,324,861	04/01/2025	1	298	$28,199.14
			04/01/2025**	1	1,084	$102,576.75
			04/02/2025	2	81	$6,803.15
			04/02/2025**	2	293	$24,608.92
			04/03/2025**	3	439	$35,896.50
04/01/2025	350	$40,149	04/01/2025	0	298	$28,199.14
			04/01/2025**	0	1,084	$102,576.75
			04/02/2025	1	81	$6,803.15
			04/02/2025**	1	293	$24,608.92
			04/03/2025**	2	439	$35,896.50
11/03/2025	11,218	$831,014	11/03/2025	0	25	$1,835.27

Table 4: Belanoff's Sales Contemporaneous with Lead Plaintiffs' Purchases

493. Defendant Guyer sold the following shares of Corcept common stock for more than $77,000, contemporaneously with Lead Plaintiffs' purchases:

[6] Purchases identified without an asterisk are purchases by ACERS; one asterisk refers to purchases by Local 817; two asterisks refer to purchases by Tallahassee.

Date of Sale	Shares Sold	Proceeds from Sales	Date of Lead Plaintiffs' Purchase	Days After Insider Sales	Shares Purchased	Purchase Amount
04/01/2025	678	$77,639	04/01/2025	0	298	$28,199.14
			04/01/2025**	0	1,084	$102,576.75
			04/02/2025	1	81	$6,803.15
			04/02/2025**	1	293	$24,608.92
			04/03/2025**	2	439	$35,896.50

Table 5: Guyer's Sales Contemporaneous with Lead Plaintiffs' Purchases

494. Defendant Maduck sold the following shares of Corcept common stock for more than $12.5 million, contemporaneously with Lead Plaintiffs' purchases:

Date of Sales	Shares Sold	Proceeds from Sales	Date of Lead Plaintiffs' Purchase	Days After Insider Sales	Shares Purchased	Purchase Amount
03/31/2025	100,000	$10,054,000	04/01/2025	1	298	$28,199.14
			04/01/2025**	1	1,084	$102,576.75
			04/02/2025	2	81	$6,803.15
			04/02/2025**	2	293	$24,608.92
			04/03/2025**	3	439	$35,896.50
04/01/2025	590	$67,584	04/01/2025	0	298	$28,199.14
			04/01/2025**	0	1,084	$102,576.75
			04/02/2025	1	81	$6,803.15
			04/02/2025**	1	293	$24,608.92
			04/03/2025**	2	439	$35,896.50
05/01/2025	12,856	$924,818	05/01/2025	0	354	$25,398.76
			05/01/2025**	0	1,280	$91,837.31
11/03/2025	20,000	$1,479,816	11/03/2025	0	25	$1,835.27

Table 6: Maduck's Sales Contemporaneous with Lead Plaintiffs' Purchases

VIII. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR

495. The PSLRA's statutory safe harbor and/or bespeaks caution doctrine applicable to forward-looking statements under certain circumstances do not apply to any of the materially false and misleading statements pleaded here—none was a forward-looking statement, instead, each was a statement of purported, current facts and conditions existing at the time or prior to when the statements were made, or a statement rendered materially misleading for omitting existing facts.

496. To the extent that any of Defendants' materially false and misleading statements alleged herein can be construed as forward-looking, those statements were not accompanied by

meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statements. As alleged in detail above, given the then-existing facts contradicting Defendants' statements, of which they were aware or recklessly disregarded, any generalized risk disclosures made by Defendants were insufficient to insulate them from liability for their materially false and misleading statements or omissions of material facts.

497. Moreover, to the extent the statutory safe harbor otherwise would apply to any materially false and misleading statement complained of herein, Defendants are liable for those materially false and misleading statements because, at the time each of those statements was made, the speaker knew that the particular forward-looking statement was false or misleading, or the statement was authored, drafted, authorized, and/or approved by an executive officer of Corcept who knew that the statement was false or misleading when made.

IX. PRESUMPTION OF RELIANCE

498. The Class is entitled to a presumption of reliance on Defendants' material misrepresentations and omissions pursuant to the fraud-on-the-market doctrine because, at all relevant times, the market for Corcept's common stock was an efficient market for the following reasons, among others:

- Corcept's common stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;
- Corcept's common stock traded at high weekly volumes;
- As a regulated issuer, Corcept filed periodic reports with the SEC;
- Corcept was eligible to and did file registration statements with the SEC on Form S-3;
- Corcept regularly and publicly communicated with 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, securities analysts, and other similar reporting services;

- Corcept and its stock were followed by numerous securities analysts employed by major brokerage firms who wrote public reports which were distributed to those brokerage firms' sales force and certain customers, and the public;
- There was a cause and effect relationship between unexpected corporate events or financial releases and movements in Corcept's stock price;
- The material representations and omissions alleged herein would tend to induce a reasonable investor to misjudge the value of Corcept stock; and
- Without knowledge of the misrepresented or omitted material facts alleged herein, Lead Plaintiffs and other Class members purchased or acquired Corcept common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed.

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

500. A Class-wide presumption of reliance is also appropriate in this action under the United States Supreme Court holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the claims asserted herein against Defendants are predicated upon omissions of material fact for which there is a duty to disclose, so 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 FDA's feedback to Defendants about their Phase 3 trials, the importance of relacorilant's efficacy and safety as demonstrated by its Phase 3 clinical trials, and the impact FDA's denial could have on the Company's future revenue, that requirement is satisfied here.

X. CLASS ACTION ALLEGATIONS

501. Lead Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil

Procedure 23(a) and 23(b)(3) on behalf of a Class consisting of all persons and entities that purchased or otherwise acquired Corcept's publicly-traded common stock after market close on October 30, 2024 and before market open on December 31, 2025, both dates inclusive, and who were damaged thereby. 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, director, or control person of Corcept during the Class Period, and members of their immediate families; (iv) any firm, trust, corporation, or other entity in which any Defendant has or had a controlling or beneficial interest; (v) Corcept's employee retirement and benefit plan(s), if any, and their participants or beneficiaries, to the extent they made purchases through such plan(s); and (vi) the legal representatives, affiliates, heirs, successors-in-interest, or assigns of any such excluded person, in their capacities as such.

502. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Corcept shares were actively traded on the NASDAQ and there were over 100 million shares of Corcept common stock outstanding at all times. On October 23, 2025, for example, there were approximately 105 million shares of Corcept common stock outstanding. While the exact number of Class members is unknown to Lead Plaintiffs at this time and can only be ascertained through appropriate discovery, Lead Plaintiffs believe that there are at least thousands of Class members. Class members who purchased Corcept common stock may be identified from records maintained by Corcept or its transfer agent(s) and may be notified of this class action using a form of notice similar to that customarily used in securities class actions. Disposition of their claims in a class action will provide substantial benefits to the parties and the Court.

503. Lead Plaintiffs' claims are typical of Class members' claims, as all Class members were similarly affected by Defendants' wrongful conduct in violation of the federal securities laws as complained of herein.

504. Lead Plaintiffs will fairly and adequately protect Class members' interests and have retained competent counsel experienced in class actions and securities litigation. Lead Plaintiffs have no interest that conflicts with the interests of the Class.

505. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of fact and law common to the Class are: (a) whether Defendants' misrepresentations and omissions and deceptive acts as alleged herein violated the federal securities laws; (b) whether the Individual Defendants are personally liable for the alleged misrepresentations and omissions and deceptive acts described herein; (c) whether Defendants' misrepresentations and omissions and deceptive acts as alleged herein caused the Class members to suffer a compensable loss; and (d) the proper measure of damages.

506. A class action is superior to all other available methods for the fair and efficient adjudication of this action. Joinder of all Class members is impracticable. Additionally, the damages suffered by some Class members may be relatively small so that the burden and expense of individual litigation make it practically impossible for such members to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

XI. CLAIMS FOR RELIEF

COUNT I

For Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5(b)
(Against All Defendants)

507. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

508. This Count is asserted pursuant to Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5(b) promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5(b), on behalf of Lead Plaintiffs and the Class, against Defendants.

509. During the Class Period, Defendants carried out a plan, scheme, and course of conduct which was intended to and, throughout the Class Period, did (1) deceive the investing public, including Lead Plaintiffs and other Class members, as alleged herein, and (2) cause Lead Plaintiffs and other Class members to purchase Corcept stock at artificially inflated prices.

510. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(b) in that, during the Class Period, Defendants made, disseminated, and/or approved the materially false and

misleading statements and omitted the material facts alleged herein, which they knew, or at minimum were reckless in not knowing, were false and misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

511. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, made various untrue and/or misleading statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, and made the above statements and omissions intentionally or with severe recklessness.

512. Defendant Corcept is liable for all materially false or misleading statements made during the Class Period, as alleged above.

513. The Individual Defendants are liable for the false or misleading statements they made, disseminated, and/or approved and for which they were responsible, as alleged above.

514. As alleged above, Defendants acted with scienter throughout the Class Period in that they had actual knowledge of the misrepresentations and omissions of material fact set forth herein, and either acted with intent to deceive, manipulate, or defraud or were deliberately reckless in not knowing the true facts that were available to them. Defendants engaged in this misconduct to conceal Corcept's true condition from the investing public and to support the artificially inflated prices of Corcept's common stock.

515. Lead Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Corcept's common stock. Lead Plaintiffs and the Class would not have purchased Corcept's common stock at the prices they paid, or at all, had they been aware that the market prices for Corcept's common stock had been artificially inflated by Defendants' fraudulent course of conduct.

516. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and the other Class members suffered damages in connection with their respective purchases of the Company's common stock during the Class Period.

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

COUNT II

For Violations of Section 10(b) of the Exchange Act and SEC Rules 10b-5(a) and (c) (Against All Defendants)

518. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

519. This Count is asserted pursuant to Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5(a) and (c) promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5(a) and (c), on behalf of Lead Plaintiffs and the Class, against all Defendants.

520. During the Class Period, Defendants violated Section 10(b) of the Exchange Act and SEC Rule 10b-5(a) and (c) issued thereunder, in that Defendants: (1) employed devices, schemes, and artifices to defraud; and (2) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon Lead Plaintiffs and others similarly situated in connection with their purchases of Corcept common stock during the Class Period in an effort to maintain artificially inflated prices for Corcept common stock.

521. Corcept and the Individual Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails, intentionally or with reckless disregard for the truth, employed devices, schemes, and artifices to defraud and engaged and participated in a continuous course of conduct that operated as a fraud and deceit upon the purchasers of Corcept's common stock, which did (i) deceive the investing public, including Lead Plaintiffs and the Class, regarding, among other things, the true facts regarding the relacorilant NDA and Defendants' interactions with FDA; (ii) artificially inflate and maintain the market price of Corcept's common stock; and (iii) cause Lead Plaintiffs and other Class members to purchase Corcept common stock at artificially inflated prices and suffer losses when the true facts became known.

522. As part of their scheme to defraud investors in violation of Rule 10b-5(a) and (c), Defendants engaged in the fraudulent scheme to prevent the true facts about the relacorilant NDA

and their interactions with FDA from becoming known through the acts described above in §§IV-VII, including by:

- concealing the heightened risk to the GRACE and GRADIENT studies posed by their decision to prematurely terminate patient enrollment and rush to submit the NDA regardless of FDA's concerns;
- directing and participating in a rush to submit the NDA regardless of FDA's concerns;
- ignoring warnings from Corcept employees and others about the sufficiency of the Phase 3 trials to establish efficacy and taking actions against employees who expressed such warnings;
- keeping FDA's feedback about the relacorilant NDA hidden from Corcept employees;
- disseminating materially false and misleading statements about the relacorilant NDA made by others and making additional false and misleading statements, as alleged ¶¶230-359; and
- engaging in extensive insider stock sales while in possession of material non-public information about Corcept and its common stock.

523. These deceptive acts were part of a course of conduct that operated as a fraud and deceit upon Lead Plaintiffs and others similarly situated in connection with their purchases of Corcept common stock during the Class Period in an effort to maintain artificially high market prices for Corcept common stock.

524. As described above, Corcept and the Individual Defendants acted with scienter throughout the Class Period, in that they either had actual knowledge of the scheme and the misrepresentations or omissions of material facts set forth herein, acted with intent to deceive and/or reckless disregard for the true facts, even though such facts were available to them. Defendants engaged in this misconduct to conceal the true facts about Corcept's relacorilant NDA from the investing public and to support the artificially inflated prices of Corcept's common stock. The Individual Defendants' state of mind is imputed to Corcept.

525. Lead Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Corcept's common stock, which artificial inflation was removed from the stock when the true facts became known. Lead Plaintiffs and the Class would not have purchased Corcept's common stock at the prices they paid, or at all, had they been aware that the market prices for Corcept's common stock had been artificially inflated by Defendants' fraudulent course of conduct.

526. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and the other Class members suffered damages attributable to the fraud alleged herein in connection with their respective purchases of Corcept's common stock during the Class Period.

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

COUNT III

For Violations of Section 20(a) of the Exchange Act (Against the Individual Defendants)

528. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

529. The Individual Defendants acted as controlling persons of Corcept within the meaning of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), as alleged herein.

530. By reason of their high-level positions of control and authority as Corcept's most senior officers, the Individual Defendants had the authority to influence and control, and did influence and control, Corcept's and its employees' decision-making and activities, and to cause Corcept to engage in the wrongful conduct complained of herein. The Individual Defendants were able to influence and control, and did influence and control, directly and indirectly, the content and dissemination of the public statements made by Corcept during the Class Period, thereby causing the dissemination of the materially false and misleading statements and omissions of material facts as alleged herein. The Individual Defendants were virtually the only Corcept officers who communicated substantively with investors on earnings calls and at investor conferences on Corcept's behalf. The Individual Defendants were provided with, or had unlimited access to,

copies of the Company's press releases, public filings, and other statements alleged by Lead Plaintiffs to be misleading prior to and/or shortly after these statements were made and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

531. Each of the Individual Defendants spoke to investors or the public on behalf of Corcept during the Class Period. Therefore, each Individual Defendant was able to influence and control, and did influence and control, directly and indirectly, the content and dissemination of the public statements made by Corcept during the Class Period, thereby causing the dissemination of the materially false and misleading statements and omissions of material facts as alleged herein.

532. As set forth above, Corcept violated Section 10(b) of the Exchange Act by its acts and omissions and fraudulent course of conduct as alleged in this Complaint.

533. By virtue of their position as a controlling person of Corcept and as a result of their own aforementioned conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act, jointly and severally with, and to the same extent as, the Company is liable under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, to Lead Plaintiffs and the other Class members who purchased or otherwise acquired Corcept common stock. As detailed above, during the Class Period, these Individual Defendants served as officers, directors, and/or senior personnel of Corcept, including as its CEO (Defendant Belanoff), its Chief Development Officer (Defendant Guyer), its Chief Business Officer (Defendant Robb), and the President of Corcept's Endocrinology Division (Defendant Maduck).

534. As a direct and proximate result of the Individual Defendants' conduct, Lead Plaintiffs and the other Class members suffered damages in connection with their purchase or acquisition of Corcept common stock.

COUNT IV

For Violations of Sections 10(b) and 20A of the Exchange Act and Rule 10b-5 Thereunder for Insider Trading (Against the Individual Defendants)

535. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

536. This count is asserted for violations of Section 20A of the Exchange Act, 15 U.S.C.

§ 78t-1, on behalf of Lead Plaintiffs and all other Class members who purchased Corcept stock contemporaneously with the sale of Corcept stock by the Individual Defendants while they were in possession of material nonpublic information as alleged herein, including concerning relacorilant's efficacy and safety, the results of the relacorilant Phase 3 trials, and the communications with FDA concerning relacorilant and the relacorilant Phase 3 trials and NDA.

537. As set forth herein, the Individual Defendants violated Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 issued thereunder for the reasons stated in Counts I and II above. Additionally, the Individual Defendants further violated Section 10(b) of the Exchange Act and Rules 10b-5, and Rule 10b5-1 thereunder (17 C.F.R. § 240.10b5-1) by selling shares of Corcept's common stock while in possession of material, nonpublic adverse information concerning relacorilant's efficacy and safety, the results of the relacorilant Phase 3 trials, and the communications with FDA concerning relacorilant and the relacorilant Phase 3 trials and NDA, in breach of their duty of confidence owed to Corcept and its shareholders.

538. As detailed herein, the Individual Defendants were in possession of material non-public information concerning Corcept and took advantage of their possession of material non-public information regarding Corcept to obtain millions of dollars in insider trading profits during the Class Period.

539. The Individual Defendants' sales of Corcept common stock were made while in possession of material, nonpublic information they had a duty to disclose, but failed to disclose as alleged herein, and were made contemporaneously with Lead Plaintiffs' purchases of Corcept common stock during the Class Period. Defendants Belanoff, Guyer, and Maduck sold shares of Corcept common stock for total proceeds of more than $4 million, $77,000, and $12.5 million respectively, contemporaneously with Lead Plaintiffs' purchases of Corcept common stock. *See supra* ¶¶490-94 (relevant dates and amounts of sales of the Individual Defendants' sales of Corcept common stock); ECF No. 33-2 (Lead Plaintiffs' dates and amounts of purchases of Corcept common stock).

540. Other Class members also purchased shares of Corcept common stock contemporaneously with the Individual Defendants' sales of Corcept common stock.

541. Lead Plaintiffs and Class members who purchased shares of Corcept common stock contemporaneously with sales by the Individual Defendants have been damaged as a result of the violations of the Exchange Act alleged herein.

542. The Individual Defendants are liable to Lead Plaintiffs and other Class members who purchased shares of Corcept common stock contemporaneously with the Individual Defendants' sales of Corcept common stock during the Class Period.

543. Lead Plaintiffs and other Class members who purchased Corcept common stock contemporaneously with the Individual Defendants' sales seek disgorgement by the Individual Defendants of profits gained or losses avoided from their transactions in Corcept common stock contemporaneous with Lead Plaintiffs' and other Class members.

XII. PRAYER FOR RELIEF

544. WHEREFORE, Lead Plaintiffs pray for judgment:

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

(b) Awarding compensatory damages and disgorgement in favor of Lead Plaintiffs and other Class members against 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 Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

(d) Awarding such equitable, injunctive or other further relief as the Court may deem just and proper.

XIII. JURY DEMAND

545. Lead Plaintiffs hereby demand a trial by jury.

DATED: August 28, 2026

Respectfully submitted,

BERNSTEIN LITOWITZ BERGER & GROSSMANN LLP

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APPENDIX A: CHART OF DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

In re Corcept Therapeutics Inc. Securities Litigation, No. 3:26-cv-1525-TLT

#	AC ¶[1]	Place and Date of Statement	Speaker(s)	False and Misleading Statement and Omission
False and Misleading Statements About Relacorilant's Efficacy				
False and Misleading Statements About GRACE				
1.	¶233	October 30, 2024 – 3Q2024 Earnings Press Release	Corcept (reviewed and approved by Belanoff and Guyer)	"The pivotal Phase 3 GRACE trial is the basis for relacorilant's NDA in Cushing's syndrome and ***met its primary endpoint***. Patients in GRACE's initial, ***open-label phase exhibited clinically meaningful and statistically significant improvements in hypertension***, hyperglycemia and other symptoms experienced by patients with Cushing's syndrome. In the randomized withdrawal phase, ***GRACE met its primary endpoint*** and demonstrated that patients who remained on relacorilant maintained these improvements while those who received placebo saw a significant worsening in their signs and symptoms of hypercortisolism."
2.	¶234	October 30, 2024 – 3Q2024 Earnings Call	Corcept, Belanoff, Maduck	**Belanoff:** "Patients in the open-label phase in GRACE ***exhibited clinically meaningful and statistically significant improvements in hypertension … These outcomes would, on their own***, ***provide powerful evidence for our NDA***, but they do not stand on their own." **Maduck:** "Korlym is a great product, but ***relacorilant is going to be even better. It shows efficacy across multiple, and all signs and symptoms of Cushing's syndrome, as*** Bill [Guyer] just walked through and ***Joe [Belanoff] walked through in his comments***, and has significant safety benefit."

[1] Many of these statements are addressed in multiple locations within the Amended Complaint. The reference in this column is to the paragraph where the false and misleading statement is listed in Section V of the Amended Complaint.

APPENDIX A: CHART OF DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

In re Corcept Therapeutics Inc. Securities Litigation, No. 3:26-cv-1525-TLT

#	AC ¶[1]	Place and Date of Statement	Speaker(s)	False and Misleading Statement and Omission
3.	¶235	October 30, 2024 – 3Q2024 Earnings Call	Corcept, Guyer, Maduck	**Analyst Question**: "[W]hat gives you confidence that you will be able to, not only file, but be able to get approval here with the GRADIENT data in hand, given that backdrop?" **Guyer**: "Altogether, this gives us the largest NDA package for Cushing's syndrome and we have hundreds of patients. So going to the FDA with this large of a package, no other company has done that thus far. Now, GRADIENT, from its inception, was always designed to be supportive of GRACE and GRACE was always going to be our pivotal study and that's our agreement with the FDA. And ***we met our primary endpoint for GRACE***." **Maduck**: "Korlym is a great product, but relacorilant is going to be even better. ***It shows efficacy across multiple, and all signs and symptoms of Cushing's syndrome, as Bill [Guyer] just walked through*** and Joe walked through in his comments, and has significant safety benefit. It doesn't have the off-target progesterone effects that we see with Korlym."
4.	¶236	October 30, 2024 – 3Q2024 Earnings Call Slide Deck	Corcept	"GRACE … ***Primary endpoint [was] met***." "GRACE … ***Open-label phase results*** … ***Clinically meaningful and statistically significant improvements in hypertension***, hyperglycemia and other signs and symptoms of Cushing's syndrome." "GRACE … ***Randomized withdrawal phase results*** … ***Met [its] primary endpoint***."
5.	¶237	October 30, 2024 – Form 10-Q	Corcept (signed by Belanoff)	"***In [GRACE's] open-label phase, patients experienced clinically meaningful and statistically significant improvements in a wide-array of Cushing's syndrome signs and symptoms, including hypertension***, hyperglycemia, weight, waist circumference, fat and lean body mass, cognition and Cushing's Quality of Life score."

APPENDIX A: CHART OF DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

In re Corcept Therapeutics Inc. Securities Litigation, No. 3:26-cv-1525-TLT

#	AC ¶[1]	Place and Date of Statement	Speaker(s)	False and Misleading Statement and Omission
6.	¶239	February 26, 2025 – 4Q2024 Earnings Press Release	Corcept (reviewed and approved by Belanoff and Guyer)	"GRACE – Pivotal Phase 3 trial of relacorilant in 152 patients with all etiologies of hypercortisolism – ***primary endpoint achieved in randomized withdrawal phase; open-label phase demonstrated clinically meaningful improvements in a broad range of hypercortisolism signs and symptoms***."
7.	¶240	February 26, 2025 – 4Q2024 Earnings Call Slide Deck	Corcept	"GRACE … ***Primary endpoint [was] met***." "GRACE … ***Open-label phase results … Clinically meaningful and statistically significant improvements in hypertension***, hyperglycemia and other signs and symptoms of Cushing's syndrome." "GRACE … ***Randomized withdrawal phase results … Met [its] primary endpoint***."
8.	¶242	May 5, 2025 – Form 10-Q	Corcept (signed by Belanoff)	"***GRACE met its primary endpoint***." "***In [GRACE's] open-label phase, patients experienced clinically meaningful and statistically significant improvements in a wide-array of hypercortisolism signs and symptoms, including hypertension***, hyperglycemia, weight, waist circumference, fat and lean body mass, cognition and Cushing's Quality of Life score."
9.	¶243	May 5, 2025 – 1Q2025 Earnings Call Slide Deck	Corcept	"GRACE … ***Open-label phase results … Clinically meaningful and statistically significant improvements in hypertension***, hyperglycemia and other signs and symptoms of Cushing's syndrome." "GRACE … ***Randomized withdrawal phase results … Met [its] primary endpoint***."
10.	¶244	June 26, 2025 – Truist report	Corcept	Truist analysts reported that they "***caught up with [Corcept's] mgmnt***."

APPENDIX A: CHART OF DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

In re Corcept Therapeutics Inc. Securities Litigation, No. 3:26-cv-1525-TLT

#	AC ¶[1]	Place and Date of Statement	Speaker(s)	False and Misleading Statement and Omission
				"***Regarding high drop out rates seen in Ph3 GRACE***, which is a common concern for investors heading into PDUFA, ***mgmnt shared that it's consistent with 1) dropouts seen in Korlym study, 2) that of other trials in Cushings [sic] and 3) with real-world experience with Korlym. These are all driven by the severity of the disease, per mgmnt***."
11.	¶246	July 31, 2025 – Form 10-Q	Corcept (signed by Belanoff)	"***GRACE met its primary endpoint***." "***In [GRACE's] open-label phase, patients experienced clinically meaningful and statistically significant improvements in a wide-array of hypercortisolism signs and symptoms, including hypertension***, hyperglycemia, weight, waist circumference, fat and lean body mass, cognition and Cushing's Quality of Life score."
12.	¶247	July 31, 2025 – 2Q2025 Earnings Call Slide Deck	Corcept	"GRACE … ***Open-label phase results … Clinically meaningful and statistically significant improvements in hypertension***, hyperglycemia and other signs and symptoms of hypercortisolism." "GRACE … ***Randomized withdrawal phase results … Met [its] primary endpoint***."
False and Misleading Statements About GRADIENT				
13.	¶254	October 30, 2024 – 3Q2024 Earnings Press Release	Corcept (reviewed and approved by Belanoff and Guyer)	"***Results from Phase 3 GRADIENT trial support findings from pivotal Phase 3 GRACE study***; new drug application (NDA) of relacorilant to be submitted this quarter." "***GRADIENT – Supportive trial data for NDA***." "As part of relacorilant's NDA in Cushing's syndrome, the 22-week Phase 3 ***GRADIENT study supports the GRACE trial by providing further evidence of relacorilant's efficacy and safety profile. Patients treated with relacorilant***

APPENDIX A: CHART OF DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

In re Corcept Therapeutics Inc. Securities Litigation, No. 3:26-cv-1525-TLT

#	AC ¶[1]	Place and Date of Statement	Speaker(s)	False and Misleading Statement and Omission
				in the GRADIENT study exhibited clinically meaningful and statistically significant improvements in hypertension, hyperglycemia, weight and body composition compared to baseline, while patients who received placebo did not."
14.	¶255	October 30, 2024 – 3Q2024 Earnings Press Release	Corcept (reviewed and approved by Belanoff and Guyer)	"***GRADIENT's positive results in patients*** with Cushing's syndrome ***confirm relacorilant's promise*** as a significant medical advancement for the treatment of this deadly disease. As was true in the GRACE study, patients in GRADIENT who received relacorilant experienced clinically meaningful improvements in a broad range of hypercortisolism signs and symptoms, without suffering some of the serious adverse effects that can arise in patients taking currently approved treatments. These [sic] data ***will be a powerful addition to relacorilant's NDA***, which we plan to submit by year-end."
15.	¶256	October 30, 2024 – Form 10-Q	Corcept (signed by Belanoff)	"***Our Phase 3 GRADIENT study supports the GRACE trial by providing further evidence of relacorilant's efficacy*** and safety." "***Patients in GRADIENT who received relacorilant exhibited clinically meaningful and statistically significant improvements in hypertension***, hyperglycemia, weight and body composition compared to baseline, while patients who received placebo did not."
16.	¶257	October 30, 2024 – 3Q2024 Earnings Call	Corcept, Belanoff, Maduck	**Belanoff:** "***GRADIENT's data will support our NDA by providing further evidence of relacorilant[']s] efficacy and safety, confirming what we found in GRACE. Patients treated with relacorilant in GRADIENT exhibited clinically meaningful and statistically significant improvements in hypertension***, hyperglycemia, weight and body composition compared to baseline, while patients who received placebo did not." **Maduck:** "Korlym is a great product, but relacorilant is going to be even better. ***It shows efficacy across multiple, and all signs and symptoms of***

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#	AC ¶[1]	Place and Date of Statement	Speaker(s)	False and Misleading Statement and Omission
				Cushing's syndrome, as Bill [Guyer] just walked through and ***Joe [Belanoff] walked through in his comments***, and has significant safety benefit."
17.	¶258	October 30, 2024 – 3Q2024 Earnings Call	Corcept, Guyer, Maduck	**Analyst Question:** "[W]hat gives you confidence that you will be able to, not only file, but be able to get approval here with the GRADIENT data in hand, given that backdrop?" **Guyer:** "***[W]hen you look at the results from GRADIENT, it supports the successful path to an NDA, because we see clinically significant improvements in all signs and symptoms of Cushing's syndrome, including improvements in blood pressure***, blood glucose, weight, just to name a few ... So, all together, this speak[s] to the ***broad improvement of Cushing's syndrome from the GRADIENT study***." **Maduck:** "Korlym is a great product, but ***relacorilant is going to be even better. It shows efficacy across multiple, and all signs and symptoms of Cushing's syndrome, as Bill [Guyer] just walked through*** and Joe walked through in his comments, and has significant safety benefit."
18.	¶259	October 30, 2024 – 3Q2024 Earnings Call Slide Deck	Corcept	"***GRADIENT Results Support Findings from Pivotal GRACE Trial … Relacorilant arm: clinically meaningful and statistically significant improvements in hypertension***, hyperglycemia, weight and body composition compared to baseline."
19.	¶260	February 26, 2025 – 4Q2024 Earnings Press Release	Corcept (reviewed and approved by Belanoff and Guyer)	"***GRADIENT – Supportive data for NDA – Patients treated with relacorilant exhibited clinically meaningful improvements in a broad range of hypercortisolism signs and symptoms*** in randomized, double-blind, placebo-controlled, Phase 3 trial in 137 patients with hypercortisolism caused by adrenal gland pathology."

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20.	¶261	February 26, 2025 – Form 10-K	Corcept (signed by Belanoff)	"***Patients in GRADIENT who received relacorilant exhibited clinically meaningful and statistically significant improvements in hypertension***, hyperglycemia, weight and body composition compared to baseline, while patients who received placebo did not."
21.	¶262	May 5, 2025 – Form 10-Q	Corcept (signed by Belanoff)	"***Patients in GRADIENT who received relacorilant exhibited clinically meaningful and statistically significant improvements in hypertension***, hyperglycemia, weight and body composition compared to baseline, while patients who received placebo did not."
22.	¶263	July 31, 2025 – Form 10-Q	Corcept (signed by Belanoff)	"***Patients in GRADIENT who received relacorilant exhibited clinically meaningful improvements in a wide array of hypercortisolism's signs and symptoms, including hypertension***, hyperglycemia, weight and body composition, while patients who received placebo did not."
23.	¶264	July 31, 2025 – 2Q2025 Earnings Call Slide Deck	Corcept	"***GRADIENT Results Support Findings from Pivotal GRACE Trial***."
24.	¶266	November 4, 2025 – Form 10-Q	Corcept (signed by Belanoff)	"***Patients in GRADIENT who received relacorilant exhibited clinically meaningful improvements in a wide array of hypercortisolism's signs and symptoms, including hypertension***, hyperglycemia, weight and body composition, while patients who received placebo did not."
False and Misleading Statements About the Overall Efficacy Shown by the Relacorilant Clinical Development Program				
25.	¶272	October 30, 2024 – 3Q2024 Earnings Press Release	Corcept (reviewed and approved by Belanoff and Guyer)	"***As was true in the GRACE study, patients in GRADIENT who received relacorilant experienced clinically meaningful improvements in a broad range of hypercortisolism signs and symptoms***."

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26.	¶273	October 30, 2024 – Form 10-Q	Corcept (signed by Belanoff)	"***In both trials [GRACE and GRADIENT], patients exhibited clinically meaningful improvements in hypertension***, glucose control, weight and body composition, as well as other Cushing's syndrome signs and symptoms."
27.	¶274	October 30, 2024 – 3Q2024 Earnings Call	Corcept, Belanoff	"***Patients in the GRACE and GRADIENT studies experience meaningful improvements in hypertension***, glucose control, weight and body composition, as well as other signs and symptoms of Cushing's syndrome."
28.	¶275	October 30, 2024 – 3Q2024 Earnings Call	Corcept, Maduck	"***Korlym is a great product, but relacorilant is going to be even better. It shows efficacy across multiple, and all signs and symptoms of Cushing's syndrome***."
29.	¶276	October 30, 2024 – 3Q2024 Earnings Call	Corcept, Robb	**Analyst Question:** "Your characterization of GRADIENT seems to be as a supportive study, while GRACE is the pivotal. Is that view shared by the FDA?" **Robb:** "The answer is yes. And I think one thing I'm sure you understand, but maybe not all of our listeners do is that this isn't some – a dark art where we have to guess what's on the FDA's mind. I mean, there's published guidance, as well as any conversations the sponsor may have, or the FDA has made it clear that a single well-controlled study, which we have in the form of our GRACE and ***the data from GRACE, along with confirmatory evidence, is sufficient to demonstrate [relacorilant's] safety and efficacy***. And Bill gave you really the strong clinical view."
30.	¶277	October 30, 2024 – Canaccord report	Corcept	Canaccord analysts reported statements made by Corcept "management" that "***the data package in rela[corilant]'s submission will be composed of more than sufficient supporting clinical evidence***, and importantly, the ***efficacy measurements demonstrate a broad clinical benefit of rela[corilant] for Cushing's patients***. Given the clean safety profile of rela on top of the

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				efficacy results, management remains confident in the potential FDA approval."
31.	¶279	December 30, 2024 – Press Release	Corcept (reviewed and approved by Belanoff)	"Corcept's ***NDA is based on positive results from the pivotal GRACE trial and confirmatory evidence from the Phase 3 GRADIENT*** and long-term extension studies and a Phase 2 study in hypercortisolism." **Belanoff:** "***Relacorilant's combination of efficacy and safety give it the potential to become the standard of care for the medical treatment of patients with hypercortisolism***."
32.	¶280	February 26, 2025 – 4Q2024 Earnings Press Release	Corcept (reviewed and approved by Belanoff and Guyer)	"***The positive results from our pivotal GRACE study, and confirmatory evidence from our GRADIENT***, long-term extension and Phase 2 studies, ***provide powerful support for relacorilant's NDA in hypercortisolism***. ***Patients in these studies experienced clinically significant improvements in a wide array of hypercortisolism's signs and symptoms***, without the off-target effects and toxicities that accompany currently available treatments. ***Relacorilant's strong efficacy and safety profile positions it to become the new standard of care for patients with hypercortisolism***."
33.	¶281	February 26, 2025 – Form 10-K	Corcept (signed by Belanoff)	"***The NDA is based on positive results from our pivotal trial 'GRACE', as well as confirmatory evidence from our Phase 3 'GRADIENT' trial***, our Phase 3 long-term extension study and our Phase 2 study. ***In all of these trials, patients exhibited clinically meaningful improvements in a wide range of hypercortisolism signs and symptoms, including hypertension***, glucose control, weight and body composition." "Patients in GRADIENT who received relacorilant exhibited ***clinically meaningful and statistically significant improvements in hypertension***, hyperglycemia, weight and body composition compared to baseline, while patients who received placebo did not."

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				"***In the [GRACE] open-label phase, patients experienced clinically meaningful and statistically significant improvements in a wide-array of hypercortisolism signs and symptoms, including hypertension***, hyperglycemia, weight, waist circumference, fat and lean body mass, cognition and Cushing's Quality of Life score."
34.	¶282	February 26, 2025 – 4Q2024 Earnings Call	Corcept, Belanoff	"***Relacorilant's strong efficacy and safety profile positions it to become the new standard of care for patients with hypercortisolism. The positive results from our GRACE, GRADIENT*** long term extension and Phase 2 studies ***provide powerful support for successful relacorilant NDA in hypercortisolism***." "Our ***NDA is based on compelling results from the GRACE, GRADIENT***, long term extension and Phase 2 relacorilant studies. … ***Relacorilant's efficacy and safety … is clearly evident*** when one follows the clinical course of patients as they enter the Phase 2 [*sic*] GRACE or GRADIENT study."
35.	¶284	March 3, 2025 – Press Release	Corcept (reviewed and approved by Belanoff)	"Corcept's ***NDA is based on positive results from the pivotal GRACE trial and confirmatory evidence from the Phase 3 GRADIENT trial***, long-term extension trial, and a Phase 2 trial in hypercortisolism. ***Patients in these trials who received relacorilant experienced improvements in a wide array of hypercortisolism's signs and symptoms***." **Belanoff:** "***Relacorilant's combination of efficacy and safety gives it the potential to become the new standard of care***."
36.	¶285	April 25, 2025 – Proxy Statement	Corcept	"Our ***NDA is based on positive results from our pivotal GRACE trial, Phase 3 GRADIENT trial***, long-term extension trial and Phase 2 trial."
37.	¶286	May 5, 2025 – 1Q2025 Earnings Press Release	Corcept (reviewed and approved by	"***The positive results from our pivotal GRACE, GRADIENT***, long-term extension and Phase 2 ***studies provide powerful support for the NDA for***

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			Belanoff and Guyer)	***relacorilant in hypercortisolism. Patients in these studies experienced clinically significant improvements in a wide array of the signs and symptoms of hypercortisolism***."
38.	¶287	May 5, 2025 – Form 10-Q	Corcept (signed by Belanoff)	"The ***NDA is based on positive results from our pivotal GRACE trial, as well as confirmatory evidence from our Phase 3 GRADIENT trial***, our Phase 3 long-term extension study and our Phase 2 study. ***Patients in these trials exhibited clinically meaningful improvements in a wide range of hypercortisolism signs and symptoms, including hypertension***, glucose control, weight and body composition."
39.	¶288	May 5, 2025 – 1Q2025 Earnings Call	Corcept, Belanoff	"***Relacorilant's strong efficacy and safety profile gives us the potential to become the new standard of care for patients with hypercortisolism***." "***Patients treated with relacorilant in these studies experienced clinically meaningful and statistically significant improvements across all of the signs and symptoms of hypercortisolism in hypertension***, hypoglycemia, weight, lean muscle mass, waist circumference, cognition, Cushing's quality of life score and other important clinical measures. There was ***a high level of consistency and durability*** of therapeutic benefit across our studies."
40.	¶289	July 31, 2025 – 2Q2025 Earnings Press Release	Corcept (reviewed and approved by Belanoff and Guyer)	"***In our studies, patients who received relacorilant exhibited clinically and statistically significant improvements in a wide array of hypercortisolism's signs and symptoms***."
41.	¶290	July 31, 2025 – Form 10-Q	Corcept (signed by Belanoff)	"***The NDA is based on positive results from our pivotal GRACE trial, with confirmatory evidence from our Phase 3 GRADIENT trial***, our Phase 3 long-term extension study and our Phase 2 study. ***Patients in these trials exhibited clinically meaningful improvements in a wide range of***

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				hypercortisolism signs and symptoms, including hypertension, glucose control, weight and body composition."
42.	¶291	July 31, 2025 – 2Q2025 Earnings Call	Corcept, Belanoff	"***Relacorilant's NDA is supported by our pivotal Phase 3 GRACE trial, as well as our GRADIENT[,]*** long-term extension and Phase 2 trials. ***In these studies, patients treated with relacorilant experienced clinically meaningful improvements across all of the signs and symptoms of hypercortisolism, including hypertension***, hyperglycemia, weight, lean muscle mass, waist circumference, cognition, Cushing's Quality-of-Life score and other important clinical measures. ***These benefits were observed consistently and durably with improvements emerging early and continuing or deepening over time***." "While Korlym's effectiveness in treating hypercortisolism is well-established, ***relacorilant is a substantial advance. Its strong efficacy and safety positions it to become a new standard of care***." "I want to reiterate a few of the points we've made already, but they're important, which is that ***relacorilant is a better medication than Korlym***. Korlym works extremely well but ***relacorilant has very, very tangible advantages***."
43.	¶292	July 31, 2025 – 2Q2025 Earnings Call	Corcept, Maduck	"***While Korlym is a great medication, relacorilant is even better***."
44.	¶293	November 4, 2025 – 3Q2025 Earnings Press Release	Corcept (reviewed and approved by Belanoff and Guyer)	"***Relacorilant has the potential to become the new standard of care for patients with hypercortisolism***. In its Phase 2 and ***Phase 3 studies, patients treated with relacorilant showed clinically meaningful and statistically significant improvements in a wide range of hypercortisolism's signs and symptoms***, without off-target effects and toxicities associated with currently available treatments."

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45.	¶294	November 4, 2025 – Form 10-Q	Corcept (signed by Belanoff)	"***The NDA is based on positive results from our pivotal GRACE trial, with confirmatory evidence from our Phase 3 GRADIENT trial***, our Phase 3 long-term extension study and our Phase 2 study. ***Patients in these trials exhibited clinically meaningful improvements in a wide range of hypercortisolism signs and symptoms, including hypertension***, glucose control, weight and body composition."
46.	¶295	November 4, 2025 – 3Q2025 Earnings Call	Corcept, Belanoff	"Relacorilant's NDA is supported by our pivotal Phase 3 GRACE trial as well as our GRADIENT[,] long-term extension and Phase 2 trials. ***In these studies, patients treated with relacorilant experienced clinically meaningful improvements in all the measures of hypercortisolism, including hypertension***, hypoglycemia, weight, lean muscle mass, waist circumference, cognition, and Cushing's quality of life score. ***These benefits were observed consistently and durably, with improvements emerging early and continuing or deepening over time***."
False and Misleading Statements About the "Path" to Approval				
47.	¶302	October 30, 2024 – 3Q2024 Earnings Call	Corcept, Belanoff	"This is a very exciting time at Corcept. Physician awareness and understanding of hypercortisolism is accelerating. ***The results from our GRACE and GRADIENT Phase 3 studies clear the path for relacorilant's new drug application in Cushing's syndrome***, which we will submit by year-end."

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#	AC ¶[1]	Place and Date of Statement	Speaker(s)	False and Misleading Statement and Omission
48.	¶303	October 30, 2024 – 3Q2024 Earnings Call	Corcept, Guyer	**Analyst Question:** "[W]hat gives you confidence that you will be able to, not only file, but be able to get approval here with the GRADIENT data in hand, given that backdrop?" **Guyer:** "***When you look at the results from GRADIENT, it supports the successful path to an NDA***, because we see clinically significant improvements in all signs and symptoms of Cushing's syndrome, including improvements in blood pressure, blood glucose, weight, just to name a few. … Now that the GRADIENT study is unblinded, we can evaluate and look at this data, and I will tell you that I was highly supportive of what we've seen in all of our studies, because hypertension response shows clinically significant and statistically significant improvements in both systolic and diastolic blood pressure at month six, and it continues out and continues to improve out two years. So, ***when you look at the totality of evidence that we see from all of these studies, we believe we have a successful path to a positive NDA for relacorilant that will happen in the coming weeks***."
49.	¶304	October 30, 2024 – Canaccord report	Corcept	"We had a call with [Corcept] management post the earnings release, and ***the company is as confident now as prior to the GRADIENT trial data that relacorilant is very likely to receive FDA approval***."
50.	¶305	May 5, 2025 – 1Q2025 Earnings Press Release	Corcept (reviewed and approved by Belanoff and Guyer)	"***Our New Drug Application (NDA) for relacorilant in hypercortisolism is progressing towards approval by the end of this year***."
51.	¶306	May 5, 2025 – 1Q2025 Earnings Call	Corcept, Belanoff	"***Our new drug application for relacorilant in hypercortisolism is progressing towards approval by the end of this year***."

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52.	¶307	July 31, 2025 – 2Q2025 Earnings Call	Corcept, Belanoff	"Concurrent with the rapidly increasing physician awareness of hypercortisolism, ***relacorilant is approaching approval***." "While Korlym's effectiveness in treating hypercortisolism is well-established, relacorilant is a substantial advance. Its strong efficacy and safety positions it to become a new standard of care. ***We expect its approval in hypercortisolism by the end of this year***."
53.	¶308	November 4, 2025 – 3Q2025 Earnings Call	Corcept, Belanoff	"Let me reiterate our important developments. ***Next month, we expect FDA approval of relacorilant*** for the treatment of hypercortisolism."
False and Misleading Statements About Interactions with FDA				
54.	¶312	October 30, 2024 – 3Q2024 Earnings Call	Corcept, Belanoff	**Analyst Question:** "Your characterization of GRADIENT seems to be as a supportive study, while GRACE is the pivotal. Is that view shared by the FDA?" **Belanoff:** "***Yes***." **Analyst Question:** "And when was the last interaction with the FDA? And have you already ha[d] a pre NDA meeting with the FDA? It seems like you're planning to submit the NDA within weeks. So just curious if you've already had that conversation with the FDA?" **Belanoff:** "I can say that ***we've talked to the FDA plenty about this program, about all of our programs, and I foresee absolutely no impediments to getting our NDA in***."
55.	¶313	October 30, 2024 – 3Q2024 Earnings Call	Corcept, Robb	**Analyst Question:** "Your characterization of GRADIENT seems to be as a supportive study, while GRACE is the pivotal. Is that view shared by the FDA?" **Robb:** "***The answer is yes***. And I think one thing I'm sure you understand, but maybe not all of our listeners do is that this isn't some – a dark art where we

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				have to guess what's on the FDA's mind. I mean, there's published guidance, as well as any conversations the sponsor may have, or ***the FDA has made it clear that a single well-controlled study, which we have in the form of our GRACE and the data from GRACE, along with confirmatory evidence, is sufficient to demonstrate a drug safety and efficacy. But I just wanted to underscore, from the perspective of the person who has to go in with the team and present the arguments to the FDA, just what a good position we're in.*** I mean, we have studied, as Bill pointed out, relacorilant in more patients with Cushing's syndrome than any other company with approved treatments out there. So, we have a tremendous amount of data. And our findings have been remarkably consistent from Phase 2 to GRACE to our extension study, and now, to GRADIENT. Patients who receive relacorilant got better across the entire range of Cushing's syndrome signs and symptoms. It's really as simple as that. ***It's that easy an argument to present to the FDA.***"
56.	¶314	October 30, 2024 – 3Q2024 Earnings Call	Corcept, Guyer	**Analyst Question:** "Has your communication with the FDA changed regarding the role of GRADIENT in the NDA?" **Guyer:** "GRADIENT, from its inception, was always designed to be supportive of GRACE and GRACE was always going to be our pivotal study and ***that's our agreement with the FDA***."

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57.	¶315	February 26, 2025 – 4Q2024 Earnings Call	Corcept, Robb	**Analyst Question:** "First, can you talk to when we should hear about NDA acceptance and what are your thoughts on the potential for an AdCom here and is that something you're preparing for?" **Robb:** "[W]e've been receiving that ***very ordinary course routine correspondence*** and responding to it over the past 60 days. So ***the process has been moving exactly as we understood it to move*** … And ***we are not expecting an AdCom***. I mean, the past couple of medications for Cushing's syndrome were approved without them, Korlym was approved without one and ***there's nothing about relacorilant's efficacy or safety that we think would require one***."
58.	¶316	March 25, 2025 – Canaccord report	Corcept	Canaccord analysts reported statements made by "the management of Corcept" during "two full days of meetings" Canaccord had hosted. Corcept told Canaccord, "***[n]o surprises have come out of communications with the FDA*** and no AdCom has been requested to date, and we believe one will not likely be required."
59.	¶317	June 26, 2025 – Truist report	Corcept	Truist analysts reported that they "caught up with [Corcept's] ***mgmnt***" and that "***[m]gmnt shared*** that they recently had a mid-cycle review on relacorilant NDA during ***which the FDA continued to communicate that an AdCom won't be needed***."
60.	¶318	November 4, 2025 – 3Q2025 Earnings Call	Corcept, Robb	**Analyst Question:** "And then, just as a follow-up, on the upcoming PDUFA for relacorilant, have you had a late cycle review for relacorilant? And if so, can you share?" **Robb:** "When the FDA agrees to review your New Drug Application, they give you a letter that sets out sort of the key milestones that are going to happen during the review process. And one of them is the mid-cycle review meeting with the – between the sponsor and the FDA. And the second is, as you know,

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				or another one is this late-cycle review meeting. I can tell you that we've had both. I cannot tell you sort of what transpired or the nature of our back and forth with the FDA, because we just can't – just can't comment on that. But we held them both exactly on the schedule the FDA set out in its original letter to us. ***Things have moved per schedule, very ordinary course***."
False and Misleading Statements About Relacorilant's Safety				
61.	¶322	October 30, 2024 – 3Q2024 Earnings Press Release	Corcept (reviewed and approved by Belanoff and Guyer)	"***[R]elacorilant was well-tolerated, with a safety profile consistent with the GRACE study***, including no cases of relacorilant induced hypokalemia, endometrial hypertrophy or related vaginal bleeding, adrenal insufficiency or QT prolongation." "***Consistent with its known safety profile, relacorilant was well-tolerated in both phases of GRACE***."
62.	¶323	October 30, 2024 – Form 10-Q	Corcept (signed by Belanoff)	"***Relacorilant was well-tolerated***." "***Relacorilant was well tolerated in GRADIENT***, with side effects consistent with those seen in its Phase 2 and GRACE trials."
63.	¶324	October 30, 2024 – 3Q2024 Earnings Call	Corcept, Belanoff	"***Relacorilant was very well tolerated and do[es] not cause some of the serious adverse events that can be caused by other medications used to treat Cushing's syndrome***, in particular, hypokalemia, endometrial hypertrophy, its related vaginal bleeding, QT prolongation, and adrenal insufficiency." "***An important feature of relacorilant is how well it was tolerated in both GRACE and GRADIENT.*** In both studies, the most common adverse events were mild-to-moderate nausea, pain in the extremities and back, and fatigue."

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64.	¶325	October 30, 2024 – 3Q2024 Earnings Call	Corcept, Guyer	"***[W]hen you look at [relacorilant's] safety profile, it confirms what we saw in GRACE***, as well as Phase 2, and ***it's consistent with a known safety profile of relacorilant, and no new safety signals were seen in the GRADIENT trial***."
65.	¶326	October 30, 2024 – 3Q2024 Earnings Call	Corcept, Maduck	"Korlym is a great product, but ***relacorilant is going to be even better***. It shows efficacy across multiple, and all signs and symptoms of Cushing's syndrome, as Bill just walked through and Joe walked through in his comments, and ***has significant safety benefit[s]***."
66.	¶327	October 30, 2024 – 3Q2024 Earnings Call Slide Deck	Corcept	"***Relacorilant Safety Results … In both GRACE and GRADIENT trials, relacorilant was well-tolerated, consistent with its known safety profile***."
67.	¶328	December 30, 2024 – Press Release	Corcept (reviewed and approved by Belanoff)	"***Patients in these studies who received relacorilant*** experienced improvements in a wide array of hypercortisolism's signs and symptoms, ***with an acceptable safety burden***."
68.	¶329	December 30, 2024 – Press Release	Corcept (reviewed and approved by Belanoff)	"***Relacorilant's combination of efficacy and safety*** give it the potential to become the standard of care for the medical treatment of patients with hypercortisolism."
69.	¶330	February 26, 2025 – 4Q2024 Earnings Press Release	Corcept (reviewed and approved by Belanoff and Guyer)	"GRACE … ***relacorilant was well-tolerated, consistent with its known safety profile***, with no cases of endometrial hypertrophy or drug-induced vaginal bleeding, relacorilant-induced hypokalemia, adrenal insufficiency or QT prolongation." "GRADIENT … ***relacorilant was well-tolerated, consistent with its known safety profile***, including no cases of endometrial hypertrophy or drug-induced vaginal bleeding, relacorilant-induced hypokalemia, adrenal insufficiency or QT prolongation."

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In re Corcept Therapeutics Inc. Securities Litigation, No. 3:26-cv-1525-TLT

#	AC ¶[1]	Place and Date of Statement	Speaker(s)	False and Misleading Statement and Omission
70.	¶331	February 26, 2025 – Form 10-K	Corcept (signed by Belanoff)	"***Relacorilant was well-tolerated in all of the trials***."
71.	¶332	February 26, 2025 – 4Q2024 Earnings Call	Corcept, Belanoff	"***Just as important as relacorilant's efficacy is its safety. Relacorilant has been well tolerated in all of its studies***."
72.	¶333	February 26, 2025 – 4Q2024 Earnings Call Slide Deck	Corcept	"***Relacorilant Safety Results … In all its studies, relacorilant has been well-tolerated, consistent with its known safety profile***."
73.	¶334	March 3, 2025 – Press Release	Corcept (reviewed and approved by Belanoff)	"***Relacorilant was well tolerated***."
74.	¶335	May 5, 2025 – 1Q2025 Earnings Press Release	Corcept (reviewed and approved by Belanoff and Guyer)	"The positive results from our pivotal GRACE, GRADIENT, long-term extension and Phase 2 studies provide powerful support for the NDA for relacorilant in hypercortisolism. Patients in these studies experienced clinically significant improvements in a wide array of the signs and symptoms of hypercortisolism, ***without the off-target effects and toxicities that accompany currently available treatments***."
75.	¶336	May 5, 2025 – Form 10-Q	Corcept (signed by Belanoff)	"***Relacorilant has been well-tolerated in all of its trials***." "***Consistent with its known safety profile, relacorilant was well-tolerated***."
76.	¶337	May 5, 2025 – 1Q2025 Earnings Call	Corcept, Belanoff	"***Relacorilant has been well tolerated in all of its studies***."
77.	¶338	May 5, 2025 – 1Q2025 Earnings Call Slide Deck	Corcept	"***In all its studies, relacorilant has been well-tolerated, consistent with its known safety profile***."

APPENDIX A: CHART OF DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

In re Corcept Therapeutics Inc. Securities Litigation, No. 3:26-cv-1525-TLT

#	AC ¶[1]	Place and Date of Statement	Speaker(s)	False and Misleading Statement and Omission
78.	¶339	July 31, 2025 – 2Q2025 Earnings Press Release	Corcept (reviewed and approved by Belanoff and Guyer)	"***In our studies, patients who received relacorilant*** exhibited clinically and statistically significant improvements in a wide array of hypercortisolism's signs and symptoms, ***without the off-target effects and toxicities that accompany currently available treatments***."
79.	¶340	July 31, 2025 – Form 10-Q	Corcept (signed by Belanoff)	"***Relacorilant has been well-tolerated in all of its trials***." "***Consistent with its known safety profile***, ***relacorilant was well-tolerated***."
80.	¶341	July 31, 2025 – 2Q2025 Earnings Call	Corcept, Belanoff	"Equally noteworthy are relacorilant's safety characteristics. ***Relacorilant has been well-tolerated in all of its studies***."
81.	¶342	July 31, 2025 – 2Q2025 Earnings Call Slide Deck	Corcept	"***In all its studies, relacorilant has been well-tolerated, consistent with its known safety profile***."
82.	¶343	November 4, 2025 – 3Q2025 Earnings Press Release	Corcept (reviewed and approved by Belanoff and Guyer)	"***In its*** Phase 2 and ***Phase 3 studies, patients treated with relacorilant showed*** clinically meaningful and statistically significant improvements in a wide range of hypercortisolism's signs and symptoms, ***without off-target effects and toxicities associated with currently available treatments***."
83.	¶344	November 4, 2025 – Form 10-Q	Corcept (signed by Belanoff)	"***Relacorilant has been well-tolerated in all of its clinical trials***." "***Consistent with its known safety profile***, ***relacorilant was well-tolerated***."

APPENDIX A: CHART OF DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

In re Corcept Therapeutics Inc. Securities Litigation, No. 3:26-cv-1525-TLT

#	AC ¶[1]	Place and Date of Statement	Speaker(s)	False and Misleading Statement and Omission
False and Misleading Statements About Existing Risks to Corcept				
84.	¶349	October 30, 2024 – Form 10-Q	Corcept (signed by Belanoff)	"Our ***current clinical trials may prove inadequate*** to support marketing approvals. Even trials ***that generate positive results may have to be confirmed in much larger, more expensive and lengthier trials before we could seek regulatory approval. Clinical trials may*** take longer to complete, cost more than expected and ***fail for many reasons, including: failure to show efficacy or acceptable safety***." "At any time prior to the regulatory approval of a product candidate, we may decide, or the ***FDA or other regulatory authorities may require us, to conduct more pre-clinical or clinical studies, provide additional analysis of existing data*** or change the size or design of a trial already underway." "Our products and product candidates ***may cause undesirable side effects that*** halt their clinical development, ***prevent their regulatory approval, limit their commercial potential*** or cause us significant liability."
85.	¶350	February 26, 2025 – Form 10-K	Corcept (signed by Belanoff)	*See* Statement 84
86.	¶351	May 5, 2025 – Form 10-Q	Corcept (signed by Belanoff)	*See* Statement 84
87.	¶352	July 31, 2025 – Form 10-Q	Corcept (signed by Belanoff)	*See* Statement 84
88.	¶353	November 4, 2025 – Form 10-Q	Corcept (signed by Belanoff)	*See* Statement 84