LEVI & KORSINSKY, LLP
Adam M. Apton (SBN 316506)
Adam C. McCall (SBN 302130)
388 Market Street, Suite 1300
San Francisco, CA 94111
Tel: (415) 373-1671
Email: aapton@zlk.com
Email: amccall@zlk.com

LEVI & KORSINSKY, LLP
Shannon L. Hopkins (admitted *pro hac vice*)
Sebastiano Tornatore (admitted *pro hac vice*)
1111 Summer Street, Suite 403
Stamford, CT 06905
Tel: (203) 992-4523
Email: shopkins@zlk.com
Email: stornatore@zlk.com

Counsel for Lead Plaintiff the Ferraro Family Foundation, Inc. and James L. Ferraro

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

FERRARO FAMILY FOUNDATION, INC. and JAMES L. FERRARO, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

CORCEPT THERAPEUTICS INCORPORATED, JOSEPH K. BELANOFF, CHARLES ROBB, and SEAN MADUCK

Defendants.

Case No. 19-CV-01372-LHK

CLASS ACTION

THIRD AMENDED COMPLAINT

Judge: Hon. Lucy H. Koh
Courtroom: 8, 4th floor

TABLE OF CONTENTS

Court-appointed Lead Plaintiff Ferraro Family Foundation, Inc. and James L. Ferraro (collectively, "Plaintiff" or the "Ferraro Group") bring this action against Corcept Therapeutics Incorporated ("Corcept" or the "Company"), its Chief Executive Officer Joseph K. Belanoff ("Belanoff"), its Chief Financial Officer Charles Robb ("Robb"), and its Vice President of Commercial Sean Maduck ("Maduck," and collectively with Corcept, Belanoff, and Robb, the "Defendants") pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder on behalf of themselves and all other persons similarly situated who purchased or otherwise acquired Corcept securities between August 2, 2017 and January 31, 2019, inclusive (the "Class Period"), and were damaged thereby.

Plaintiff alleges the following based upon personal knowledge as to itself and its own acts, and upon information and belief as to all other matters. Plaintiff's information and belief is based on the investigation of its undersigned Lead Counsel, which included, among other things, review and analysis of: (i) Corcept's public filings with the U.S. Securities and Exchange Commission ("SEC") and Food and Drug Administration ("FDA"); (ii) Corcept's other public statements, including press releases and investor conference calls; (iii) interviews with former Corcept employees and confidential physician witnesses with firsthand experience with Corcept's sales staff; (iv) reports of securities and financial analysts, news articles, and other commentary and analysis concerning Corcept and the industry in which it operates; and (v) court filings. Lead Counsel's investigation also includes consultation with a subject matter expert. Lead Counsel's investigation into the matters alleged herein is continuing, and many relevant facts are known only to, or are exclusively within, the custody or control of the Defendants. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. SUMMARY OF THE ACTION

1. At the core of this securities fraud class action is a pervasive Company-wide off-label marketing scheme orchestrated by Defendants to dupe unsuspecting physicians unfamiliar with the proper diagnosis and treatment of endogenous Cushing's Syndrome into inappropriately prescribing Korlym, Corcept's only FDA-approved commercial drug, for conditions other than the narrow subset of endogenous Cushing's Syndrome defined within the FDA label. Throughout the Class Period,

Defendants engaged in a pervasive off-label scheme to expand the market for Korlym beyond its very narrow FDA-approved indication and finance the development of a new drug candidate before the period of market exclusivity for Korlym expired in February 2019.

2. Corcept purports to be a pharmaceutical Company engaged in the development and commercialization of drugs that treat severe metabolic, oncologic, and psychiatric disorders by modulating the effects of the hormone cortisol. The Company's only FDA-approved drug, Korlym, generates all of the Company's revenues and carries an astronomical yearly retail price tag of between $180,000 and $700,000 per patient depending on the dose.

3. Korlym sales not only fund Corcept's day-to-day operations but are also relied upon to finance the Company's ongoing clinical trials. Corcept is presently conducting clinical trials for its Korlym replacement, Relacorilant, as market exclusivity to distribute Korlym has come to an end and well-capitalized generic competitors wait in the wings, held off only by a statutory stay pending ongoing patent infringement litigation.

4. Despite the Company's best efforts to gain broad regulatory approval for the use of Korlym as a general treatment for endogenous Cushing's Syndrome, a rare disease affecting only approximately 20,000 patients in the United States, in 2012 the FDA approved the drug's use for a narrow subset of endogenous Cushing's Syndrome: "to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's Syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery."[1] Further, the FDA added this specific limitation to Korlym's label: "Do not use [Korlym] for the treatment of type 2 diabetes mellitus *unrelated* to endogenous Cushing's syndrome."

5. Based on Corcept's originally proposed broad indication for Korlym, the FDA estimated the potential number of Cushing's Syndrome patients in the U.S. qualified to be on Korlym was "approximately 5,000 patients." However, the FDA subsequently restricted the indication for Korlym, reducing this number even further. Additionally, treating the entirety of this reduced patient pool with Korlym would be nearly impossible since there exist other preferred drugs to treat endogenous Cushing's Syndrome and diabetes, and some patients may refuse Korlym therapy because of its cost or

[1] https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202107s000lbl.pdf.

side effects. Thus, only a very small fraction of endogenous Cushing's Syndrome patients in the U.S. are likely to ever be prescribed Korlym based on the FDA approved label.

6. Because Korlym's main active ingredient is mifepristone, Corcept engaged Dohmen Life Sciences Services, LLC ("Dohmen") as its specialty pharmacy in 2013 to distribute Korlym. At that time, the Company's espoused marketing strategy for Korlym was to target the 300 Specialist Endocrinologists (those who specialize in diagnosing and treating endogenous Cushing's Syndrome patients) who treat approximately70% of all Cushing's Syndrome patients in the United States.

7. An Endocrinologist is a physician who specializes in diagnosing and treating conditions that affect the body's glandular systems, including the adrenal glands, hypothalamus, pancreas, parathyroid glands, pituitary gland, reproductive glands, and thyroid, in addition to bone and lipid metabolism. An Endocrinologist is uniquely qualified to both diagnose and treat Cushing's Syndrome because Cushing's Syndrome affects the pituitary and cortisol-producing adrenal glands. Because endogenous Cushing's is so rare, however, only a small subset of Endocrinologists nationwide specialize in diagnosing and treating Cushing's Syndrome patients (referred to herein as "Specialist Endocrinologists"). Thus, it is common for non-Specialist Endocrinologists and other physicians to refer patients with signs and symptoms of Cushing's Syndrome to a Specialist Endocrinologist who routinely cares for such patients.

8. Corcept's initial marketing focus on Specialist Endocrinologists paid immediate dividends as a first-to-market mifepristone treatment for its approved indication, driving Company revenue from approximately $3.3 million in 2012 to $50.28 million in 2015.

9. However, looming in February 2019 was the end of the marketing exclusivity for Korlym afforded the Company by the Orphan Drug designation it had previously been granted – the expiration of which would open the door to price competition from generic competitors that would ultimately erode the Company's only revenue source. Moreover, Specialist Endocrinologists became reluctant to use Korlym as anything but a last resort therapy due to the drug's side effects and the fact there are other more effective and less expensive drugs on the market for the treatment of endogenous Cushing's Syndrome.

10. Faced with the looming expiration of exclusivity, distaste among the Specialist Endocrinologists for Korlym as anything but a last resort therapy for Cushing's Syndrome patients, and the fact that, as a tertiary treatment for a rare disease, the total addressable market for Korlym was very limited, according to former Corcept employees, starting in early 2016, the Individual Defendants directed Corcept clinical specialists responsible for promoting Korlym to physicians to engage in a multi-faceted scheme to market Korlym off-label by targeting non-Specialist Endocrinologists unfamiliar with the protocol for diagnosing and treating endogenous Cushing's Syndrome patients in an effort to increase Korlym sales. Defendants fed these physicians misinformation regarding the screening and diagnostic procedures for Cushing's Syndrome, while also pushing them to prescribe Korlym off-label as a first-line therapy in diabetic and obese patients without a confirmed diagnosis of Cushing's Syndrome. In addition to providing improper diagnosis guidelines, Defendants were promoting Korlym as a treatment for other conditions, such as diabetes, obesity and depression.

11. According to former Corcept clinical specialists and a former regional sales manager, prior to and throughout the Class Period, Defendant Maduck and Tom Burke, Corcept's VP of Sales who reported to Maduck, instructed them to find physicians willing to prescribe Korlym for patients with diabetes, obesity, Cushingoid appearance or other "unknown" condition with elevated cortisol levels if their dexamethasone suppression test ("DST") score was in the grey area or below and promote Korlym to these physicians as a first line treatment to expand the market for Korlym. These witnesses stated that Maduck and Burke told Corcept's sales staff that it was the new "direction of the company" to target patients these subclinical patients with DST scores below the industry guidelines, in direct violation of the FDA label.

12. Confidential witness physicians have confirmed that prior to and throughout the Class Period, Corcept's clinical specialists aggressively marketed Korlym to physicians for off-label use. According to these physicians, during office visits and at dinners and other functions, Corcept clinical specialists directed physicians to use Korlym as a treatment for patients with diabetes, obesity or Cushingoid appearance if their dexamethasone suppression test ("DST") came back in a "grey area" or even below the grey area. The clinical specialists showed the physicians off-label marketing materials containing medical studies claiming to demonstrate the purported benefits of treating patients who had

"mild" or "subclinical" Cushing's Syndrome with Korlym as a first-line treatment referred to internally at Corcept as the "Korlym trial." Corcept specifically targeted physicians who were already prescribing insulin to their diabetic patients and told them that Korlym could bring down the glucose levels in those patients, despite the FDA approved label ***explicitly*** stated not to use Korlym to treat diabetes absent a confirmed Cushing's Syndrome diagnosis.

13. Corcept clinical specialists[2] also instructed physicians to employ a single test to screen for Cushing's Syndrome—the single 1-mg overnight DST—and if it came back above 1.0 (well below the industry guideline of 1.8), advised the doctor to immediately prescribe Korlym without further evaluation of the patient. The clinical specialists further told physicians that if these patients showed any sign of improvement after being put on Korlym then physicians should interpret it as a confirmed diagnosis of Cushing's Syndrome. In other words, Corcept's clinical specialists marketed Korlym as a first-line therapy for conditions other than Cushing's Syndrome and as a "diagnostic tool" for Cushing's Syndrome in violation of the FDA-approved indication and widely-accepted industry guidelines for diagnosis and treatment of Cushing's Syndrome developed by the Endocrinology professional societies—the Endocrine Society and the American Association of Clinical Endocrinologists (AACE).

14. According to several former Corcept employees, Defendant Belanoff would join clinical specialists to visit "important" physicians and provide the physicians with off-label messages because, according to Defendant Belanoff, "I can say whatever I want."

15. Confidential witness physicians further confirmed that Corcept clinical specialists instructed physicians to "proactively" use Korlym pre-operatively in patients going for surgical resection of adrenal masses, again outside of the FDA-approved indication for Korlym and professional Endocrinology society guidelines for treatment of these patients.

16. As stated in myriad scholarly articles authored by Endocrinologists across the country, and confirmed by Plaintiff's CWs and Plaintiff's Expert ("PE"), a practicing Endocrinologist in Western Massachusetts with over twenty years of experience who has published on Cushing's Syndrome, the DST is unreliable as a standalone test for diagnosing Cushing's Syndrome because it is highly

[2] A clinical specialist is a representative of the company who markets the company's products to health care professionals such as physicians, usually in the physician's office or at medical conferences.

susceptible to generating false positives results and, instead, should only be used as an initial screening tool to inform additional testing. This position is supported by the findings of Dr. Lynn Loriaux, an Endocrinologist and Professor of Medicine at the Oregon Health & Science University who noted in his 2017 article in the New England Journal of Medicine titled "Diagnosis and Differential Diagnosis of Cushing's Syndrome," N Engl J Med 2017; 376:1451-1459, that the DST is particularly unhelpful in diagnosing endogenous Cushing's Syndrome in an obese patient population having a positive predictive value of *just 0.4%* -- meaning that, for those obese patients Corcept's marketing team was explicitly pushing non-Specialist Endocrinologists and PCP's to test, among those that screened as abnormal with the DST, just 0.4% would actually be diagnosed with endogenous Cushing's Syndrome following an appropriate workup. Because of the low odds of a patient's DST coming back over 1.8ug/dL, Corcept unilaterally lowered the thresholds required for a "positive" DST test below FDA and industry guidelines to further increase the patient pool. According to CWs, some clinical specialists recommended to physicians putting patients on Korlym if the DST came back with any non-zero number. Despite the remote likelihood of a confirmed Cushing's diagnosis in these patients, Corcept's clinical specialists advocated for the immediate commencement of Korlym in these patients upon DST results that were borderline or even clearly below appropriate levels.

17. As a result of the Individual Defendants' off-label marketing directive and the significant pressure Defendants placed on clinical specialists to find physicians willing to help them expand the market for Korlym, physicians interviewed by Plaintiff's counsel recalled that Corcept's clinical specialists were relentless and visited physician offices weekly to search for new potential patients or follow up on the results of a DST for existing patients, and even provided instructions and assisted in the completion of forms required by insurance companies for approval of Korlym therapy. Corcept clinical specialists were given instructions on how to properly fill out the enrollment forms to ensure insurance approval, despite the fact that, according to the CWs, clinical specialists filling out the enrollment forms being "a big no-no." The Company's clinical specialists advised physicians to simply check the box on the form stating that the patient did not qualify for surgery so the prescription would be approved by the insurance company. If the enrollment forms were still incorrectly filled out, a physician at Corcept would change the forms to "put what the doctors really meant" to ensure insurance

reimbursement. CWs stated that Corcept representatives advised physicians that patients "don't really want surgery" and that Korlym should be tried in place of potentially curative surgical intervention, in clear violation of the FDA approved label and the Endocrinology societies' guidelines for treatment of Cushing's Syndrome patients.

18. To solidify support for the use of Korlym among these newly targeted non-Specialist Endocrinologists and PCP's (including Family Medicine and Internal Medicine physicians and even Nurse Practitioners), the Company began leveraging its marketing dollars, drastically increasing the amount of money it paid to Family Medicine and Internal Medicine doctors to coincide with its newfound focus on these physician subgroups – with the total dollar spend on each group increasing by 267% and 367%, respectively, from 2016 to 2017 based on data available in the Centers for Medicare and Medicaid Services Open Payments database.

19. The Company's new marketing approach is best exemplified by a ***single General Internist*** practicing in North Charleston, South Carolina: Dr. Jerry Back. According to publicly available Medicare Part D data, Dr. Back had 115 Medicare Part D claims for Korlym originate from his office in 2017 (representing 5% of ***all claims submitted nationwide*** to the program), worth a total drug cost of $3,562,308.06. Dr. Back's Medicare claims were the highest of any physician submitting Korlym claims to the system and he was the only physician with more than 100 claims – a sharp increase from the 19 Korlym claims he submitted in 2016 (after submitting **zero** claims in 2014 and 2015). Unsurprisingly, Dr. Back was also one of the largest recipients of monetary benefits from Corcept's increased focus on Internists and Family Medicine physicians, seeing his monetary receipts from Corcept skyrocket from $154.38 in 2016 (for food and beverage payments) to $55,454.60 in 2017 ($47,000 of which were honoraria payments), with an additional $31,099.16 ($20,000 of which were honoraria payments) flowing to Dr. Back in 2018 from Corcept.

20. This exponential rise in supposedly confirmed cases of endogenous Cushing's Syndrome in a patient population that otherwise purportedly met the narrow indication set forth in the Korlym label by a General Internist in North Charleston, South Carolina (a city with an estimated population of approximately 110,000) raises the specter of impropriety on its own, particularly as the known incidence rate of endogenous Cushing's Syndrome is approximately 1 to 2 ***per million people***. The anomalous

nature of these alleged diagnoses is compounded by the fact that, according to 2017 Medicare Part D data, the second highest prescriber of Korlym was Dr. Joseph Mathews – a non-Specialist Endocrinologist practicing in Summerville, South Carolina, just twenty minutes from Dr. Back.

21. Like Dr. Back, Dr. Mathews saw his number of Korlym claims submitted to Medicare Part D increase from 16 in 2016 to 85 in 2017 (or 3.6% of all claims submitted nationwide to Medicare that year) accounting for a total drug cost of $374,151.80 and $2,053,739.20, respectively, after submitting zero Korlym claims in 2014 or 2015. Also, like Dr. Back, Dr. Mathews lined his pockets with payments from Corcept during this same period, receiving $73,777 from Corcept in 2017, including $48,000 in honoraria payments.

22. Together, Drs. Back and Mathews' collective Medicare Part D submissions accounted for more than $5.6 million, or 3.5% of the Company's net product revenue for 2017, alone, without factoring in the financial impact of additional undisclosed prescriptions these physicians presumably wrote during the same period that were reimbursed by private insurance companies and which are not publicly reported. Further, given the rarity of true endogenous Cushing's Syndrome, there is essentially a zero percent chance of having such a large cluster of affected individuals in and around North Charleston, South Carolina. Yet, Drs. Back and Mathews have each purportedly identified large groups of Cushing's patients in a small geographic area just minutes from one another.

23. According to former Corcept employees, Defendants Belanoff and Maduck, closely monitored every Korlym prescription that came in, real time, as they waited by the fax machine and exchanged "high fives" for each new enrollment form received. Defendants then sent congratulatory emails to the clinical specialist. Defendant Maduck also received weekly reports from each sales region detailing the new prescriptions for the week. Korlym prescriptions were also discussed at quarterly sales meetings with Defendant Maduck and Tom Burke and at the Company's Annual National Sales meetings where they lauded the sales achieved by their top clinical specialists, Carl Balzanti and Tyler Franklin, who were widely known throughout Corcept to be engaging in off-labeling marketing.

24. Former Corcept employees estimate based upon the reports they saw, discussions at sales meetings and the rarity of Cushing's Syndrome that off-label prescriptions accounted for approximately 60% of Corcept's annual sales and majority of Corcept's growth came from targeting off-label

subclinical Cushing's patients with elevated cortisol levels but with a DST scores below industry guidelines.

25. Indeed, the Company's revenue flourished, nearly doubling in 2017 before growing an additional 58% in 2018:

Fiscal Year	Product Revenue
2016	$81,321,000
2017	$159,201,000
2018	$251,247,000

26. Spurred by the sharp uptick in costly Korlym prescriptions, beginning in 2018, several private insurance companies began to tighten their requirements for approving Korlym prescriptions, requiring documented physical evidence that the Korlym prescription met the FDA-approved indication for this drug. These changes in the private insurance approval process for Korlym coincided with a decline in revenue growth year-over-year from 2017 to 2019. Specifically, revenue growth declined from 96% in 2017 to 58% in 2018 and 22% in 2019 as the insurance companies became wise to Corcept and Optime's scheme and it became more difficult for Optime to secure insurance approval for this extremely expensive drug, severely cutting into Corcept's growth.

27. The truth about Corcept's off-label marketing scheme for Korlym began to surface on January 25, 2019, when the Southern Investigative Reporting Foundation ("SIRF") published a report titled "Corcept Therapeutics: The Company That Perfectly Explains the Health Care Crisis" (the "SIRF Report"). The SIRF Report questioned the off-label use of Korlym in light of increasing deaths associated with it, as reported to the FDA's adverse events reporting system, while highlighting the Company's increased use of honoraria and speaker payments to physicians whose Korlym prescriptions drastically increased during the same period.

28. Upon the release of the SIRF Report, the Company's common stock price fell $1.52, or more than 11%, to close at $12.29 per share on January 25, 2019, on unusually heavy trading volume.

29. Then, after the close of the market on January 31, 2019, due to the increased scrutiny of its illicit sales practices involving Korlym, the Company forecasted a slowdown in Korlym sales, projecting full-year 2019 revenue of $285 million to $315 million, well below the $328 million expected

by analysts. On this news, the Company's share price fell $1.15, or more than 10%, to close at $10.03 per share on February 1, 2019, on unusually heavy trading volume.

30. Shortly after the Class Period, on February 5, 2019, prominent short-selling activist investment firm Blue Orca Capital ("Blue Orca") published on its website its investment thesis for Corcept valuing the Company at just $5.42 per share (nearly half of the then-prevailing common stock price of $10.20 per share) endorsing the SIRF Report and noting the Company's relationship with Optime as a controlled party (the "Blue Orca Report"). Blue Orca also concurrently posted on YouTube the audio of an investigative call to Optime wherein multiple Optime employees asserted that they were, in fact, Corcept employees.

31. As alleged herein, throughout the Class Period, Defendants made a series of materially false and misleading statements and failed to disclose material facts regarding, *inter alia*, Defendants' off-label marketing scheme, which targeted a broader population of non-Specialist Endocrinologists and PCPs, the basis for the Company's revenue growth, and Defendants' compliance with FDA-regulations.

32. Each of the Defendants acted with the requisite scienter during the Class Period, either knowingly or recklessly disregarding the truth about the Company's uniform and pervasive off-label marketing strategy for Korlym employed across the country in all six of Corcept's sales regions to artificially prop up Corcept's revenue and stock price. Defendants' scienter is multi-faceted and shows a desperate Company on the verge of losing its marketing exclusivity for Korlym - its only source of revenue and method of financing clinical trials - which was already shackled by a very narrow FDA-approved indication. Instead, the way forward for the Defendants was simple: a pivot towards an illicit off-label marketing scheme that preyed on physicians less knowledgeable about the established diagnosis and treatment protocols for endogenous Cushing's Syndrome, a very rare disorder.

33. As a result of the fraud alleged herein, Plaintiff and the putative Class have suffered significant harm.

II. JURISDICTION AND VENUE

34. The claims asserted herein arise pursuant to Section 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and SEC Rule 10b-5 promulgated therein, 17 C.F.R. § 240.10b-5.

35. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331, § 27 of the Exchange Act, 15 U.S.C. §78aa. In connection with the acts, conduct and other wrongs alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the U.S. mail, interstate telephone communications and the facilities of the national securities exchange. Corcept trades in an efficient market on the NASDAQ Stock Market ("Nasdaq").

36. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act, 15 U.S.C. § 78aa. Many of the acts charged herein, including the preparation and/or dissemination of materially false or misleading information, occurred in substantial part in this District. Additionally, Defendant Corcept maintains executive offices in this District at 149 Commonwealth Drive, Menlo Park, California.

III. THE PARTIES

A. Plaintiff

37. Plaintiff purchased Corcept securities during the Class Period at artificially inflated prices and was damaged thereby, as previously set forth in the PSLRA certification accompanying Plaintiff's motion for appointment as lead plaintiff (ECF No. 19), incorporated herein by reference.

B. Defendants

38. Defendant Corcept is a pharmaceutical company engaged in the development and commercialization of drugs that treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of the hormone cortisol. According to the Company's website, Corcept is "committed to improving patient lives through the discovery and development of drugs that address serious unmet medical needs related to excess cortisol activity." Corcept maintains its executive offices at 149 Commonwealth Drive, Menlo Park, California 94025. The Company's common stock is traded on the Nasdaq under the ticker symbol "CORT."

39. Defendant Joseph K. Belanoff, a co-founder of Corcept, has served as the Company's Chief Executive Officer and Director since 1999, and was appointed President in 2014. Defendant Belanoff is a medical doctor and, in addition to his role as Company CEO, is an Adjunct Professor of Psychiatry at Stanford University (School of Medicine) where he has held positions in the Department

of Psychiatry and Behavioral Sciences since 1992. As stated in the Company's Definitive Proxy Statement filed with the SEC on April 24, 2019, "Dr. Belanoff brings to our Board a deep knowledge of our financial activities, commercial operations and our research and development programs. He also has valuable expertise in business administration, drug discovery, clinical medicine and psychopharmacology."

40. Defendant Charles Robb has served as the Company's Chief Financial Officer since 2011.

41. Defendant Sean Maduck has been employed by Corcept since 2012. From 2012 to 2016 Maduck was Corcept's Vice President, Sales & Marketing. Since 2016, Maduck has been Corcept's Senior Vice President, Commercial.

42. Defendants Belanoff, Robb, and Maduck are collectively referred to herein as the "Individual Defendants" and, together with Corcept, as the "Defendants."

43. Each of the Individual Defendants, by virtue of his high-level position with Corcept, directly participated in the management of the Company, was directly involved in the day-to-day operations of the Company at the highest levels, and was privy to confidential and proprietary information concerning the Company and its business, operations, growth, financial statements, and financial condition during his respective tenure with the Company, as alleged herein. As alleged below in Sections V and VII, the materially false or misleading information conveyed to the public resulted from the collective actions of the Individual Defendants. Each of these individuals, during his tenure with the Company, was involved in drafting, producing, reviewing, and/or disseminating the statements at issue in this case, approved or ratified these statements, and knew or recklessly disregarded that these statements were being issued regarding the Company.

44. As executive officers of a publicly-held company whose common stock was, and is, registered with the SEC pursuant to the Exchange Act, and whose common stock was, and is, traded on the Nasdaq, and governed by federal securities laws, each of the Individual Defendants had a duty to disseminate prompt, accurate, and truthful information with respect to the Company's business, operations, financial statements, and internal controls, and to correct any previously issued statements that had become materially misleading or untrue, so that the market prices of the Company's publicly

traded securities would be based on accurate information. Each of the Individual Defendants violated these requirements and obligations during the Class Period.

45. Each of the Individual Defendants, because of his position of control and authority as an executive officer of Corcept, was able to and did control the content of the SEC filings, press releases, and other public statements that Corcept issued during the Class Period, was provided with copies of the statements at issue in this action before they were made to the public, and had the ability to prevent their issuance or cause them to be corrected. Accordingly, each of the Individual Defendants is responsible for the accuracy of the materially false or misleading public statements alleged herein.

46. Each of the Individual Defendants, because of his position of control and authority as an executive officer of Corcept, had access to the adverse undisclosed information about Corcept's business, operations, financial statements, and internal controls through access to internal corporate documents, conversations with other Corcept officers and employees, attendance at Corcept management meetings, and via reports and other information received in connection therewith, and knew or recklessly disregarded that these adverse undisclosed facts rendered the representations made by or about Corcept materially false or misleading.

47. Each of the Individual Defendants is liable as a participant in a fraudulent scheme or course of conduct that operated as a fraud or deceit on purchasers of Corcept securities by disseminating materially false or misleading statements and/or concealing adverse facts. The scheme: (i) deceived the investing public regarding Corcept's products, business, operations, and management, and the intrinsic value of Corcept securities; and (ii) caused Plaintiff and members of the Class to acquire Corcept common stock at artificially inflated prices.

C. Relevant Non-Parties

48. Non-Party Dohmen Life Sciences Services, LLC (now known as EVERSANA) ("Dohmen") is a company engaged in the wholesale distribution of prescription drugs, proprietary drugs, and toiletries. Dohmen was contracted by Corcept from 2013 to 2017 as its specialty pharmacy to provide services for a direct to patient distribution model for Korlym. Dohmen acted as conduit between Corcept and patients prescribed Korlym, responsible for, among other things, inventory control services, prescription fulfillment services, product distribution services, patient reimbursement support services,

insurer contract management services, accounts receivable services, account management services, financial reporting services, and patient support services.[3]

49. Non-party Optime Care, LLC ("Optime") purports to be a "nationally recognized pharmacy, distribution, and patient management organization, that brings to the market a suite of comprehensive services tailored to maximize the therapeutic opportunities for the treatment of orphan and rare disorders." Optime was incorporated in 2015.

50. Non-party Donovan Quill ("Quill") is the current President and CEO of Optime. Quill previously worked for Dohmen as the Vice-President of Client Services from 2012 to 2015 and as Senior Vice President Direct to Patient Programs in 2015. From 2015 to 2016, Quill opened his own consulting agency, DJQ Consulting LLC. Quill officially joined Optime as its President in September of 2016.

51. Non-party Michelle Hefley ("Hefley") co-founded Optime. Hefley has been a managing partner at Optime since 2015. Hefley was the President of Centric Health until 2014 and executed the original services agreement between Centric and Corcept on behalf of Centric.

52. Non-party Lawrence Glasscott ("Glasscott") was the CFO and Senior VP of Payer Reimbursement for Centric/Dohmen until 2015. Glasscott has been the CFO of Optime since 2015.

53. Non-party Tom Burke ("Burke") has worked at Corcept since 2015. Burke started as the Northeast Region Manager until he was promoted to National Sales Director in June 2016. Burke remained the National Sales Director until February 2020 when he was promoted to Vice President of Sales.

54. Non-party Tyler Franklin ("Franklin") has worked at Corcept as a clinical specialist since 2015. According to his publicly available LinkedIn profile, Franklin has been the recipient of several Company awards and accolades since joining Corcept as a Clinical Specialist in 2015, including: 2016: Clinical Specialist of the Year; President's Club; Rookie of the Year; Peer Impact Award; 2017: Clinical Specialist of the Year; President's Club; Promoted to Senior Clinical Specialist; 2018: Clinical Specialist of the Year; President's Club; Peer Impact Award; Promoted to Executive Clinical Specialist.

[3] Centric Health Services ("Centric") was a specialty pharmacy purchased by Dohmen in 2011. Centric was initially allowed to continue operating under the Centric name until 2014, when it adopted the Dohmen name. Dohmen's initial contract with Corcept was signed through its Centric subsidiary.

55. Non-party Carl Balzanti ("Balzanti") worked at Corcept from June 2014 through January 2018. Balzanti was a clinical specialist from June 2014 through 2016, when he was promoted to Region Manager – West Region.

56. Non-party Dr. Andreas Moraitis ("Moraitis") has worked at Corcept since June 2014, most recently as the Senior Medical Director. Dr. Moraitis was an Assistant Professor, Endocrine Oncology with the University of Michigan Medical School from October 2012 to June 2014. CW11 stated that Moraitis had been prescribing Korlym frequently off-label and was put on Corcept's speakers' program. CW11 understood that this caused issues with the University eventually leading to Dr. Moraitis' departure. According to CW11, Corcept had to quickly hire Dr. Moraitis to prevent him from speaking out against the Company.

IV. FACTUAL ALLEGATIONS

A. Corcept is a Pharmaceutical Company that Relies on a Single Drug Product to Generate all of its Revenue

57. During the 1970's, French pharmaceutical company Roussel-Uclaf S.A. began developing glucocorticoid receptor antagonists, the most well-known of which is mifepristone, that was first synthesized in 1980. Mifepristone was later combined with misoprostol to make RU-486, an abortion pill approved in France in 1987 and in the U.S. in 2000. While the FDA approved mifepristone/misoprostol under the brand name Mifeprex for medical abortions in 2000, Defendant Belanoff and Corcept were simultaneously exploring alternative uses for mifepristone, including for the treatment of psychiatric and neurological diseases.

58. Corcept was founded in 1998 after Defendant Belanoff supposedly observed encouraging results in the testing of mifepristone for individuals with psychotic major depression ("PMD"). In reality, despite garnering national interest, the clinical trial results failed to validate the Company's theories. Several prominent psychiatric researchers observed that the test results provided no statistical backing for the claims that mifepristone was beneficial for those with PMD. Accordingly, in 2007, Corcept halted clinical trials without publishing any results, acknowledging in its SEC filings that none of the Phase 3 clinical trials testing mifepristone for PMD demonstrated statistically significant response rates compared with placebo.

59. With the Company's future in jeopardy, and deeply in debt, Corcept was desperate for a lifeline. That lifeline came in July 2007 with the FDA's granting of the orphan drug designation for the Company's mifepristone drug, Korlym,[4] for the treatment of endogenous Cushing's Syndrome. Designation of Korlym as an orphan drug conferred market exclusivity, tax credits, research support and other benefits to Corcept under the Orphan Drug Act of 1983.

60. There are two types of Cushing's Syndrome: exogenous and endogenous. Exogenous Cushing's Syndrome, by far the more common form of Cushing's Syndrome, is caused by taking glucocorticoid hormones, better known as corticosteroids, and is treated by decreasing and eventually discontinuing intake of these corticosteroids, allowing the body to return to natural cortisol levels without the need for other medication. Physicians routinely prescribe glucocorticoid drugs to patients with a variety of inflammatory conditions, such as rheumatoid arthritis, lupus, and asthma.

61. Endogenous Cushing's Syndrome, on the other hand, is a debilitating and rare disease that occurs when the body is exposed to high levels of cortisol[5] produced by the adrenal glands for a sustained period of time and requires treatment through surgery, radiation and/or medications. Endogenous Cushing's Syndrome is most commonly caused by a hormone-secreting tumor in the adrenal or pituitary glands. In the adrenal glands, the tumor produces too much cortisol. In the pituitary gland, the tumor produces too much ACTH (adrenocorticotropic hormone), a neuroendocrine hormone that tells the adrenal glands to produce cortisol. Both types of tumors result in excess cortisol production leading to Cushing's Syndrome. Occasionally tumors arise elsewhere in the body that may spontaneously produce ACTH, which also causes the adrenal glands to produce too much cortisol, leading to Cushing's Syndrome. When an ACTH tumor or adenoma arises in the pituitary gland in the brain which causes excess cortisol production by the adrenal glands, the term for this condition is Cushing's Disease. Cushing's Disease is a subcategory of Cushing's Syndrome, but it is the most

[4] Korlym was previously known as "Corlux." For the sake of clarity, this complaint only uses the name "Korlym" when referring to the drug, regardless of then-prevailing marketing terminology.

[5] An INDA is the first step in the FDA's drug review process. The INDA is not an application for marketing approval. Instead, it is the avenue through which the sponsor gets from the FDA an exemption to the federal law that prohibits an unapproved drug from being transported across state borders, allowing the sponsor to commence clinical trials.

common form of endogenous Cushing's Syndrome with about 70% of Cushing's Syndrome patients falling into the category of Cushing's Disease.[6]

62. Cushing's Syndrome is typically treated by an Endocrinologist. An Endocrinologist is a physician who specializes in diagnosing and treating conditions that affect the body's adrenals, pancreas, parathyroid glands, pituitary, reproductive glands and thyroid, as well as bone and lipid metabolism. An Endocrinologist is uniquely qualified to treat Cushing's Syndrome because Cushing's Syndrome affects the cortisol-producing adrenal glands and, most often, the pituitary gland as well. Due to the rare nature of Cushing's Syndrome, it is common for other physicians to refer patients with symptoms to Endocrinologists specializing in the disorder. Given the rarity of endogenous Cushing's Syndrome, there are a limited number of Endocrinologists around the country that specialize in the diagnosis and treatment of Cushing's Syndrome patients, referred to herein as "Specialty Endocrinologists."

63. Korlym, a drug approved only to treat endogenous Cushing's Syndrome within limited parameters, is currently Corcept's only FDA-approved drug and provides the Company with 100% of its revenue.

64. As a developmental pharmaceutical company, Corcept's ability to generate revenue was entirely dependent on its ability to obtain FDA approval of Korlym. In the Company's Annual Report on Form 10-K for the year ending December 31, 2010, Corcept stated it "[did] not expect to generate significant revenue until [Korlym] has been approved by the FDA for marketing in the United States."

B. The FDA Approves Korlym to Treat a Narrow Subset of Endogenous Cushing's Syndrome, a Rare Disorder Impacting Just One to Two Patients per One Million People in the United States

65. In search of a new, profitable use for mifepristone following the unsuccessful trial results related to PMD, the Company pivoted towards the treatment of endogenous Cushing's Syndrome, looking to leverage the United States' laws and policies regarding orphan diseases and drugs.

1. Corcept Obtains FDA Approval of Korlym to Treat Endogenous Cushing's Syndrome Under the Orphan Drug Act

66. The Orphan Drug Act of 1983 was enacted to promote research and development of expensive medicines used to treat rare diseases. The designation is available for disease treatments

[6] https://www.ohsu.edu/brain-institute/cushing-disease-cushing-syndrome

affecting fewer than 200,000 patients in the United States. Along with the orphan designation, the developing sponsor obtains certain benefits, including tax credits for clinical testing, assistance from the FDA in the drug development process, and seven years of marketing exclusivity for the drug. The market exclusivity period begins when the FDA approves the drug.

67. In July 2007, the FDA granted Corcept the orphan drug designation for Korlym stating as the reason that there are an estimated 20,000 patients in the United States suffering from endogenous Cushing's Syndrome.

68. Following the Orphan Drug designation, in September 2007, Corcept filed an Investigational New Drug application ("INDA"[7]) with the FDA for Korlym for the treatment of endogenous Cushing's Syndrome. As the Company stated in its September 11, 2007 press release announcing the INDA, "[i]n the communication regarding the opening of the INDA, the FDA indicated that a single study may provide a reasonable basis for the submission of a New Drug Application (NDA) for [Korlym] for the treatment of endogenous Cushing's Syndrome, which allows us to initiate the 50-patient open label study defined by the protocol submitted with the application for the IND[A]."

69. In December 2007, Corcept initiated C1073-400, or Study 400 (also known as the SEISMIC study), a 24-week open label, uncontrolled trial that enrolled a total of 50 patients with endogenous Cushing's Syndrome.

70. An open-label study, like the one Corcept conducted, is the least rigorous type of scientific investigation because all participants know they are receiving the drug and not a placebo, and there is no control group. The stated objective of Study 400 was to evaluate the safety and efficacy of mifepristone in the treatment of the signs and symptoms of endogenous Cushing's Syndrome based on two primary endpoints: glycemic control and blood pressure.

71. Of the 50 patients enrolled in Study 400, 34 reported protocol violations. These protocol violations included: (1) missing or performing out-of-window study assessments[8] (21 incidences); (2)

[7] An INDA is the first step in the FDA's drug review process. The INDA is not an application for marketing approval. Instead, it is the avenue through which the sponsor gets from the FDA an exemption to the federal law that prohibits an unapproved drug from being transported across state borders, allowing the sponsor to commence clinical trials.

[8] An "out-of-window" visit is a visit in which the participant misses their scheduled "window" to check in with the trial.

deviations in blood pressure measurement procedures including obtaining differences in two blood pressure values of >5 mmHg (16 incidences); and (3) administration of prohibited medications or changes in doses of antihypertensive or antidiabetic medications (12 incidences).

72. While Study 400 was ongoing, the Company was twice denied a "Fast Track"[9] designation for Korlym (on September 9, 2009 and January 4, 2010) on the basis that Corcept had not demonstrated that Korlym affects a serious aspect of endogenous Cushing's Syndrome. According to the FDA, "[d]etermining whether a condition is serious is a matter of judgment, but generally is based on whether the drug will have an impact on such factors as survival, day-to-day functioning, or the likelihood that the condition, if left untreated, will progress from a less severe condition to a more serious one."[10]

73. While Study 400 showed a clinically significant response rate in patients with Cushing's Syndrome and glucose intolerance or diabetes induced by hypercortisolemia, it produced no evidence that Korlym was effective in producing a clinically meaningful improvement of hypertension induced by hypercortisolemia in patients with Cushing's Syndrome.

74. In April 2011, the Company submitted a New Drug Application (the "NDA") for Korlym to the FDA. Importantly, this NDA sought regulatory approval for Korlym as a ***general*** treatment for all forms of endogenous Cushing's Syndrome (as opposed to the vastly more limited indication ultimately approved by the FDA).

75. The FDA approved Korlym on February 17, 2012 to treat endogenous Cushing's Syndrome in patients with hyperglycemia who have type 2 diabetes or glucose intolerance and who have failed or are ineligible for surgery—a much narrower subset of patients than what Defendants had sought in the NDA. As set forth on the FDA-approved label of Korlym:

> Korlym (mifepristone) is a cortisol receptor blocker indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's Syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.
>
> Important Limitations of Use (1.1)

[9] "Fast track" is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

[10] https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track

- Do not use for the treatment of type 2 diabetes mellitus unrelated to endogenous Cushing's Syndrome.

76. According to the Korlym label, the starting dose is 300mg dose once daily, which may be increased to a maximum dose of 1200mg daily.

77. Side effects listed on the Korlym label include nausea, fatigue, headache, decreased blood potassium, arthralgia, vomiting, peripheral edema, hypertension, dizziness, decreased appetite, and endometrial hypertrophy. The FDA has also issued warnings and precautions for those taking Korlym, including adrenal insufficiency, hypokalemia,[11] vaginal bleeding and endometrial changes, exacerbation of conditions treated with corticosteroids (e.g., autoimmune disorders), and an increased risk for opportunistic infections such as pneumonia. Since mifepristone is the active ingredient in Korlym, it also presents hazards during pregnancy. The FDA does not prohibit the use of Korlym during pregnancy, but requires patients who are pregnant or who become pregnant while using Korlym to be apprised of the potential hazards.

78. Importantly, the FDA ***did not*** approve Korlym for the treatment of hypertension in patients with endogenous Cushing's Syndrome (as sought by Corcept), noting that the response rate in this patient cohort in Study 400 was equivocal and potentially adversely impacted by the study's design flaws.

79. The FDA further noted that, despite Corcept's efforts to prove efficacy across the general population of endogenous Cushing's Syndrome patients, Korlym had only demonstrated limited efficacy for treating hyperglycemia associated with diabetes or glucose intolerance in endogenous Cushing's Syndrome, warning that "the observed effects should not be extrapolated beyond this patient population and it would be inappropriate to consider the use of Korlym in the management of diabetes unrelated to hypercortisolism due to [endogenous] Cushing's Syndrome."[12]

80. The FDA also concluded that the Study 400 trial design was flawed based on its open label structure and lack of control group, but that it would be "unethical to randomize any patient to placebo" given the seriousness of Cushing's Syndrome.

[11] "Hypokalemia" refers to abnormally low levels of potassium in an individual's blood.
[12] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000SumR.pdf.

81. In connection with its approval, the FDA issued a Summary Review[13] discussing the scientific and regulatory issues surrounding Korlym, noting several key factors related to its approval, including that:[14]

> The diagnosis of Cushing's Syndrome **requires a multitude of laboratory and radiologic tests** whose discussion extends beyond the scope of [the Summary Review]. The objective of the laboratory tests is to demonstrate inappropriate and sustained hypercortisolism to distinguish these patients from conditions such as pseudo-Cushing's, severe depression, or cyclical Cushing's. **Reliance on just clinical presentations is not possible or acceptable as patients' presentations are highly variable and span a wide spectrum that includes textbook descriptions of buffalo hump, violaceous striae, hirsutism and facial plethora to more subtle signs of just diabetes and depression.**

82. Korlym is an astronomically expensive medication. Drugs.com estimates the monthly cost (28 tablets) for a 300 mg Korlym prescription at approximately $14,600[15] (totaling more than $190,000 for an entire year at $521.43 per 300 mg pill). Notably, the FDA's approved dosing guidelines provide that Korlym's daily dosage may be increased in 300 mg increments up to 1200 mg per day, meaning that in a single year a patient on Korlym could pay up to **$760,000 for their prescription at the highest recommended dose**.

2. Korlym's Total Addressable Market for its FDA-Approved Indication is but a Fraction of all Cushing's Patients

83. In the FDA's Clinical Review related to its approval of Korlym, Dr. Marina Zemskova estimated that "at any given time there are approximately 20,000 patients with [endogenous] Cushing's Syndrome in the U.S."[16]

84. Further, in the redacted section of her Clinical Review labeled "Applicant's Proposed Indication," Dr. Zemskova lays out *Corcept's* **proposed** indication for Korlym before estimating that, in the United States, "approximately 5,000 patients with Cushing's Syndrome would be considered candidates for the chronic treatment with Korlym":

> The Sponsor proposes Korlym to treat clinical and metabolic effects of hypercortisolemia in patients with endogenous Cushing's Syndrome, including:
> - patients with Cushing's disease who have not adequately responded or relapsed after surgery
> - patients with Cushing's disease who are not candidates for surgery

[13] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000SumR.pdf.
[14] Unless otherwise indicated, all emphasis is added.
[15] https://www.drugs.com/price-guide/korlym
[16] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000MedR.pdf.

85. Notably, Corcept's proposed indication underlying the 5,000-patient estimate ***is not the same indication that was ultimately approved by the FDA***. Instead, as acknowledged in the FDA's Summary Review, the "FDA has already **negotiated a more limited patient population** with Korlym than was originally proposed by [Corcept]." That more limited patient population necessarily reduced the estimated total addressable market well below the 5,000 patients originally forecasted by the Company.

86. The Company never ascribed a figure to the limited subset of Cushing's patients actually eligible to use Korlym *on label*. However, throughout the Class Period and continuing to this day, the Company claims there are 20,000 estimated Cushing's patients in the United States at any given time (and forecasting an additional 3,000 newly diagnosed patients per year who replace those endogenous Cushing's Syndromes who pass away) as a reliable figure in its corporate press releases. [17]

87. Similarly, Defendant Belanoff touted the 20,000 figure during the Class Period on earnings calls, while also incredulously claiming that approximately 50% of the total Cushing's Syndrome population is a candidate for treatment with Korlym (despite the limited indication requiring type 2 diabetes or glucose intolerance):

- "There are about 20,000 patients diagnosed with Cushing's Syndrome in the United States. Approximately half of them have been cured by surgery. The rest are candidates for treatment with Korlym." Earnings Call, January 30, 2017.
- "As a reminder, at least 20,000 people in the United States have been diagnosed with Cushing's Syndrome. 3,000 new cases of Cushing's Syndrome are diagnosed each year. Half of these cases are cured by surgery, but that leaves at least 10,000 patients in need of medical therapy. Some of these patients have been treated with Korlym, but there are many more that can benefit from it." Earnings Call, November 1, 2018.

88. According to PE, Cushing's Syndrome is a very rare disease Endocrinologists encounter only in the rarest of situations. PE screens for Cushing's after observing signs and symptoms that could be indicative of Cushing's or if the patient has an adrenal mass. In addition, PE receives referrals from

[17] *See* Corcept press releases issued on: January 30, 2017; March 6, 2017; May 1, 2017; August 1, 2017; November 2, 2017; February 1, 2018; February 22, 2018; March 15, 2018; May 8, 2018; August 9, 2018; November 1, 2018; November 19, 2018; December 13, 2018; January 31, 2019; February 25, 2019; May 2, 2019; May 9, 2019; August 1, 2019; and November 7, 2019.

other physicians of patients who they believe might have Cushing's Syndrome. Despite this, PE sees only two to three patients who actually have endogenous Cushing's Syndrome each year.

C. Endogenous Cushing's Syndrome Has Well-Established Diagnosis and Treatment Guidelines that Require Multiple Diagnostic Tests Be Performed to Confirm the Presence of Cushing's Syndrome

89. As discussed above, cortisol is the body's main stress hormone. Cortisol works with certain parts of the brain to control mood, motivation and fear, as well as certain aspects of metabolism.

90. According to the Clinical Guidelines Subcommittee of the Endocrine Society in its published practice guideline titled "The Diagnosis of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline" (the "Diagnosis Guideline"), "[a]lthough Cushing's syndrome is clinically unmistakable when full blown, the spectrum of clinical presentation is broad, and the diagnosis can be challenging in mild cases." As set forth in the below table from the Diagnosis Guidelines, the symptoms and signs of Cushing's significantly overlap with other, more common ailments:

TABLE 1. Overlapping conditions and clinical features of Cushing's syndrome[a]

Symptoms	Signs	Overlapping conditions
Features that best discriminate Cushing's syndrome; most do not have a high sensitivity		
	Easy bruising	
	Facial plethora	
	Proximal myopathy (or proximal muscle weakness)	
	Striae (especially if reddish purple and > 1 cm wide)	
	In children, weight gain with decreasing growth velocity	
Cushing's syndrome features in the general population that are common and/or less discriminatory		
Depression	Dorsocervical fat pad ("buffalo hump")	Hypertension[b]
Fatigue	Facial fullness	Incidental adrenal mass
Weight gain	Obesity	Vertebral osteoporosis[b]
Back pain	Supraclavicular fullness	Polycystic ovary syndrome
Changes in appetite	Thin skin[b]	Type 2 diabetes[b]
Decreased concentration	Peripheral edema	Hypokalemia
Decreased libido	Acne	Kidney stones
Impaired memory (especially short term)	Hirsutism or female balding	Unusual infections
Insomnia	Poor skin healing	
Irritability		
Menstrual abnormalities		
In children, slow growth	In children, abnormal genital virilization	
	In children, short stature	
	In children, pseudoprecocious puberty or delayed puberty	

[a] Features are listed in random order.

[b] Cushing's syndrome is more likely if onset of the feature is at a younger age.

91. As discussed above, endogenous Cushing's Syndrome is the rarer form of Cushing's Syndrome. The incidence of endogenous Cushing's Syndrome ranges from .7 to 2.4 per million population per year.

92. Women are five times more likely to suffer from endogenous Cushing's Syndrome than men.

93. Because of its rarity, the robust Diagnosis Guidelines created by the Endocrine Society recommend against widespread testing for Cushing's Syndrome in any other patient group besides:

- Patients with unusual features for age (e.g., osteoporosis, hypertension);
- Patients with multiple and progressive features, particularly those who are more predictive of Cushing's Syndrome;
- Children with decreasing height percentile and increasing weight;
- Patients with adrenal incidentaloma compatible with adenoma found on imaging studies.

94. For those patients who fall in this recommended testing population, the consensus process established by the Endocrine Society recommends the initial use of one of the four established hypercortisolism tests, with those patients with abnormal results recommended to see an Endocrinologist for a second confirmatory test and clinical analysis. These recommended tests include:

- Urinary free cortisol ("UFC") test (at least two measurements), which measures the amount of cortisol in the urine. This test is done over a 24-hour period where the patient collects his or her urine to be sent to a lab for testing. A normal adult range for cortisol levels in urine is usually < 40 – 50 ug/d. A result higher than 50 ug/d could be indicative of Cushing's Syndrome;
- Late-night salivary cortisol ("LNSC") (two measurements) measures the patient's cortisol between 11 pm and midnight. Patients with Cushing's Syndrome typically have elevated cortisol levels during this time of day compared to other individuals. The normal range of cortisol at this time is 0.10-0.15 ug/dL. A result higher than .15 ug/dL could be indicative of Cushing's Syndrome;

- 1-mg overnight DST suppresses the cortisol production of patients through the use of the synthetic steroid dexamethasone. The patient receives the steroid at 11 pm followed by a measurement of serum cortisol early the following morning. Normal subjects should suppress their cortisol level to less than 1.8 ug/dL. A result higher than 5.0 ug/dL could be indicative of Cushing's Syndrome. A result between 1.8 and 5.0 ug/dL is, according to PE, a "gray area;"[18]
- Longer low-dose DST (2 mg/d for 48 h) is the same test as the DST, but dexamethasone is administered in 0.5 mg tablets every 6 hours for 48 hours as opposed to one dose at 11 pm the night before measuring the serum cortisol.

95. While the Diagnosis Guideline provides that a non-Endocrinologist clinician such as a Primary Care Physician ("PCP") may perform an initial screen for Cushing's Syndrome using one of the above tests, in the event the initial test is abnormal, a further evaluation by an Endocrinologist (including the performance of a second screening test to either confirm the initial test or identify a false positive) is recommended to confirm or exclude a diagnosis of endogenous Cushing's Syndrome. An evaluation by an Endocrinologist is also recommended where the patient tests normal, but the pretest probability is high (i.e., patients with clinical features suggestive of Cushing's Syndrome).

96. As set forth in the Diagnosis Guidelines:

> If the initial test result is abnormal, further evaluation by an endocrinologist will ensure that the disorder is confirmed or refuted and that the possibility of a false-positive result will be considered.
>
> Conversely, in cases in which there is a high pretest probability of Cushing's Syndrome but a normal initial test, use of an additional alternative test has the potential benefit of disclosing those with milder disease.

97. The importance of confirming any diagnosis with an endocrinologist who specializes in diagnosing and treating Cushing's Syndrome and through full laboratory testing lies in both the rarity of the disease and the difficulty in diagnosing it in mild cases, particularly as each of the four preliminary screening tests are susceptible to false negatives or false positives based on external factors, including pre-existing conditions and interference from other medications.

[18] As used herein, a "positive" DST is one returning results greater than 1.8 ug/dL.

98. For example, a recent study observed a high rate of false negatives in the UFC test due to interference from other medications. As noted by several doctors in the clinical case report *Diagnosis of Cushing's*[19] Clin Case Rep. 2016 Dec; 4(12): 1181–1183:

> A recent study demonstrated a high rate of normal UFC test results in patients with Cushing's syndrome, which suggests that negative UFC test results are not uncommon despite the presence of hypercortisolism-related disease[20]. Moreover, drugs such as carbamazepine, fenofibrate, and carbenoxolone have been reported to increase the cortisol levels and interfere with the accurate interpretation of UFC results[21]. These observations have important clinical implications because they suggested that the UFC screening method can fail to indicate disease and that ***complementary tests are potentially needed to help with the diagnosis of CD***. Furthermore, current clinical practice guidelines recommend additional testing and further evaluation by an endocrinologist to confirm or exclude the diagnosis of CD in individuals with normal UFC test results.

99. Likewise, the 1-mg overnight DST and longer dose DST screening tests are subject to a high level of false positive readings and are not to be relied upon in isolation as the sole basis for a Cushing's diagnosis. As noted by Drs. Teresa Brown, Regina Belokovskaya and Rachel Pessah Pollack in their chapter titled "Pseudo-Cushing's Syndrome: A Diagnostic Dilemma" in the 2019 book *Management of Patients with Pseudo-Endocrine Disorder*, edited by Endocrinologist Dr. Michael T. McDermott:

> Dexamethasone metabolism in individual patients can affect the results of the 1 mg DST. Drugs that induce the hepatic clearance of dexamethasone via the CYP 3A4 enzyme (phenytoin, phenobarbital, carbamazepine, rifampicin, and alcohol) can reduce plasma dexamethasone levels and result in false-positive results. Drugs that impair dexamethasone metabolism via inhibition of CYP 3A4 (aprepitant/fosaprepitant, itraconazole, ritonavir, fluoxetine, diltiazem, and cimetidine) can increase dexamethasone levels and potentially produce false-negative results. Patients with liver or renal failure may also have reduced clearance of dexamethasone. There is also variation in dexamethasone metabolism among healthy individuals with no other medical problems. It is therefore recommended that a serum dexamethasone level be measured along with the cortisol level to ensure that plasma dexamethasone concentrations are appropriate. The 1 mg DST results in false-positive result in up to 50% of females taking oral contraceptive pills.

100. Moreover, according to PE, the DST can provide false positive results in patients with cyclical Cushing's Syndrome, depression, and excessive alcohol use.

[19] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5134332/
[20] https://www.thieme-connect.com/products/ejournals/html/10.1055/s-0030-1263128
[21] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2386281/

101. The current state of these initial screening tests for Cushing's Syndrome was summarized by Drs. Ernest Yorke, Yacoba Atiase, Josephine Akpalu, and Osei Sarfo-Kantanka in their article published in the *International Journal of Endocrinology* titled "Screening for Cushing Syndrome at the Primary Care Level: What Every General Practitioner Must Know," Int J Endocrinol. 2017; 2017: 1547358.[22] This article, which relied on the Endocrine Society's guidelines, observed: (i) that the UFC test's "sensitivity and specificity are lower than other tests and hence mild [Cushing's Syndrome] can be missed. Moreover, it gives false positive and negative results in many conditions and with many drugs [and] [h]igh fluid intake, incomplete collection, contamination, and decreasing GFR (<60 ml/min) can make UFC unreliable;" (ii) "LNSC is not reliable in patients with disturbed sleep, shift work, smoking, chewing tobacco, brisk brushing of teeth, depression, and critical illness;" and (iii) in the DST, "[e]xercise and poor sleep after dexamethasone will lead to false positivity [and] [e]nzyme inducers, gastrointestinal malabsorption, and rapid transit time decrease the available drug for suppression and may lead to false positive results," while noting that a recent study concluded that "in populations with a high prevalence of obesity such as the United States of America, **the positive predictive value of the [DST] is only 0.4%** and therefore [that study's author] discourages its use in diagnosing [Cushing's Syndrome]." These authors concluded that "[m]ost often in clinical practice, LNSC is preferred because of its higher sensitivity and specificity compared to the others though strict precautions should be followed prior to sampling such as avoiding smoking, tobacco, brisk brushing of teeth, and irregular sleep patterns. **It is recommended to combine more than one investigation based on the patient's presentation and medical history. Any abnormal finding can then be combined with a low-dose DST, and if that also turns out positive, further screening and referral to an endocrinologist should be done to localize the source**."

102. As stated in the Diagnosis Guideline, "[m]ore often patients have a number of features that are caused by cortisol excess but that are also common in the general population, such as obesity, depression, diabetes, hypertension, or menstrual irregularity. As a result, there is an overlap in the clinical presentation of individuals with and without the disorder. We encourage caregivers to consider

[22] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5551520/

Cushing's Syndrome as a ***secondary cause*** of these conditions, particularly if additional features of the disorder are present."

103. Additionally, "overactivity of the hypothalamic-pituitary-adrenal (HPA) axis occurs without true Cushing's Syndrome, so that there is an overlap between physiological and pathophysiological causes of hypercortisolism. Thus, certain psychiatric disorders (depression, anxiety disorder, obsessive-compulsive disorder), **poorly controlled diabetes mellitus**, and alcoholism can be associated with mild hypercortisolism and **may produce test results suggestive of Cushing's Syndrome, including abnormal dexamethasone suppressibility** and mildly elevated UFC."

104. Thus, as discussed in the above articles authored by well-respected physicians in the field and the Diagnosis Guidelines established by the Endocrine Society, the need for multiple rounds of confirmatory laboratory testing (as opposed to diagnosing a patient based only on physical appearance or as a result of a single initial screening test) is paramount. As stated by the National Adrenal Diseases Foundation, the risk of misdiagnosing a patient with pseudo-Cushing's based on physical appearance is high, particularly as these symptoms are often manifestations of other, less rare diseases:[23]

> Most people who appear to have some of the classic physical features of Cushing's Syndrome (Cushingoid appearance) do not actually have the disease. Other reasons for these features include iatrogenic Cushing's (high dose steroids taken for treatment of a condition), polycystic ovary Syndrome (androgen excess from the ovaries), ovarian tumors, congenital adrenal hyperplasia, ordinary obesity, excessive alcohol consumption, family tendency to have a round face and abdomen with high blood pressure and high blood sugar.
>
> Because Cushing's Syndrome is a rare but serious disorder, it is very important to carefully exclude (rule out) other disorders and then separate the different types, leading eventually to a specific cause that can be treated. This process of testing and excluding usually takes days to weeks and requires a lot of patience and cooperation by the person being tested.

105. Because of the rarity of true endogenous Cushing's Syndrome and the risks associated with misdiagnosing an individual with pseudo-Cushing's, Endocrinologists have established a consensus protocol for the treatment for endogenous Cushing's Syndrome, as set forth in the Endocrine Society Clinical Practice Guideline for the Treatment of Cushing's Syndrome (the "Treatment Guidelines"). Importantly, these specialized experts specifically recommend *against* treatment to reduce cortisol levels or action if there is not an **established diagnosis** of Cushing's Syndrome (which,

[23] https://www.nadf.us/adrenal-diseases/cushings-Syndrome/

according to Diagnosis Guidelines, should be done after evaluation by an endocrinologist and multiple rounds of laboratory testing), while also suggesting **against treatments** designed to normalize cortisol or its action when there is **only borderline biochemical abnormality** of the hypothalamic-pituitary-adrenal (HPA) axis without any specific signs of Cushing's Syndrome.

106. Assuming an established diagnosis of endogenous Cushing's Syndrome, the Treatment Guidelines recommend a **first-line treatment option** of surgical resection of the primary lesions underlying Cushing's Syndrome whenever possible. According to the Treatment Guidelines, the first-line surgical treatment is especially effective: "In the absence of overt metastatic disease, ectopic ACTH-producing **tumor resection cured 76% of patients**, as demonstrated by observational studies."

107. For those individuals for whom initial surgery was ineffective or not an option, there exist a host of second and third-line therapeutic options. These options include: (i) a second surgery; (ii) radiation therapy/radiosurgery; and (iii) medical treatments, including the use of ketoconazole among other drugs. Each of these options has been shown to be more effective than Korlym while carrying less risk of adverse reactions.

108. Repeat surgery is suggested by the Treatment Guidelines, particularly in patients with evidence of incomplete resection or a pituitary lesion on imaging studies.

109. The Treatment Guidelines also make clear that mifepristone (the active ingredient in Korlym), which is a glucocorticoid antagonist, is only suggested for patients with diabetes or glucose intolerance who are not surgical candidates or who have persistent Cushing's Syndrome after surgery.

110. The Treatment Guidelines also highlight the difficulties with administering mifepristone, as the drug blocks cortisol at the glucocorticoid receptor, but does not actually decrease cortisol levels. "Because practitioners must use clinical cortisol-dependent variables for these purposes, it is difficult to estimate the correct dose," making the drug difficult to titrate[24] and endometrial thickening, contributing to the Treatment Guidelines' limited recommendation of its usage. limited recommendation of its usage.

111. The Treatment Guidelines provide a chart of pros and cons for each medical treatment available for Cushing's Syndrome. Mifepristone is the only treatment without any listed pros:

[24] Drug titration refers to the process of adjusting a dose of a medication for the maximum benefit without the adverse effects.

Table 1. Medical Treatment of CS

Drug	Pros	Cons	Dose[a]
Steroidogenesis inhibitors			
Ketoconazole[b]	Quick onset of action	Adverse effects: GI, hepatic dyscrasia (death), male hypogonadism; requires acid for biological activity; DDIs	400–1600 mg/d; every 6–8 h dosing
Metyrapone[b]	Quick onset of action	Adverse effects: GI, hirsutism, HT, hypokalemia; accessibility variable across countries	500 mg/d to 6 g/d; every 6–8 h dosing
Mitotane[c]	Adrenolytic, approved for adrenal cancer	Slow onset of action; lipophilic/long half-life, teratogenic; adverse effects: GI, CNS, gynecomastia, low WBC and T_4, ↑ LFTs; ↑ CBG, DDIs	Starting dose, 250 mg; 500 mg/d to 8 g/d
Etomidate	Intravenous, quick onset of action	Requires monitoring in ICU	Bolus and titrate
Pituitary-directed			
Cabergoline		Adverse effects: asthenia, GI, dizziness	1–7 mg/wk
Pasireotide[d]		Most successful when UFC <2-fold normal; sc administration; adverse effects: diarrhea, nausea, cholelithiasis, hyperglycemia, transient ↑ LFTs; ↑ QTc	600–900 μg twice daily
Glucocorticoid receptor-directed			
Mifepristone[e]		Difficult to titrate (no biomarker); abortifacient; adverse effects: fatigue, nausea, vomiting, arthralgias, headache, hypertension, hypokalemia, edema, endometrial thickening	300–1200 mg/d

Abbreviations: GI, gastrointestinal; DDI, drug-drug interactions; HT, hypertension; CNS, central nervous system; WBC, white blood cell count; LFTs, liver function tests; CBG, corticosteroid binding globulin; ICU, intensive care unit; QTc, corrected QT interval.

[a] Except as noted, the lowest dose may be used initially, unless the patient has severe hypercortisolism (UFC more than five times normal), in which case the starting dose may be doubled.

[b] Ketoconazole and metyrapone are approved by the European Medicines Agency for the treatment of CS.

[c] Mitotane has FDA approval for treatment of adrenal cancer.

[d] Pasireotide has FDA approval for treatment of patients with CD who are not surgical candidates or have failed surgery. The agent is also approved in Europe.

[e] Mifepristone has FDA approval for treatment of patients with CS and diabetes or glucose intolerance who are not surgical candidates or have failed surgery.

The use of other agents listed here represents an off-label use for the treatment of CS.

D. Corcept Engages Dohmen as a Specialty Pharmacy to Distribute Korlym Directly to Patients

112. In its Summary Review, the FDA required that Corcept "establish a distribution program through a central pharmacy" where "physicians can submit their prescriptions through this central pharmacy to have Korlym delivered directly to the patient." The FDA required Corcept to use this distribution method to "limit [Korlym's] availability for potential off-label use."

113. A specialty pharmacy focuses on high cost, high touch medications[25] rare and complex diseases. Specialty pharmacies are used in these situations because community pharmacies generally do not carry medications that are very rarely prescribed by physicians..

114. The specialty pharmacy works with the prescriber and insurance companies to negotiate the price and to get expensive drugs approved for the patients. The pharmaceutical company supplying the drug is typically not involved in these transactions.

115. Upon approval of the Korlym NDA, Corcept set out to secure a specialty pharmacy for Korlym's distribution. Following an approximately one-year period where the Company retained a different specialty pharmacy and distributor (each with the same corporate parent), Corcept entered into a services agreement with Dohmen on May 21, 2013 to provide specialty pharmacy services on a consignment basis (i.e., sales are made directly to patients without Dohmen taking title to the Korlym prescriptions they help facilitate). The services agreement carried a three-year term with an option to be renewed for an additional three years, in perpetuity, so long as no party had given written notice of non-renewal not less than 180 days prior to the end of the current term.

116. Under the agreement, Dohmen was responsible for "design[ing] and develop[ing]" an "exclusive distribution and patient services program…for furnishing [Korlym] in the United States to individuals who register and are accepted for participation by [Dohmen]." Dohmen was required to "prepare detailed work plans, identify key vendor relationships, develop patient services programs, develop training programs…hire and train staff for the Program, and conduct test runs of the services prior to launch."

[25] High touch medicines are medicines which have a higher degree of complexity in terms of distribution, administration, or patient management which drives up the cost of the drugs.

117. Dohmen was also to provide "services including inventory control, order fulfillment, product distribution, patient services, patient reimbursement support, payer contract management, accounts receivable management, account management and reporting."

118. Corcept would be responsible for all marketing of Korlym and would publicly "disclose the extent to which services are provided by Dohmen." Dohmen would also have the opportunity to "review and approve" all marketing materials referencing Dohmen before they were distributed. Additionally, both parties would need prior written consent to "issue any press release or public statement relating to the relationship of the parties to th[e] Agreement."

119. As Corcept's exclusive specialty pharmacy, Dohmen was responsible for distributing Korlym to patients, without taking title to the drug. Dohmen was required to use a system that recorded "receipt, inventory levels, and shipments on a Product-by-Product basis." If there were any credible complaints regarding Korlym, Dohmen was required to notify Corcept within 48 hours of receiving the information.

120. Dohmen was also required to provide Corcept with an itemized invoice every month for the services provided. In addition to this invoice, Dohmen provided Corcept with six daily financial reports.

121. As Corcept's exclusive specialty pharmacy, Dohmen received "a range of prices for Korlym" and "negotiate[d] with Pharmacy Benefit Managers ('PBMs'[26]) and payers to establish the prices that PBMs and payers would pay for Korlym."[27]

122. Dohmen was also required to "maintain an operations system for the purposes of order processing, distribution, billing of Customer and management of accounts receivables" and provide regular "inventory and distribution" reports to Corcept.

123. The agreement allowed for either party to terminate the relationship in the event of a material breach if the breach remained uncured for 30 days following the breaching party's receipt of written notice of such breach from the non-breaching party.

[26] Pharmacy Benefits Managers or "PBMs" are companies that manage prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, large employers, and other payers.

[27] *Dohmen Life Sciences Services, LLC. v. Corcept Therapeutics Incorporated*, 2017-0567-TMR.

124. The Corcept/Dohmen services agreement automatically renewed in May 2016. Corcept's Annual Report on Form 10-K for the period-ending December 31, 2016, filed with the SEC on March 6, 2017, makes no mention of any intention to discontinue the relationship with Dohmen, nor any past issues in dealing with the pharmacy. The Company's quarterly report on Form 10-Q for the period ending June 30, 2017, filed with the SEC on August 2, 2017 similarly makes no disclosures regarding the Dohmen relationship.

125. As discussed below, however, as market exclusivity for Korlym was set to expire in February 2019, Defendants had been aggressively pushing off-label use of Korlym in order to quickly generate revenue and sufficient cash flow to sustain the Company's business while developing its next drug, Relacorilant (CORT-125134). [28] When Dohmen was no longer willing to push through all the approvals for off-label Korlym prescriptions, Defendants abruptly terminated the relationship with Dohmen in favor of a newly created specialty pharmacy effectively controlled by Corcept.

E. With the End of Market Exclusivity for Korlym Looming, Corcept Fires Dohmen for Refusing to Acquiesce to its Off-Label Marketing Scheme and Creates Optime, a New Specialty Pharmacy Willing to go Along with the Company's Aggressive Off-Label Marketing Scheme

1. Corcept's Intellectual Property Rights Over Mifepristone were Limited and the Company's Market Exclusivity was Winding Down

126. Korlym's active ingredient, mifepristone, was developed in 1980 and its underlying composition of matter patent has expired. Instead, Corcept relies on 10 patents covering the use of mifepristone in the FDA's Orange Book.[29]

127. Throughout the Class Period, the Company touted its intellectual property in its filings with the SEC, claiming that "[p]atents and other proprietary rights are important to our business." Further, the Company's SEC filings highlight the tenuous nature and risks associated with the Company's mifepristone-related patents:

> **The mifepristone patents that we own or license cover the use of mifepristone, not its composition, which may make it more difficult to prevent patent infringement if**

[28] Relacorilant is Corcept's new version of Korlym. Relacorilant is currently in Phase 3 trials to be approved by the FDA. Corcept stated it believes relacorilant will fully replace Korlym if it gets approved by the FDA. Relacorilant is very similar to Korlym except that it does not bind to the progesterone receptor.

[29] The Orange Book identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug and Cosmetic Act and related patent and exclusivity information.

physicians prescribe another manufacturer's mifepristone or if patients acquire mifepristone from other sources, such as the internet or underground market.

We own or have exclusively licensed issued U.S. patents covering the use of cortisol modulators to treat a variety of disorders, including TNBC and CRPC. A method of use patent covers only a particular use of a compound, not its composition. Because our patents do not cover the composition of mifepristone, we cannot prevent others from commercializing mifepristone to treat disorders not covered by our method of use patents. The availability of mifepristone for these disorders may enable patients to obtain mifepristone for indications covered by our patents. Although any such "off-label" use would violate our patents, effectively monitoring compliance and enforcing our rights may be difficult and costly. Patients may be able to purchase mifepristone through the internet or underground market. Mifepristone is sold in the United States by Danco Laboratories for the termination of pregnancy. Although distribution is limited to a single dose provided in the physician's office and covered by other restrictions, we cannot be certain that patients with Cushing's syndrome will not be able to obtain mifepristone from this or other sources, should another company receive approval to market mifepristone for another indication.

128. In addition to its use patents, Corcept was also particularly reliant on the seven years of marketing exclusivity following the FDA's approval in February 2012 afforded for Korlym based on its Orphan Drug designation. Not unexpectedly, larger competitors took note of the end of Corcept's exclusivity for Korlym set for February 2019 and began taking measures to enter the market upon expiration. As Defendants stated in Corcept's Annual Report on Form 10-K for the period-ending December 31, 2017 filed with the SEC on February 28, 2018, "[i]n February 2018, [Corcept] received notice that Teva [Pharmaceuticals USA, Inc. ("Teva")] had filed an [Abbreviated New Drug Application ("ANDA")] requesting approval to market a generic version of Korlym. Teva's Paragraph IV certification stated that [Corcept's] patents in the Orange Book for Korlym are invalid, unenforceable or will not be infringed by Teva's proposed generic product."

129. Similarly, according to the Company's quarterly report on Form 10-Q for the period ended June 30, 2019, filed with the SEC on August 1, 2019, the Company received a "Paragraph IV Notice Letter advising that Sun Pharmaceutical Industries Limited ('Sun Ltd.'), had submitted an Abbreviated New Drug Application ('ANDA') to the FDA seeking authorization to manufacture, use or sell a generic version of Korlym in the United States prior to the expiration of certain of [Corcept's] patents."

130. In response, Corcept has filed two lawsuits against Teva (the first of which was filed in March 2018 and the second in February 2019) and a lawsuit against Sun Ltd. Corcept has alleged infringement of its intellectual property, triggering an automatic injunction against the final approval of any ANDA by the FDA until the earlier of 30 months following the initiation of Corcept's lawsuits or a court opinion finding the patents in question invalid, unenforceable, or not infringed under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act.

2. Corcept Contracts with Optime, a Self-Created Specialty Pharmacy with No Other Clients, to Facilitate Off-Label Sales of Korlym

131. Shortly after the FDA approved Korlym, Corcept clinical specialists began aggressively marketing Korlym to Endocrinologists in order to quickly generate substantial revenue growth to support the Company's operations and continued drug development. Initially, the targeted Endocrinologists were comprised of Endocrinologists who specialized in treating endogenous Cushing's Syndrome patients ("Specialist Endocrinologists").

132. Defendants had limited success in convincing Specialist Endocrinologists to prescribe Korlym. This was because Specialist Endocrinologists well understood the need to conduct a full diagnostic evaluation using multiple tests in order to properly diagnose endogenous Cushing's Syndrome and the dangers associated with an incorrect diagnosis and improper treatment based on that incorrect diagnosis.

133. In fact, Specialist Endocrinologists wanted little to do with Korlym because of its lack of efficacy, severe adverse side effects, and extremely high cost. Thus, these Specialist Endocrinologists viewed Korlym as a fourth-line or last resort therapy for an already rare disease that was better addressed through alternative approaches (i.e., surgical resection, radiation therapy, or one of the other well-established endogenous Cushing's Syndrome drug treatments).

134. Indeed, according to PE, PE will only consider Korlym for medical treatment as a last resort because: (i) Korlym has a different mechanism of action than other medical treatments for Cushing's Syndrome as it blocks the body from utilizing the excess cortisol that is being produced thereby leading to increased cortisol levels instead of stopping the production of the cortisol, making it difficult to track Korlym's efficacy because it is impossible to measure whether actual cortisol levels

have decreased; (ii) Korlym carries with it too many high-risk side effects, such as hypokalemia and adrenal insufficiency; (iii) Korlym interferes with the metabolism of numerous other drugs, making it a risky choice in patients taking other medications; (iv) Korlym is not as effective as other options such as ketoconazole; and (v) Korlym is extremely expensive.

135. Similarly, CW1, an Endocrinologist practicing in the Southeastern United States with decades of experience, has never prescribed Korlym because the drug has never been clinically indicated, in addition to concerns regarding Korlym's lack of efficacy and high potential for dangerous side effects. CW1 has seen patients come in who were already prescribed Korlym and declared the results to be "pretty much disastrous."

136. Thus, Defendants needed a new plan; one that involved preying on less knowledgeable non-Specialist Endocrinologists and PCPs such as Internal Medicine physicians (also known as Internists)[30] and Family Medicine physicians,[31] by inducing them to prescribe Korlym for off-label use, thus artificially expanding the total addressable market for Korlym and increasing Company revenue.[32] In a 2012 study on diagnosing Cushing's Syndrome, researchers noted that "A [Family Physicians]'s lifetime experience of CS is likely to be relatively low, due to the low incidence of the disease in addition to the variety of the disorder. This underlines the importance of the Endocrinologist who is familiar with the clinical features of the disease." Cipoli DE, Martinez EZ, de Castro Md, Moreira AC. *Clinical judgment to estimate pretest probability in the diagnosis of Cushing's syndrome under a Bayesian perspective.* Arq Bras Endocrinol Metabol. 2012;56:633–637.

137. In order to execute the multi-year plan, Defendants first replaced Corcept's entire marketing team. Steven Lo, Corcept's former Vice President/Head of Commercial Operations and Chief

[30] An Internal Medicine physician, commonly referred to as an Internist, is equipped to handle a broad and comprehensive spectrum of illnesses that affect adults. Internists are not limited to one type of medical problem or organ system. An Internist, by the very nature of their broad patient population, will be less familiar with diagnostic and treatment protocols for rare diseases, such as Cushing's Syndrome.

[31] Family Medicine physicians are similar to Internists except that they treat patients of all ages. A Family Medicine physician is uniquely qualified to provide ongoing, comprehensive medical care to each member of the family. However, Family Medicine physicians generally have no specialization in any specific disease or organ system.

[32] Collectively, Family Medicine physicians and Internal Medicine physicians (Internists) are referred to as Primary Care physicians (PCPs) since they are the entry-level physicians that typically evaluate and treat patients entering the medical system with a broad array of diseases.

Commercial Officer, departed the Company in September 2015 and Corcept brought in an entirely new marketing group led by Defendant Maduck, who assumed the role of Senior Vice President of Commercial in April 2016, after acting as the Company's Vice President of Sales and Marketing from 2012 to that point.

138. Next, in order to support these non-Specialist Endocrinologists and PCPs throughout the prescription (and insurance approval) process, Corcept needed an additional ally in the form of a collaborating and cooperating specialty pharmacy: Optime, which was being created and incorporated by former Dohmen executives who had previously *worked with Corcept*. Optime purports to provide comprehensive, customized, patient-centered, services to small, specialized patient populations. Optime's first, and only, customer is Corcept.

139. Donovan Quill, Michelle Hefley, and Lawrence Glasscott all previously worked for Dohmen. Quill, currently the president and CEO of Optime, previously worked for Dohmen as the Vice-President of Client Services from 2012 to 2015 and Senior Vice President Direct to Patient Programs in 2015. Quill left Dohmen in 2015 to open his own consulting agency before starting work at Optime in 2016. Michelle Hefley was a co-founder of Centric Health and president until 2014. Hefley co-founded Optime and has been a managing partner since 2015. Lawrence Glasscott was the CFO and Senior VP of Payer Reimbursement for Centric Health until 2015. Glasscott is currently the CFO of Optime.

140. Quill, Hefley and Glasscott all had experience working with Corcept through their time working at Dohmen.

141. In fact, Hefley was the individual who originally signed the agreement between Dohmen and Corcept on behalf of Dohmen.

142. The services agreement entered into between the Company and Optime materially differed from Corcept's agreement with respect to the tasks that Optime was to perform for Corcept.

143. Dohmen's service agreement, as mentioned above, was explicit in the tasks that Dohmen was to complete. This was not the case for Corcept's agreement with Optime.

144. Instead, Optime and Corcept left their agreement vague, agreeing that the services to be provided would be defined as "Projects," which would each be defined in separate "Task Orders." Each Task Order would be agreed upon on a Project-by-Project Basis.

145. There are no limitations on what a Project could entail outside of it being an "activity" related to a "pharmaceutical product owned or controlled by Corcept."

146. In addition to being able to assign any activity as a Task Order, Corcept can also assign a representative to be involved in the implementation of the Task Order. A representative from Corcept and a "Project Director" from Optime are to coordinate on all Projects and "[share] responsibility over all matters relating to performance of such Project on behalf of Corcept."

147. Corcept uses these task orders as a way to exert control over Optime, treating Optime as its ministerial arm while providing strict day-to-day oversight on any project it sees fit.

148. For its part, Optime is entirely dependent on Corcept. Optime has no other clients other than Corcept. If Optime were to exercise its illusory right to reject a task order, it risked losing its only client. Thus, Corcept could "request" Optime to complete any "Project" that was feasibly connected to any product of Corcept's without fear that Optime would decline. This is in stark contrast to Corcept's relationship with Dohmen, which has hundreds of clients and was less susceptible to economic pressure from the Company.

149. Corcept knew that, with Optime's backing as its specialty pharmacy, off-label uses of Korlym could still receive approval from insurance companies, as Optime would take the necessary steps to push for approval or risk facing the reprisals of Corcept (fear that did not exist for Dohmen and its vast portfolio of clients).

150. As would only come to light following the end of the Class Period, the relationship between Optime and Corcept was so entangled that Optime employees would identify themselves to inbound callers as Corcept employees, while providing marketing-related information that went well beyond the role of a specialty pharmacy. The FDA did not expect this level of collaboration between Corcept and its specialty pharmacy when Korlym was approved in 2012. In fact, the FDA expected that the use of a specialty pharmacy would limit off-label uses of Korlym.

3. Corcept Fabricates a Breach of Contract to Exit its Relationship with Dohmen and Partner Exclusively with Optime

151. Before Corcept could execute on its plan to leverage its undisclosed Optime asset into additional Korlym insurance approvals, it needed to exit its relationship with Dohmen.

152. On June 29, 2017, Corcept put its exit strategy in motion. Despite renewing its contractual relationship with Dohmen just one year prior, Corcept sent to Dohmen a letter summarizing what it claimed were purported material breaches of the service agreement. Corcept officially terminated the agreement on August 4, 2017, entering into a service agreement with Optime the same day.

153. Specifically, Corcept claimed that Dohmen had made systematic errors since 2013, including supposedly losing "almost 250 Korlym tablets" in the second half of 2013.

154. Further, Corcept claimed it was "forced to make a $75,000 negative adjust to its internal financial records" in the first quarter of 2014 as a result of "reporting errors by Dohmen."

155. In total, Corcept claimed it had to make "$350,000 in negative adjustments to its internal financial records, and to write off the cost of more the 700 lost Korlym tablets." Notably, a review of Corcept's SEC filings provides no indication of these write-downs or lost pills during Corcept's relationship with Dohmen.

156. Corcept also alleged that Dohmen was "unsuited for the task and ineffective" – a particularly incredulous claim given that Dohmen supports several hundred biotech, pharmaceutical, and medical devices companies.

157. Despite allegedly having these concerns since 2013, Corcept allowed its agreement with Dohmen to renew in 2016. In actuality, Corcept was biding its time for Optime to gain the required regulatory approvals and set up its business operations with the undisclosed assistance of Corcept.

158. Importantly, Optime was founded and is largely operated by former employees of Dohmen, providing these individuals with an inside look at Corcept's inner workings, as well as access to Corcept's management team.

159. This was not lost on Dohmen, which, in response to Corcept's suit related to Dohmen's supposed breach of contract, counterclaimed that Corcept was falsely manufacturing the breach claim to get out of the service agreement with Dohmen.

160. In its own amended complaint against the Company, Dohmen stated "that at some point prior to March 2017, Corcept began secretly negotiating with [Dohmen's] competitor, Optime Care ('Optime'), to enter a new provider agreement with Optime" – a startling development as, at the time, Optime lacked "the necessary protocols and systems in place to effectively serve Corcept."

161. Dohmen further alleged that Corcept secretly helped Optime create its system by incorporating Dohmen's own protocols and proprietary systems, going as far as to copy Dohmen's work product to create its new controlled specialty pharmacy:

> 73. As just one example, on Wednesday, April 12, 2017, Amy Hanstein, Corcept's Cost Accounting Manager sent an email to Tina Pheasant, [Optime's] Vice President of IT Pharmacy Services, in which Hanstein requested modification to Optime's mock-up reports.
>
> 74. In this email, Hanstein revealed that she "tried to bring this up on our call approximately a month ago, but you said this would have to be a phase 2, because you were only copying the existing reports."
>
> 75. The "existing reports" that Optime was "copying" were developed by [Dohmen].

162. According to Dohmen, the only problem for Corcept was its existing services agreement with Dohmen – a problem that could be addressed by Corcept's fabrication of "vague, inaccurate, and unsubstantiated assertions of a material breach against Dohmen."

163. Importantly, Corcept's claimed breach by Dohmen did not refer to any of the "Key Performance Indicators" ("KPI") set forth in the services agreement governing the parties' relationship. In fact, Dohmen had met all of the agreed upon KPIs.

164. Further, any claim of Dohmen's breach of the material terms of the service agreement was directly belied by Corcept's own past practices. Despite having "conducted annual quality reviews of [Dohmen]," Corcept had "never previously reported any deficiency or observation of material concern."

165. In the notice of breach sent to Dohmen, Corcept claimed that "[Dohmen] had not obtained 'prior authorizations' from payers in a timely enough manner." In fact, Dohmen had actually been decreasing its turn-around time for prior-authorizations of Korlym "despite the increasingly complex requirements imposed by PBMs and relevant payers."

166. Additionally, it was "Corcept's [purported] view, [Dohmen] was not diligently pursuing medical appeals of insurance coverage denials of Korlym claims." However, Dohmen had been following "Corcept's own [standard operating procedures] in pursuing medical appeals" and there were no KPIs regarding medical appeals.

167. At a meeting on July 12, 2017 attended by the CEO of Dohmen's parent company and Defendants Robb and Maduck in San Francisco, California, "Corcept was unable to refute [Dohmen's] evidence of full compliance with the requirements of the Exclusive Provider agreement." Seeking to salvage the relationship, Dohmen pressed Corcept on how it would like Dohmen to "cure" the breaches, but "Corcept was unable to identify with any reasonable specificity how Corcept could possibly be satisfied," further evidencing the illusory nature of the claimed breach and the true motive behind Corcept's actions.

168. Most importantly, during the "cure" period, Corcept made reference to another specialty pharmacy, but would not disclose the name. Dohmen interpreted this to mean "Corcept's decision to terminate the Exclusive Provider Agreement was predetermined."

169. In actuality, Corcept exited its relationship with Dohmen not because of any material breach by Dohmen, but because Optime was finally ready to take up the Company's cause and willingly assist in the off-label marketing scheme for Korlym.[33]

170. CW11 confirmed that in 2016, Dohmen became "uncomfortable" with processing off-label Korlym prescriptions. According to CW11, the Dohmen executives who had no reservations with processing off-label Korlym prescriptions went on to create Optime.

F. With the Necessary Pieces in Place, Corcept Dupes Non-Specialist Endocrinologists and Primary Care Physicians into Prescribing Korlym Off-Label to a Wider Range of Patients Not Approved by the FDA Label with Misinformation and Payments of Honoraria and Other Financial Benefits

171. Now armed with a new specialty pharmacy that was entirely dependent on its relationship with the Company (and which viewed itself as one in the same), Corcept entered the next phase of its plan to spur continued growth in Korlym prescriptions: kicking into overdrive an off-label marketing scheme that targeted non-Specialist Endocrinologists and PCPs representing a marked pivot from the strategy previously espoused publicly by the Company to only target the 300 Specialist Endocrinologists who treat approximately 70% of Cushing's Syndrome patients in the United States.

[33] Dohmen and Corcept privately settled their claims in January 2018.

172. If Corcept were able to convert these non-Specialist Endocrinologists and PCPs into Korlym prescribers, the financial benefits would be astronomical, particularly given Korlym's exorbitant price tag.

1. Confidential Witnesses Confirm that Prior to and Throughout the Class Period, Corcept Aggressively Marketed Korlym Off-Label as a First-Line Treatment for Diabetes, Obesity and Other "Unknown" Non-Cushing's Conditions, Contrary to the FDA-Approved Label

a. Former Corcept Employees Confirm Defendants and Corcept Senior Management Directed Corcept Clinical Specialists to Market Korlym Off-Label to Increase Sales and the Market for Korlym

173. Former Corcept employees have confirmed that prior to and throughout the Class Period, Corcept clinical specialists aggressively marketed Korlym for off-label use (1) to treat patients that did not have a confirmed Cushing's diagnosis and instead, had a general Cushingoid appearance,[34] subclinical Cushing's Syndrome,[35] "Pre-Cushing's," poorly controlled diabetes[36]; and (2) as a first-line therapy with no consideration of surgery or as a bridge to surgery, in contradiction of the FDA label, which only indicates that Korlym be used as a treatment for the specific situation when surgery has failed or is not a treatment option..

174. Corcept's off-label marketing was pervasive and extended across the country into each of the Company's six sales regions—Northeast, Southeast, South, Central, West, Pacific Northwest.

175. According to CW11, a former Corcept clinical sales specialist in the region comprised of Ohio, Kentucky, and Tennessee from November 2012 through July 2016 responsible for marketing and managing sales of Korlym to physicians in CW11's sales region who reported directly to a regional manager, Corcept shifted to an off-label marketing approach when Tom Burke was promoted to VP of Sales in early 2016. Burke reported to defendant Maduck throughout the Class Period.

---

[34] Cushingoid appearance is when a patient has the constellation of symptoms and signs that may be caused by an excess of cortisol hormone, but without a confirmed Cushing's Syndrome diagnosis. These symptoms include striations, adiposity, hypertension, diabetes, and osteoporosis. Such Cushingoid patients are common in the population, but they rarely have true Cushing's Syndrome.

[35] Subclinical Cushing's Syndrome is when patients with adrenal tumors present with bio-chemical evidence of mild autonomous cortisol production without development of overt Cushingoid features. Subclinical Cushing's may be associated with hypertension, obesity, diabetes mellitus, dyslipidemia and osteoporosis. Corcept has never conducted and submitted clinical trial data on patients with this condition to the FDA to gain approval to market Korlym for this condition.

[36] Diabetes is a disease in which the blood glucose, or blood sugar, levels are elevated.

176. According to CW11, in early 2016 Burke began exerting pressure on sales personnel to market Korlym to physicians as a first line medical treatment for obesity, poorly controlled diabetes, or "mild" or "sub-clinical" Cushing's syndrome and to push Korlym where the DST was 1.0 or higher. CW11 stated that Corcept was trying to lower the threshold needed for a "positive" DST test from 1.80 ug/dL to 1.0 ug/dL to further increase the odds of a patient being erroneously put on Korlym. CW11 refused to market Korlym off-label due to the potentially serious side effects of Korlym, having witnessed one of the physicians in CW11's region nearly lose a patient after using Korlym off-label. CW11 went to Defendant Belanoff and Burke to raise concerns about Corcept's off-label marketing and was told by Burke to "sit down and shut up."

177. CW12, a former Clinical Specialist in the Pacific Northwest region from July 2014 to August 2016 responsible for marketing and managing sales of Korlym to physicians in CW12's sales region, echoed CW11's account. According to CW12, when this witness started employment at Corcept, CW12's sales region had produced only two Korlym enrollment forms in the prior two years. Despite increasing that total to around 14 enrollment forms by 2015, CW12 was told by CW12's manager, David Valenzuela, that was not enough and to mirror what a colleague, Carl Balzanti, was doing to increase CW12's sales.

178. CW12 then spoke to Balzanti, who told CW12 that Balzanti was instructing physicians to target patients with mild, subclinical symptoms (diabetes, obesity, Cushingoid appearance etc.) and if any patient's DST returned with a non-zero result, i.e., any cortisol level at all was present after the test, then the patient was experiencing "an unknown source of increased cortisol" and could be put on Korlym immediately. Balzanti once recommended to CW12 that one of CW12's physicians who had a patient with a DST result of just 0.9 could be put on Korlym. Balzanti explained to CW12 that "our message" was that Cushing's was more prevalent than generally assumed because of "sub-clinical" Cushing's and that CW12 should "paint a picture" of a patient that perhaps had a difficult to treat form of diabetes, along with a slightly elevated cortisol level and target those sub-clinical Cushing's patients to get more sales. Balzanti attributed his success in getting Korlym enrollments to CW12 on account of these off-label techniques.

179. CW12 recalled numerous meetings with Balzanti about promoting Korlym off-label. For example, during a meeting, on February 12, 2015, Balzanti explained how "in a normal person, there should be no measurement of cortisol at all" after a DST. CW12 recalled Balzanti getting a patient who had a level of 1.3 on the DST get put on Korlym. About a year later, after the Annual National Sales Meeting discussing similar topics,

180. CW12 met with Balzanti three more times. In the first meeting, on March 11, 2016, CW12 recalled Balzanti prompting CW12 to target Internal Medicine physicians. According to CW12, Balzanti said "the problem with a lot of these endo's is they want to test the patient to death" while Internal Medicine physicians are much more open to immediate treatment with Korlym. Balzanti recommended using Corcept's high diabetes Internal Medicine list or any contact CW12 had in the industry with other clinical specialists that work with diabetes drugs as sources for Internal Medicine physicians for CW12 to target.

181. In two other meetings with Balzanti, on March 18 and March 23, 2016, CW12 discussed a patient CW12 had found with a DST of 0.8 whom the physician was considering putting on Korlym. The patient had not undergone any other diagnostic testing and did not have a confirmed Cushing's diagnosis. Balzanti told CW12 that the "patient needs to be on Korlym" and then walked CW12 through the steps of filling out the enrollment form to guarantee insurance approval. Balzanti told CW12 to: (1) have the physician write "after 1 mg dexamethasone, diagnosis Cushing's" and initial the test form; (2) on the prior authorization form have the physician write "patient was given 1 mg DST, results were elevated showing hypercortisolism, patient has been diagnosed with Cushing's"; (3) on the prior authorization form write in "A1C is rising and its currently [x], patient has failed [list of diabetes medication the patient is on]"; (4) list the other symptoms caused by the hypercortisolism; and (5) write down "the patient is not a candidate for surgery because the source is unknown." CW12 asked Balzanti about the low DST score, because insurance carriers would conclude that "it's not 1.8 so it's not Cushing's," but Balzanti assured CW12 that if CW12 wrote all of the other information, "the insurance carriers don't look at the numbers." In discussing a second patient, Balzanti explained the patient was a prime candidate for the "Korlym test", i.e., using Korlym as a diagnostic tool.

182. Balzanti also told CW12 that Defendant Belanoff had told Balzanti that Balzanti has single handedly changed the direction of this Company. Being that CW12 and Balzanti worked in the same sales region, they often spoke about sales methods and the number of enrollments they got. CW12 recalled from conversations with Balzanti that Balzanti had a lot of dealings with defendant Belanoff because Balzanti's sales had been very high since early on in Balzanti's tenure with Corcept.

183. According to CW12, Defendant Maduck and others would hold Balzanti and Franklin up as the examples on conference calls and at meetings and say how great they have done. CW12 understood Maduck's message to be insinuating that the other clinical specialist needed to be more like Balzanti and Franklin.

184. CW12 also recalled numerous other meetings with management at Corcept in which management promoted Corcept's off-label message. For example, in a March 4, 2016 meeting with Burke, Franklin and other clinical specialists, Burke told the clinical specialists that "the goal is to stop making Cushing's Syndrome sound as rare as it is." According to CW12, Franklin later chimed in that he has a physician with eleven patients on Korlym and three more in the pipeline. After Franklin was asked about whether the physician considered surgery, Franklin responded "he treats them [instantly]."

185. In a similar meeting on April 15, 2016, with Valenzuela, Moraitis, CW12 and clinical specialists, CW12 recalls clinical specialists talking about what to do if physicians could not find the source of the elevated cortisol in the patients. Dr. Moraitis, after asking Valenzuela if he was allowed to give this example for clinical specialists to use, told the clinical specialists to, "give [the physician] an example of what will happen [in a patient] that doesn't have Cushing's or has pseudo-Cushing's [and] receives mifepristone. Do we expect anything terrible or catastrophic will happen to that patient? No absolutely not." Dr. Moraitis and Valenzuela then told CW12 and the other clinical specialists to urge the physicians to promote the idea of using Korlym as a diagnostic tool, similar to certain hypertension medicines.

186. CW12 recalled that at the March 2016 Annual National Sales Meeting Corcept held in Las Vegas attended by all clinical specialists at the Company, along with Defendants Belanoff and Maduck and Burke, Franklin was applauded for getting 30 to 40 enrollments in his first quarter at Corcept. CW12 thought this was suspicious because CW12 was told when CW12 began at Corcept that

it was unlikely to get a single script in your first six months at the Company. CW12 further recalled that at the 2016 Annual National Sales Meeting, Tom Burke stated that things were different now and the number of scripts/quota and expectations would be higher going forward.

187. CW11 corroborated CW12's account stating that defendant Belanoff put Balzanti and Franklin on stage at the 2016 Annual National Sales Meeting in Las Vegas and promoted their sales methods as what all clinical specialists should be doing to increase sales and meet their sales quotas because that was the "direction of the Company." According to CW11, Corcept held national sales meetings twice per year in various locations, but frequently in Las Vegas. These sales meetings were always attended by all clinical specialists at Corcept, as well as Burke, Defendant Maduck, and sometimes by Defendant Belanoff.

188. CW13, a former clinical sales specialist in the Philadelphia region from September 2016 until February 2019 and then the Florida region until CW13's departure in July 2019 responsible for promoting Korlym, identifying patients who could be put on Korlym, and presenting Korlym as a solution to physicians in CW13's territory, who reported directly to a regional manager, confirmed CW11 and CW12's accounts that Tyler Franklin was put on stage at the Annual National Sales Meetings throughout the CW13's tenure as an example of what to do to increase Korlym sales and that Corcept management directed clinical specialists to promote Korlym to physicians as an alternative to an invasive surgery or MRI, stating, why not try Korlym?

189. Defendants putting Franklin and Balzanti on stage in front of the entire Company as the "direction of the Company" and the example of what to do in order to increase Korlym sales effectively served as a Company directive to continue to, and increase, off-label marketing of Korlym.

190. During a June 2016 sales meeting that CW11 attended along with Defendant Maduck and Corcept's clinical specialists, a medical science liaison ("MSL")[37] presenter got up on stage and told the Company's clinical specialists about the purported medical benefits of using Korlym to treat off-label conditions such as diabetes or obesity. CW11 understood the purpose of this message was for

[37] An MSL is a healthcare professional working for a pharmaceutical company who builds relationships with key thought leaders and provides information to health care providers in the medical community.

Corcept's clinical specialists to then take this information and use it to market Korlym to physicians for such off-label conditions by explaining the purported benefits of doing so.

191. CW11 recalled that, in an effort to reach the correct physicians for their off-label pitch, Corcept acquired a list of physicians who were prescribing Humulin R U-500 ("U-500") to patients.[38] The clinical specialists were told to go to the doctors prescribing U-500 and recommend prescribing Korlym to the patients to bring down the patients' glucose levels.

192. In late 2017 or early 2018, CW11 had a discussion with a former Medical Science Liaison at Corcept for the Southeast region, ("MSL No. 1") who was let go in July 2018. MSL No. 1 confirmed Corcept was continuing to market Corcept off-label throughout MSL No. 1's employment and that Corcept had progressively gotten more aggressive with these practices. MSL No. 1 told CW11 that she felt uncomfortable and "very upset" with Corcept's off-label marketing approach because one of the clinical specialists in her region, the South Region, was selling a lot of Korlym to treat diabetic patients based off the U-500 list. CW11 had another call with MSL No. 1 in the second half of 2018 during which MSL No. 1 told CW11 that she was let go from Corcept in July 2018 because she raised concerns to MSL Director Carol Lawson about the Company's direction of promoting Korlym off-label.

193. CW11 also stayed in touch with Corcept clinical specialists throughout the Class Period, who confirmed that Corcept continued its off-label marketing scheme throughout the Class Period, and that Defendants fired anyone who would not comply.

194. CW11 has had conversations with at least two other clinical specialists who were let go during the Class Period for refusing to market Korlym off-label. For example, in August or September 2017, around the same time that Corcept switched specialty pharmacies from Dohmen to Optime, a former co-worker told CW11 that she was fired from Corcept for refusing to promote Korlym off-label despite being a strong performer at the Company. Similarly, around January 2019, CW11 had a conversation with a former Corcept clinical specialist ("Rep No. 3") who was with the Company as a sales specialist from 2015 through July 2019. CW11 recalled that Rep No. 3 had initially engaged in off-label marketing and was preforming very well within Corcept. Rep No. 3 told CW11 that he later

[38] Humulin R U-500 is a type of insulin that is used to control high blood sugar in diabetic patients who need more than 200 units of insulin each day.

had a change of heart due to the ethical implications of promoting a dangerous drug for off-label use and refused to market the drug off-label any further. Rep No. 3 recently told CW11 that Burke fired Rep No. 3 in July 2019 for refusing to continue to market Korlym off-label.

195. CW13 confirmed that during CW13's employment, Defendant Maduck, Tom Burke and other Corcept management pushed clinical specialists to find physicians who were willing to prescribe Korlym as a first-line treatment when the DST results were in the "grey area" and that Corcept's philosophy was "go to rural areas and find someone," e.g., a physician, who would be receptive to Korlym and "run with it" as Tyler Franklin had been doing in South Carolina. CW13 recalled that the call lists provided to clinical specialists by Corcept included Family Medicine physicians and Internists, in addition to local Endocrinologists, because Endocrinologists at academic hospitals were very reluctant to use Korlym in the way Corcept was promoting it because it "wasn't appropriate." CW13 believed the practice of promoting Korlym in this manner was "crossing the line" because the literature was steadfast that a DST test score below 1.8 meant the patient likely did not have Cushing's Syndrome. Yet, CW13 recalled that Corcept management, including Defendant Maduck and Tom Burke, told clinical specialists that if the DST was in the grey area, to try and get the physical to "run a trial" of Korlym with their patients, i.e, "why not try Korlym" to address the patient's condition. According to CW13, it was well known amongst the clinical specialists that the people doing "really well" were convincing physicians to prescribe Korlym to patients in the "grey area" or below that had an elevated cortisol level.

196. CW13 stated that Tyler Franklin was a "legend" at Corcept because of how much money he had made. CW13 confirmed Franklin was featured at the 2018 and 2019 Annual National Sales Meetings and was the "poster boy" for Corcept, being held out as an example for all clinical specialists. According to CW13, everyone knew Franklin's success was a result of getting physicians to "run with" the "Korlym trial" and as such, conversations on the "Korlym trial" approach had become normalized by 2018. CW13 stated that the successful clinical specialists at Corcept had one or two "huge customers" who had written a lot prescriptions. CW13 believed this was the direction the Company was headed because they were told many times that each clinical specialist should have at least one of these physicians.

197. As alleged herein, Tyler Franklin's large customers included Dr. Jerry Back and Dr. Joseph Mathews, who collectively wrote 36 and 27 Medicare prescriptions for Korlym in 2017 and 2018, respectively. CW13 confirmed that Defendant Belanoff went out to speak with either Dr. Back or Mathews in 2018, as they were two of the highest prescribers in the Company. CW13 further confirmed that it was common knowledge at Corcept among the sales staff that Drs Back and Mathews were the type of physicians they should be looking for because they were known to be willing to, and did, prescribe Korlym as a first-line treatment for subclinical patients with a DST score in the grey area or below and with no confirmed Cushing's diagnosis.

198. CW14 was a former Regional Manager on the East coast from April 2016 to May 2019 responsible for overseeing clinical specialists and managing customer sales in CW14's region who reported to Tom Burke during the Class Period. CW14 confirmed that this witness was aware that physicians were prescribing Korlym where the DST result was below the 1.8 guideline, including as low as 0.7, and that this was happening "a lot." According to CW14, it was "clear as day" that a proper diagnosis of Cushing's Syndrome required a test result of 1.8 or greater. CW14 believed that prescribing Korlym for patients with a DST below 1.8 was "pushing the envelope" and "likely off-label."

199. Throughout the Class Period, CW14 and other regional managers met quarterly at Quarterly Managers Meetings with Burke and Defendant Maduck to discuss the state of each region, including how many enrollments had been achieved by region. CW12's regional manager, David Valenzuela, would have been present at these meetings.

200. According to CW14, at "every" quarterly meeting during the Class Period, CW14 and the other reginal managers consistently discussed the astronomical sales numbers from clinical specialists in the "performing" regions, such as Tyler Franklin and Carl Balzanti, because it would be impossible to get those numbers from only prescribing Korlym on label. In response to these concerns, Maduck and Burke told clinical specialists they just needed to find physicians who were willing to prescribe Korlym when the DST came back below the 1.8 medical guidelines. CW14 stated that in order to find such physicians, the clinical specialist would first have to present the idea that patients with a DST below 1.8 could still benefit from being treated with Korlym—e.g., off-label marketing.

201. CW14 stated that Burke told CW14 and other regional managers that they should do what Franklin was doing to increase sales.

202. CW14 further confirmed that Corcept held an Annual National Sales Meeting once per year throughout the Class Period. CW14 attended all these meetings, along with all Corcept clinical specialists, Burke and Defendants Belanoff and Maduck, among others. CW14 recalled that at the annual meeting, Defendants displayed a Ranking Report of all clinical specialist from most enrollments to least for all attendees to see. Tyler Franklin was always at the top of the list.

203. CW14 confirmed that Defendants continued to put Franklin on stage at the Annual National Sales Meetings during the Class Period as an example of how to succeed in selling Korlym and as the future of the Company.

b. Corcept Provides Clinical Specialists with Case Studies Using Korlym Off-Label and Instructs the Clinical Specialists to Distribute the Studies to Physicians as Part of an Off-Label Marketing Pitch

204. In addition to instructing Corcept clinical specialists to market Korlym for off-label use, Defendants also provided them with off-label marketing materials to share with physicians during the clinical specialists' visits to physicians' offices to market Korlym.

205. CW12 stated that in 2016, Corcept distributed marketing materials to clinical specialists via email and instructed them to use these materials when speaking with physicians as part of their marketing pitch to convince physicians to use Korlym for the treatment of mild hypercortisolism or subclinical Cushing's Syndrome. Clinical specialists were expected to show the studies and presentations to physicians on their iPads during office visits to suggest that patients with "hypercortisolism" or something similar were not really subclinical after all. CW11 confirmed CW12's account stating that Corcept distributed these studies to clinical specialists "all the time" and clinical specialists then used a medical information request or joint call with an MSL to communicate the off-label studies to physicians. CW11 recalled that the studies were used to present hypercortisolism as being the same as Cushing's Syndrome. CW13 similarly recalled receiving patient case studies during CW13's tenure with the Company, which were also discussed at speaker programs such as roundtable discussions and dinners.

206. For example, CW12 was given a peer reviewed article titled *Mifepristone Reduces Insulin Resistance in Patient Volunteers with Adrenal Incidentalomas that Secrete Low Levels of Cortisol: A Pilot Study by Debono M et al*., published in PLOS One in 2013.[39] The article concludes that "even mild cortisol excess may be deleterious on insulin sensitivity/resistance" and that mifepristone "can reduce [insulin resistance] in subjects with adrenal incidentalomas." In other words, the article promotes treating patients with insulin resistance, *but without* clinical Cushing's Syndrome, with mifepristone, which is ***the main ingredient in Korlym***—a clear off-label use of Korlym.

207. Another article provided to CW12 to use as a sales and marketing aid, titled: *Cardiovascular Events and Mortality in Patients with Adrenal Incidentalomas that are Either Non-Secreting or Associated with Intermediate Phenotype or Subclinical Cushing's Syndrome: a 15-year Retrospective Study*, by Di Dalmazi et al., published on TheLancet.com on January 29, 2014, similarly focused on patients *without* "overt" hypercortisolism, but rather those with "mild" hypercortisolism and concluded that patients with mildly increased levels of cortisol (i.e., those patients that do not have clinical Cushing's Syndrome) are at a higher risk of having a cardiovascular event than the general population and therefore should receive treatment. The article was clear that this study was *not* related to patients with Cushing's Syndrome:

> After an extensive search of published work, we identified no previous studies that had addressed specifically the incidence of cardiovascular events (myocardial infarction and stroke) and mortality in this population (panel). In a view of the known association between **overt hypercortisolism (ie, Cushing's syndrome),** cardiovascular diseases, and mortality, we aimed to ascertain whether even mild forms of hypercortisolism could have deleterious effects in patients with adrenal incidentalomas.

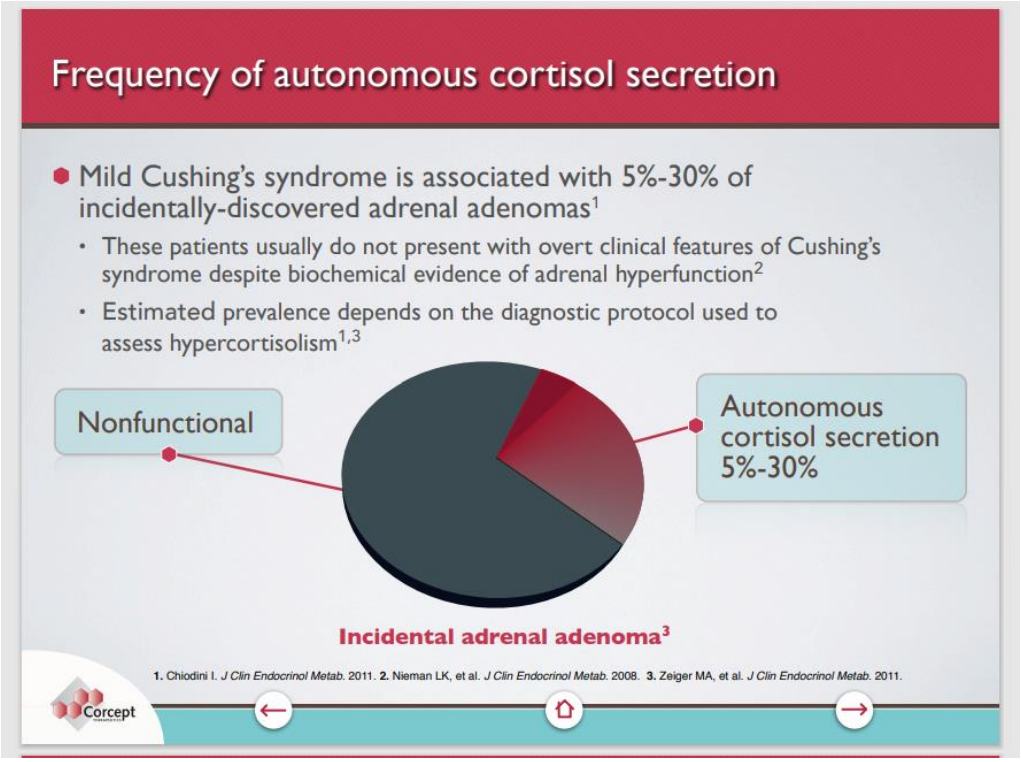
(Emphasis added.) Yet Corcept used this article to promote the idea that even mild hypercortisolism could benefit from treatment with Korlym.

208. CW12 also received an article titled: *Long-Term Follow-Up in Adrenal Incidentalomas: An Italian Multicenter Study by Valentina Morelli et al.*, published in the Journal of Clinical Endocrinology and Metabolism in March 2014[40], which expressly *excluded* individuals with "overt hypercortisolism" and "those with signs or symptoms of overt cortisol excess (i.e., moon facies, striae

[39] https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0060984
[40] https://doi.org/10.1210/jc.2013-3527

rubrae, skin atrophy, or buffalo hump)" and concluded that physicians can use the DST to determine the risk of a cardiovascular event in patients with mild hypercortisolism: "The use of 1mg-DST cortisol levels as a single parameter to predict the [Cardiovascular Event] risk seems to have an acceptable SN (77%) if a low cutoff is chosen (ie, 1.5 ug/DL [41.4nmol/L) but a low (50%)." This study similarly suggests that patients with mild hypercortisolism can benefit from treatment with Korlym. Thus, this article is another example of Corcept attempting to convince physicians to prescribe Korlym for a DST result lower than the established guidelines, even in the absence of a confirmed Cushing's Syndrome diagnosis, a clear violation of Korlym's FDA approved label.

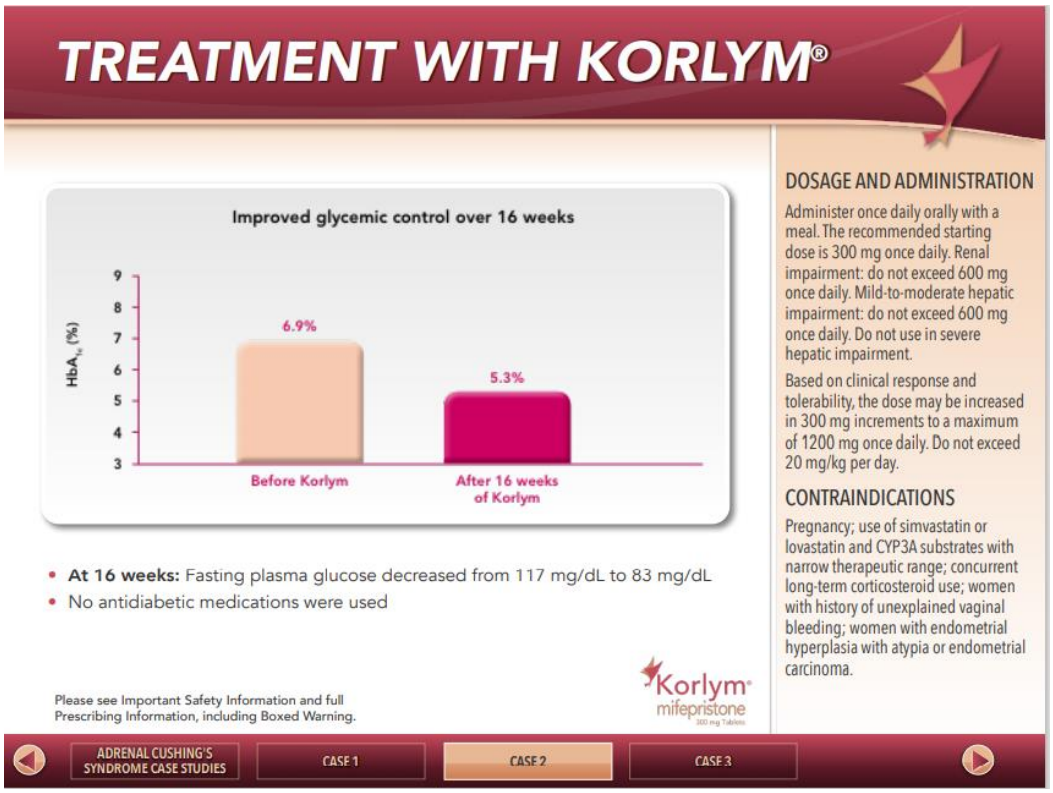
209. In addition to written studies, CW12 was also given presentation materials to show to physicians in an effort to convince them to prescribe Korlym off-label. One PowerPoint, titled "*Adrenal-Dependent Hypercortisolism*," predominantly discussed "mild Cushing's syndrome":



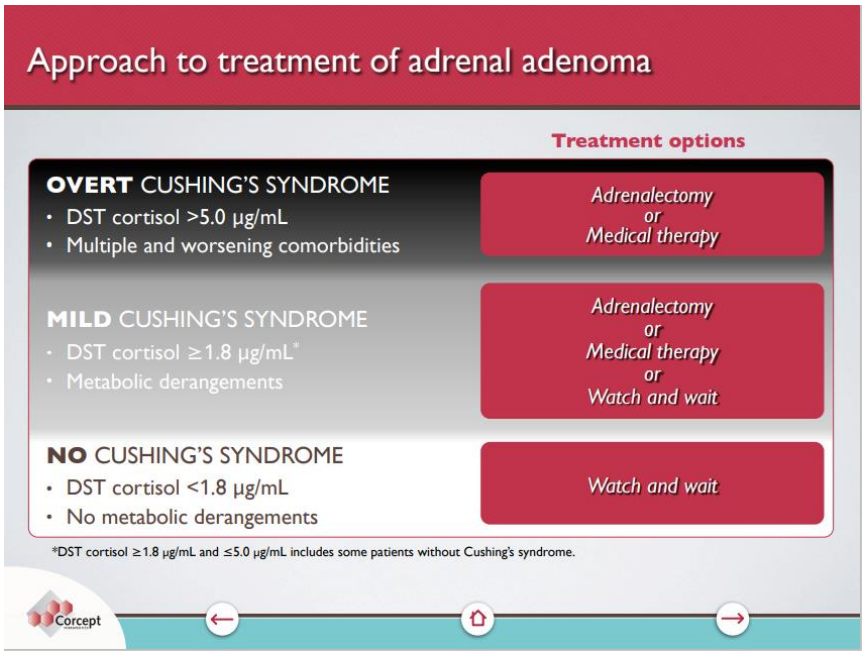
210. The presentation was a case study for one of Dr. Andreas Moraitis's patients and advocated that medical therapy (e.g,, treatment with prescription drugs) is an equal option to surgery in patients with Cushing's Syndrome, directly contradicting the established Guidelines and the FDA label

for Korlym, which only indicates Korlym as a treatment for Cushing's Syndrome where surgery has failed or is not an option. CW12 recalled discussing this study on a conference call with Dr. Moraitis and others.

211. CW12 also received a PowerPoint presentation summarizing six case studies of patients who had received Korlym treatment. One of the patients presented was a woman in her early 50's who was treated with Korlym as a first line treatment. Surgery was never even considered in the presentation, in violation of the FDA label:



212. As discussed below, PE and two of the physicians interviewed by Plaintiff's counsel (CW8 and CW9) confirmed Corcept clinical specialists presented them with off-label marketing materials during the Class Period that recommended using the DST to screen these patients and then start them on Korlym if the DST was positive.



c. Corcept Clinical Specialists Were Instructed to Complete Insurance Forms on Behalf of Physicians to Ensure Reimbursement

213. Defendants' off-label marketing scheme was not limited to just providing off-label messaging to physicians. According to CW11, Corcept clinical specialists were instructed by Carl Balzanti to fill out the insurance forms to ensure insurance approval of Korlym. CW11 attended a national sales meeting in June 2015 in Las Vegas where Carl Balzanti demonstrated to the clinical specialists how to fill out the insurance forms and instructed the clinical specialists to fill out the forms and not the physicians or their staff. CW11 stated it is "a big no-no" for clinical specialists to fill out the enrollment forms under Medicare and Medicaid regulations and that salespeople should "not mark anything" on an insurance form. CW11 stated this meeting was in front of the whole company, including Defendants Belanoff, Maduck and Robb. As detailed below, CWs 2, 7, 8 and 9 all had their clinical specialists attempt to fill out Korlym insurance forms on behalf of the prescribing physician. As

discussed above, CW12 received instructions from Balzanti on how to complete the insurance forms in order to ensure approval.

214. Corcept's attempts to guarantee insurance approval and payments did not stop there. According to CW11, occasionally insurance forms came in with undetermined or incorrect ICD-10 codes (the codes used to identify the diagnosis prompting the prescription of the medicine) which would preclude insurance payment for Korlym. In that instance, CW11 stated that prior to sending the form to the specialty pharmacy, a Corcept employee, including on occasion Defendant Belanoff, would send the insurance forms to Dr. Moraitis would then change the insurance forms "to what the doctors really meant," i.e., Cushing's syndrome, to facilitate insurance payments for Korlym.

215. CW11 stated these practices eventually led to an investigation of Corcept by the California Department of Insurance in 2019.

d. Physicians Confirm Receiving Aggressive Off-Label Marketing Messages from Corcept Clinical Specialists

216. Physicians surveyed by Plaintiff's counsel confirmed that, prior to and throughout the Class Period, Corcept representatives visited their offices, often without an appointment, recommended using the DST on patients who were pre-diabetic, had uncontrolled diabetes with poor glucose control, were insulin-resistant, obese, or had a Cushingoid appearance, and if the results were even borderline abnormal or fell within the DST's "gray area," the Corcept clinical specialists instructed the physician to immediately begin treatment with Korlym. Corcept clinical specialists further instructed many of these physicians that, if the patient shows *any* clinical improvement after starting Korlym, then they had confirmed the diagnosis of endogenous Cushing's Syndrome without any of the additional clinical testing required by professional society guidelines to make this diagnosis.

217. As demonstrated below, Corcept's clinical specialists were employing this uniform, off-label marketing pitch in every Corcept sales region across the country instructing physicians to use Korlym to treat conditions such as diabetes or obesity or use Korlym as a "diagnostic tool" to diagnose patients, with no further testing to confirm a diagnosis of endogenous Cushing's Syndrome or evaluation of whether the patient should at least be evaluated for surgery *prior* to the prescription, as required by the FDA-approved label.

218. Plaintiff has confirmed this practice occurred in 10 states representing 43% and 48%, in 2017 and 2018, respectively, of the Company's total Medicare Part D annual revenue.

219. Specifically, CW1 was visited by Corcept clinical specialist, Tyler Franklin, frequently between early 2017 and early 2019. CW1 said Franklin initially came to CW1's office and held lunches every couple of weeks and then at least once per month. CW1 described Franklin as "aggressive" in the way he frequently came to CW1's office and wanted the practicing physicians to dig up potential patients who fit the profile described above. CW1 believed that this was a very heavy presence for a drug that treats such a rare condition such as Cushing's Syndrome. CW1 said Franklin told CW1 to use the single 1-mg overnight Dexamethasone suppression test on patients and if the result was even close to positive, to start the patient on Korlym immediately. CW1 stated that the DST generated many false positives due to confounding patient variables such as obesity, depression and uncontrolled diabetes.

220. CW1 attended a dinner talk in January 2018 given by a local internal medicine physician who has been practicing for over twenty years who received nearly $80,000 in honoraria payments from the Company in 2017 and 2018. At the dinner, that physician gave multiple personal accounts of treating patients with diabetes and insulin resistance with Korlym. He claimed that he was using Korlym as a means to reduce high doses of insulin required for treatment of patients' diabetes and, by reducing the dose of insulin, Korlym helped patients lose weight. Because of this potential for weight loss, the lecturing physician stated he believed that prescribing Korlym--even with equivocal DST results--justified the risk for potential complications that the drug might cause. CW1 said the physician's understanding of the DST test was incomplete because he was using the wrong A.M. cortisol to support his diagnosis of Cushing's. CW1 stated that at the dinner, very little information was actually provided about Cushing's Syndrome.

221. CW2, a family medicine physician from Oklahoma practicing for over 13 years, similarly recalled the Corcept clinical specialist for Oklahoma ("Rep No. 1") coming to CW2's office beginning in 2018. CW2 stated Rep No. 1 advised CW2 to review CW2's patient charts for individuals with poorly controlled diabetes who were obese and had hypertension and to perform a DST on those patients. According to CW2, Rep No. 1 instructed this witness that, if the DST was positive, then CW2 should immediately start the patients on Korlym. In fact, Rep No. 1 recommended putting patients on Korlym

even if the test were normal or inconclusive because different laboratories use different levels and even a patient who tests below the threshold could still purportedly benefit from using Korlym.

222. In perhaps the most egregious example, Rep No. 1 instructed CW2 to "close [CW2's] eyes" and not just look for physical symptoms of Cushing's Syndrome because "anyone could have it." CW2 said Rep No. 1 frequently sought the opportunity to do chart reviews to find more potential candidates for Korlym.

223. CW2 described Rep No. 1 as "aggressive" in the way he frequently came to CW2's office. CW2 stated that once Rep No. 1 knew CW2 had ordered a DST for a patient, Rep No. 1 would follow up daily to get updates on the result, drawing the ire of CW2's staff.

224. CW2 recalls prescribing Korlym to two patients based on the Corcept rep's off-label marketing message. CW2 described the process of putting the patients on Korlym as if Rep No. 1 "was trying to replace the doctor," as he would instruct the staff on how to get the drug approved and even assisted them with completing the forms that were then submitted to Optime for approval by the insurance companies. For instance, Rep No. 1 said that in order to get Korlym approved, "you had to check the box on the insurance form saying the patient is not a candidate for surgery."

225. CW2's account confirms CW11's account above that Corcept clinical specialists were instructed to complete the insurance forms for the physician to ensure approval and reimbursement.

226. CW2 heard a similar improper marketing pitch while attending a dinner on Korlym, hosted by Dr. Matthew Draelos (who has received $51,192.42 from Corcept since 2017), in late 2018. At the dinner, Corcept representatives discussed, among other things, that physicians should perform the DST and, if it yielded even close to a positive result, to prescribe Korlym.

227. PE recalls attending a "Grand Rounds" lecture on Cushing's at a local hospital in early 2017 where Dr. Andreas Moraitis discussed a study using Korlym in patients with adrenal masses *prior* to surgery. After the lecture, PE was approached by a Corcept clinical specialist who, unsolicited, provided PE with materials on Korlym that included the aforementioned study. This represented a clear instance of off-label marketing, as not only was this clinical specialist advocating for the prescribing Korlym ***before*** surgery, but was also marketing the drug's use for those individuals even if diabetes or

glucose intolerance were not present, in contradiction of the FDA-approved label. Moreover, a sales representative including an off-label study in promotional materials violates FDA regulations.

228. CW3, an Endocrinologist practicing in Nebraska for over 15 years, had a similar experience with Corcept's sales staff marketing of Korlym for off-label use. CW3 stated that the Corcept regional clinical specialist has visited CW3's office approximately two times per year since mid-2017 to the present. During the clinical specialist's office visits in 2017 and 2018, the clinical specialist recommended to CW3 that CW3 should test all of CW3's type 2 diabetes patients with a DST and if the DST was positive or in the gray area, to start treating the patient with Korlym. As with other physicians, the rep then told CW3 that if the patient showed any clinical improvement after using Korlym that meant the patient had Cushing's Syndrome.

229. CW3 described this suggestion as "crazy" because of the high likelihood of obtaining a false positive with the DST. Given how rare Cushing's Syndrome is, CW3 stated, it is more likely the patient does not have Cushing's Syndrome. Thus, because of the extensive testing a patient is put through to perform a proper Cushing's diagnosis and the high likelihood of false positives, CW3 was not receptive to testing all patients with Type 2 diabetes with the DST, as the Corcept representative suggested.

230. After CW3 was not receptive to the original recommendation, in late 2018 or early 2019, the same clinical specialist returned to CW3's office and switched tactics by recommending CW3 use Korlym "proactively" to "pre-treat" patients with adrenal masses, prior to surgery.

231. CW3 recalled a recent instance of off-label marketing and use of Korlym where a patient with an adrenal tumor who failed the DST was put on Korlym prior to surgery or any Cushing's diagnosis. This patient was subsequently hospitalized due to adrenal insufficiency and taken off Korlym.

232. This second off-label use recommended by the sales rep was the same message PE heard from Dr. Moraitis during a "Grand Rounds" lecture in 2017 and at a presentation at the Endocrine Society annual meeting, discussed below.

233. CW4, an Endocrinologist practicing in Pennsylvania for over 15 years, confirmed that, from around September 2019 until February 2020, Corcept clinical specialist ("Rep No. 2") had been promoting using a single DST on obese and diabetic patients and then, if the DST was positive or in the

grey area, to start the patient on Korlym. The rep further stated that if the patient had any clinical improvement after being placed on Korlym, then the patient had Cushing's Syndrome. CW4 said the Corcept representatives proposed diagnostic process was not scientifically rigorous.

234. Additionally, CW4 said Rep No. 2 was recommending Korlym to lower serum glucose in diabetic patients – a use unsupported by the FDA-approved label in the absence of a confirmed Cushing's diagnosis.

235. CW4 attended the 12th Annual Meeting of the American Association of Clinical Endocrinology in New Jersey on February 5, 2020. During this meeting, CW4 raised concerns regarding Corcept's clinical specialists' instructions to use a single DST to diagnose Cushing's. In response to CW4's concerns, a Corcept Medical Science Liaison ("MSL") confronted CW4 after the session informing CW4 that it was improper to be asking that question in front of other physicians. CW4 found the MSL's conduct to be highly inappropriate.

236. Shortly thereafter, CW4 banned Rep No. 2 from CW4's office because of the representative's aggressive and inappropriate marketing of Korlym.

237. CW4 attended a medical conference in February 2020 in Arizona, where CW4 again heard discussions about Corcept's inappropriate marketing message to use a single DST to diagnose Cushing's patients.

238. CW5, an Endocrinologist from New York practicing for over 10 years, had similar experiences with a Corcept sales rep ("Rep No. 4") in 2017 to 2018. CW5 described Rep No. 4 as "pushy" because of the number of times Rep No. 4 came to CW5's office. Between 2017 and 2018, the rep came to CW5's office close to twenty times. CW5 noted that this made the sales rep "one of the most visible" of the sales rep despite the rarity of Cushing's Syndrome.

239. After the first couple of visits, Rep No. 4 instructed CW5 to use a single DST on CW5's patients suffering from diabetes and/or obesity. Rep No. 4 told CW5 that if the test was even borderline then to put the patients on Korlym and if the patient showed clinical improvement on Korlym then you had a diagnosis of Cushing's Syndrome. CW5 found Rep No. 4's proposed use of Korlym as a diagnostic tool to be highly inappropriate.

240. CW5 further observed that Rep No. 4 lacked any knowledge about Korlym's side effects. As a result of Rep No. 4's aggressive off-label marketing, in August 2018, CW5 instructed Rep No. 4 not to return to CW5's practice.

241. CW6, an Endocrinologist practicing in West Virginia with over 20 years of experience, similarly described Corcept reps as pushy. From the summer of 2019 through October 2019, CW6 received the same message from CW6's Corcept representative to use Korlym as a diagnostic tool to confirm a Cushing's diagnosis after a single mildly abnormal DST. CW6 believed the rep lacked sufficient knowledge on Cushing's and Korlym. In response to receiving this concerning recommendation from the Corcept sales rep to use Korlym as a diagnostic, CW6 called an MSL at Corcept to discuss the Corcept sales rep's inappropriate off-label marketing of Korlym. The next day a regional sales manager came into CW6's office with the sales rep to try and "smooth things over" by explaining to CW6 that the sales rep's marketing was purportedly consistent with the Korlym FDA-approved label. CW6 knew it was not.

242. In addition to CW6's personal experiences with Corcept reps, CW6 has heard from other physicians about Corcept's marketing strategy. CW6 believes that "non-Cushing's related endocrinologists shouldn't be prescribing [Korlym]" and is concerned about the sales reps marketing to these physicians.

243. CW7, an Endocrinologist from New York, practicing for over 6 years, experienced a similar off-label marketing message from Corcept clinical specialists. CW7 stated that Corcept clinical specialists started coming to CW7's offices approximately three to four years ago. CW7 recalled that at some point in 2016 coinciding with the time that Korlym failed the clinical trials evaluating it for the treatment of depression, a new clinical specialist started coming to CW7's offices. CW7 described the new Corcept clinical specialist as being very aggressively marketing Korlym. The rep told CW7 to screen everyone who was pre-diabetic, had diabetes, was insulin-resistant or was obese for Cushing's using the DST as a diagnostic tool. The rep told CW7 that if the patient tested at or near positive of 1.8, then CW7 should immediately put the patient on Korlym and if they get better, you have your proof the patient has Cushing's. The clinical specialist also recommended using Korlym as a "bridge" for those awaiting surgery—a clear off-label use.

244. The clinical specialist also provided CW7 with DST samples so the DST would be available in CW7's office. The Corcept clinical specialist also aggressively tried to get behind the reception desk in CW7's office to look at patient files to see who might be a potential Korlym candidate so she could follow-up on the status of those patients and push a Korlym prescription. CW7 informed the clinical specialist this was improper and would be a HIPPA violation. CW7 also confirmed that the sales rep offered to fill out the insurance paperwork for CW7 to get Korlym approved.

245. In order to get physicians to prescribe Korlym, CW7's rep told CW7 that CW7's colleague in a nearby town was prescribing Korlym. When CW7 contacted CW7's colleague about this, CW7 learned that CW7's colleague was not prescribing Korlym and that the same rep had told the colleague that CW7 was also prescribing Korlym.

246. CW7 eventually had enough of these improper off-label aggressive sales tactics and, in the spring of 2019, asked the Corcept sales rep not to return.

247. CW8, an Endocrinologist from Texas practicing for over nine years, experienced the same message from a Corcept rep. CW8 said the rep had been coming to CW8's offices since 2015 but in 2016 or early 2017 the rep's message began to change to focus on trying to get CW8 to screen all diabetic and obese patients with the DST. If the results were positive, the rep told CW8 to immediately put the patient on Korlym and if the patient showed improvement then that confirmed the patient had Cushing's. CW8 understood this to mean the rep was recommending using Korlym as a diagnostic tool.

248. In one instance, CW8 had a patient who CW8 screened with the DST. The DST came back abnormal and the rep recommended immediately starting the patient on Korlym without any additional testing. The rep said this was consistent with the Cushing's guidelines.

249. CW8 also recalled the rep was very pushy and aggressive. The rep offered to fill out the insurance paperwork for patients to help get Korlym approved. In addition, the rep instructed CW8 to check a box on the paperwork for "automatic titration" because, according to the rep, 300 mg was never sufficient. By checking the automatic titration box on the insurance form, the patient dosage would automatically increase from 300 mg to 600 mg.

250. By instructing physicians to check the automatic titration box on the approval form, the Company's clinical specialists were attempting to lock in the added benefit for the Company of increased drug costs and revenues without having to subject the prescription to further insurance scrutiny.

251. CW8 recalled the Corcept rep inserting case studies into promotional materials that also promoted Korlym for off-label use. The case studies recommended using the DST to screen these patients and then start them on Korlym if the DST was positive.

252. CW9, an Endocrinologist from Ohio practicing for over twenty years, confirmed this witness received a similar improper off-label marketing message from CW9's very aggressive, pushy Corcept sales rep. Specifically, the rep instructed CW9 to test obese and diabetic patients with a single DST and if the test results was even borderline positive, to put the patient on Korlym right away. The Corcept sales rep further advised that if the patient showed improvement after being put on Korlym, then the patient had Cushing's. CW9 has been hearing this message from CW9's rep from at least 2017 to the present. The rep comes every couple of months for scheduled lunches.

253. CW9 told the rep, "you don't expect us to treat with Korlym based on a single DST do you?" To which the rep responded that the studies show to do this.

254. CW9 said the rep also suggested using Korlym inappropriately as a "bridge" to surgery, meaning the physician should put the patient on Korlym during the period the patient was awaiting surgery—a clear off-label use.

255. As with other physicians, CW9's Corcept sales rep also offered to fill out the insurance paperwork to get Korlym approved.

256. According to CW10, a family medicine physician from California practicing for over 20 years, the Corcept sales rep from CW10's region came to CW10's offices during the period of March 2017 through October 2017 pursuant to scheduled lunches with CW10 and other physicians CW10 works with.

257. CW10 confirmed that during these office visits, the Corcept sales rep was very pushy and aggressive and essentially promoted Korlym as the new treatment for diabetes. The rep told CW10 to test CW10's obese and/or diabetic patients with a single DST and if it was even borderline positive to immediately prescribe Korlym and if the patient improved, the patient had Cushing's. CW10 also recalled the rep giving CW10 a tear sheet that promoted Korlym as a front line therapy for diabetic patients.

258. CW10 prescribed Korlym to one patient based on the rep's marketing message where the DST was positive and the patient had what CW10 perceived as several visible signs of Cushing's. The rep's marketing message made sense to CW10 because elevated cortisol levels make you gain weight so prescribing Korlym to reduce cortisol levels and, thus, weight loss seemed logical.

259. CW10 recalled that the Corcept sales rep came weekly to check on this patient on Korlym and to ask if there were others that could be tested. CW10 stated that this rep was the most aggressive rep CW10 had ever seen.

260. CW10 stated that CW10 has only seen one patient with actual Cushing's Syndrome in 20 years, which was not surprising to CW10 given how rare Cushing's Syndrome is.

261. Corcept's sales team's uniform off-label marketing message to physicians instructing them to rely solely on the DST as a diagnostic tool to support treatment with Korlym as a first line therapy for endogenous Cushing's Syndrome is particularly troublesome because, not only is it encouraging physicians to put their patients in serious danger from adverse events associated with Korlym, as discussed above, but also because it is based on the unreliable DST.

262. As set forth above, the DST is unreliable as a standalone test for diagnosing Cushing's Syndrome because it is highly susceptible to generating false positives and negatives. As Dr. Lynn Loriaux noted in his article titled "Diagnosis and Differential Diagnosis of Cushing's Syndrome," N Engl J Med 2017; 376:1451-1459, the DST is particularly unhelpful in diagnosing endogenous Cushing's in an obese patient population, with **a positive predictive value of just 0.4%** - meaning that,

for those obese patients whom Corcept's marketing team was explicitly pushing non-Endocrinologists to test, among those that screened as abnormal with the DST, just 0.4% would actually be diagnosed with endogenous Cushing's following an appropriate workup (or just 4 out of every 1000 patients, meaning the other 996 patients would improperly receive Korlym). In addition, CW11 stated that Corcept was unilaterally changing the result required to determine a "positive" Cushing's syndrome diagnosis from a DST from 1.80 ug/mL to 1.0 ug/mL to further increase the likelihood of patient's tests erroneously coming back "positive." CW12, after being directed to follow his lead by Defendant Belanoff, was told by Balzanti that any result over 0.0 was a situation where a patient could be placed on Korlym.

263. Indeed, according to PE and the Diagnostic Guidelines, Corcept's advocated method for diagnosing Cushing's Syndrome with just one DST test is not a proper method for testing for endogenous Cushing's Syndrome. For example, PE uses one of the common Cushing's Syndrome screening tests, as stated in ¶94 above, to initially determine if the patient is likely to have Cushing's Syndrome. If the test comes back positive, PE will then conduct a second test to confirm the diagnosis. PE performs a second test to confirm the diagnosis because there are many variables involved in cortisol levels that can produce a false positive diagnosis of Cushing's Syndrome. Third, PE would then use medical imaging to locate the tumor causing the increased cortisol.

264. PE and the Treatment Guidelines also believe medical treatment should not be the first option for treating Cushing's Syndrome. PE stated, in accordance with the FDA-approved label, "the first, second, and third step [for treating Cushing's] ***is surgery***."

265. The Company has also aggressively pushed off-label uses of Korlym at public Endocrinology meetings and conferences. For example, in 2017 at the Endocrine Society annual meeting, Corcept co-sponsored a presentation on the use of Korlym in treating an individual with "Subclinical" Cushing's Syndrome. There, the patient's response to a low dose of mifepristone, Korlym's active ingredient, was supposedly "well tolerated and elicited metabolic benefits." The presentation concluded that "[m]edically modulating the underlying cortisol excess may be an option for patients [with Subclinical Cushing's Syndrome] in whom surgical benefit is uncertain, particularly those who potentially have bilateral adrenal disease" – a medical suggestion that represents a boon to

Corcept as it opens the door to a new set of potential patients to bolster its total addressable market outside of the FDA approved label for Korlym.

266. Corcept was promoting Korlym for the above off-label uses throughout the Class Period.

e. Defendants Closely Tracked and Monitored All New Prescriptions on a Real-Time Basis

267. According to CW11, the Individual Defendants, along with the Chairman of the Board and Tom Burke reviewed every prescription enrollment form. CW11 recalled that the Individual Defendants, along with other senior management, would wait by the fax machine when a prescription was coming in and celebrate each enrollment form that came in with a round of "high fives." Defendants Belanoff and Maduck would even send congratulatory emails to the clinical specialists the same day that the enrollment forms would arrive.

268. CW12 similarly stated that new prescriptions were tracked at Corcept on a daily basis. According to CW12, clinical specialists had to fax into the corporate office the "Spark[41] forms" for a prescription to get written/started. Defendants would watch the fax machine daily, and even the regional managers would know instantly when a new prescription came in. Balzanti told CW12 that Balzanti would call and check if his faxes were received, and/or if any of his physicians had sent in any prescriptions. CW12 stated that when it was time for commissions to be paid, each clinical specialist, including CW12, received a spreadsheet that tracked their individual prescriptions (new prescriptions and refills), and commissions would be paid out based upon the spreadsheet.

269. In addition, CW13 attended weekly meetings with CW13's regional manager and other clinical specialists in CW13's region to discuss Korlym prescriptions and sales and how many prescriptions each clinical specialist had achieved. CW13 stated that Defendant Maduck would also get this information every week. In addition to the weekly meetings, CW13 confirmed CW11 and CW12's

[41] "Spark" refers to the "Support Program for Access & Reimbursement for Korlym" - a Company-sponsored program to coordinate insurance approval and fulfillment of Korlym prescriptions.

accounts that the number of prescriptions achieved by each clinical specialist was presented at the Annual National Sales Meetings, which were always attended by Defendant Maduck, Burke, and Defendant Belanoff (usually for one of the days).

270. According to CW11, the number of new prescriptions was so important to Corcept that it was discussed at every meeting and during every conference call.

2. Corcept Drastically Increases Payments to Non-Specialist Endocrinologists and Primary Care Physicians to Induce Korlym Prescriptions and Gain Physician Allies in its Off-Label Marketing Scheme

271. When Korlym was first approved, Steven Lo, then Vice President of Commercial Operations for Corcept, touted the competitive advantage Corcept had based on the rarity of Cushing's Syndrome and the limited number of physicians who would actually use it, stating, "I don't have to hire an army of clinical specialists."[42] Instead, Corcept's initial marketing strategy was to target the 300 Endocrinologists who treat approximately 70% of US Cushing's Syndrome patients. These are the Endocrinologists alleged herein to be the Specialist Endocrinologists.

272. The Company's payments reported under the Physicians Payments Sunshine Act[43] support this initial marketing strategy. In 2013, Corcept only made payments to 298 physicians, 203 of whom were Endocrinologists.

273. According to Open Payments data, since 2013,[44] Corcept has made payments to more than just the 300 Endocrinologists Corcept had previously announced it was targeting, showing the Company has rapidly expanded its focus well beyond these individuals:

Year	Endocrinologists Paid	Total Physicians Paid	% Endocrinologists	% Non-Endocrinologist Physicians Paid
2013	203	298	68%	32%
2014	637	1107	58%	42%
2015	891	1467	61%	39%

[42] https://www.mmm-online.com/home/channel/features/orphan-drugs-small-is-the-new-big/

[43] The Physician Payments Sunshine Act was established to increase transparency of financial relationships between health care providers and pharmaceutical manufacturers. Information reported under the Sunshine Act is referred to herein as "Open Payments" data.

[44] https://openpaymentsdata.cms.gov/company/100000000247/general-payments

2016	894	1651	54%	46%
2017	989	2305	43%	57%
2018	1072	2438	44%	56%

274. Indeed, from 2014 forward when the number of paid endocrinologists exceeds 300, it can be inferred that Corcept was focusing on non-Specialist Endocrinologists, rather than the 300 Specialist Endocrinologists originally targeted because, as discussed below, Specialist Endocrinologists were not fooled by Corcept's off-label marketing scheme because of their expertise in diagnosing and treating this condition. The Open Payments data in the above chart demonstrates that Corcept has been aggressively targeting PCPs as the percentage of total Endocrinologists has steadily declined while the percentage of PCPs has steadily increased to over 50%. Notably, this inflection point coincided with Corcept's shift from Dohmen to Optime. The number of payments to Endocrinologists follows a similar pattern, with a noticeable dip in 2017:

Year	**Payments to Endocrinologists**	**Total Payments**	**% to Endocrinologists**
2013	426	547	78%
2014	1144	1699	67%
2015	2068	2944	70%
2016	2770	4050	68%
2017	3712	6215	60%
2018	4204	6940	60%

275. Further, as demonstrated in the chart below, since 2013 the total number of all types of payments to physicians classified as Internists has ballooned from 29 in 2013 to 586 in 2018, representing an increase of 1,920.69%. Similarly, the total number of all types of payments to Family Medicine physicians has increased from just 14 in 2013 to 414 in 2018 representing, an increase of 2,857.14%. During the same timeframe, the total number of Endocrinologists receiving any type of payment increased just 428.08%, showing the marked shift in emphasis on these PCPs. By contrast, the total number of physicians receiving payments from Corcept only increased 646.67% from 2013 to 2018, demonstrating the outlier nature of the increases in the Internist and Family Medicine categories:

Year	Internal Medicine Physicians Paid (% of total)	Family Medicine Physicians Paid (% of total)	Total Physicians Paid
2013	29 (10%)	14 (5%)	298
2014	95 (8.6%)	18 (1.6%)	1107
2015	230 (15.7%)	62 (4.2%)	1467
2016	325 (19.7%)	107 (6.5%)	1651
2017	516 (22.4%)	323 (14%)	2305
2018	586 (24%)	414 (17%)	2438

276. Similarly, the total number of any type of payments to Internists and Family Medicine physicians also grew at an exceptional rate compared to all other specialties. The total number of payments for this period for Internists increased 3,841.67%, and the total number of payments to Family Medicine physicians increased 6,160%. For comparison, in the same timeframe, the total number of payments to Endocrinologists increased only 1,168.74%.

277. As the chart above shows, the largest jump in targeting internists and Family Medicine physicians occurs in 2017. The year over year increase in 2017 was 59% for Internists and 202% for Family Medicine physicians. Both figures far exceed the 40% increase in total physicians paid by Corcept in 2017.

278. As reflected in the Company's Open Payments data, Endocrinologists, Internists, and Family Medicine physicians were the only medical specialties to ever exceed 100 physicians receiving payments from Corcept in a single year. In fact, no other medical specialty had more than 16 physicians receive payments in 2017 and 2018.

279. As to be expected with the large increase in payments, the total dollars spent on Internists and Family Medicine physicians also saw massive increases between 2013 and 2018:

Year	$ Spent on Internists	$ Spent on Family Medicine
2013	$2,902.05	$221.56
2014	$22,249.79	$340.24
2015	$14,593.98	$1,940.51
2016	$17,344.99	$4,216.37
2017	$80,963.91	$15,460.36
2018	$89,104.38	$19,302.72

280. In 2017, Corcept increased its spending by 366.79% and 266.67% on Internists and Family Medicine physicians, respectively. The total increase in spending by Corcept to Endocrinologists increased only 88.95% in the same timeframe. The total increase in spending by Corcept from 2016 to 2017 was only 103.57%.

281. While Corcept's spending on Endocrinologists in whole dollars still exceeded its spending on Internists and Family Medicine physicians, this is because, as demonstrated above, Corcept expanded its targeted market well beyond the 300 Specialist Endocrinologists to non-Specialist Endocrinologists who were less familiar with diagnosing and treating Cushing's Syndrome and more susceptible to Corcept's off-label messaging regarding Korlym.

282. Indeed, Corcept's reasoning for targeting non-Specialist Endocrinologists with their Korlym marketing is clear – the Company perceived these physicians as being unlikely to have the same in-depth understanding of endogenous Cushing's Syndrome as Specialist Endocrinologists – a group of specialists who have declined to embrace Korlym. Since these non-Specialist Endocrinologists are presumed to be less familiar with Cushing's Syndrome, they would also be less familiar with the other medical treatment options available such as ketoconazole, metyrapone, mitotane, or etomidate and thus, would be more susceptible to prescribing Korlym as a first-line therapy, even in preference to surgical intervention, the clear first-line therapy for Cushing's Syndrome.

3. CWs Confirm that Defendants' Off-Label Marketing Scheme Materially Contributed to Corcept's Sales and Bottom Line

283. Due to the exorbitant price of Korlym, any patient enrolled in Korlym was a windfall for Corcept. CW11 said that senior management, including Defendants Belanoff, Maduck and Robb, would "wait by the fax machine" when they thought potential enrollment forms would be arriving. If an enrollment form arrived, Defendants Belanoff, Maduck, and other senior management would exchange "high-fives" and send congratulatory emails to the clinical specialist who obtained the prescription. CW11 stated "there were so many emails congratulating" a clinical specialist for each new enrollment form from senior management.

284. In order to increase Korlym sales, Defendants pressured clinical specialists to come up with more and more enrollments. According to CW11, originally, the sales quotas for a clinical specialist

was between 2 to 5 enrollments per quarter, or roughly a maximum of 20 enrollments per year. If a clinical specialist got up to 8 enrollments in a quarter, they "were a rockstar." CW12 confirmed that, as a result of his aggressive off-label marketing, Balzanti was enrolling up to 30-40 patients per quarter which could not be done by "legitimate" means. CW12 knows this because it was presented at the Annual National Sales Meetings and discussed during weekly meetings with CW12's regional manager and colleagues. CW12 stated that much of Balzanti's success was in enrolling patients with any result over "0" on a DST.

285. CWs 11, 12 and 13 attributed the massive increase in Corcept's sales and growth to enrollments of patients with subclinical Cushing's Syndrome.

286. Based upon reports CW11 saw and discussions at regular sales meetings CW11 attended, CW11 recalled that during CW11's tenure, approximately 60% of all Korlym sales were off-label and that the number would have increased as Corcept "displaced" clinical specialists who refused to engage in off-label marketing. CW11 estimated that Tyler Franklin's sales were roughly 10% on label based on the bonuses Franklin was receiving. CW12 was similarly aware based on CW12's personal conversations with Franklin and from Franklin speaking at the national sales meetings, that Franklin was mainly targeting patients with diabetes, regardless of whether they had Cushing's Syndrome. Franklin told CW12 that Franklin learned a lot from Balzanti and was using his approach.

287. CW11 believes the "sky is the limit" to the number of enrollments a clinical specialist could get in a year if they engaged in off-label marketing.

288. An analysis of publicly available Medicare Part D prescription data, as well as the Company's Open Payments information, illustrates the material impact the Company's off-label marketing strategies have had on its bottom line.

289. In 2017, Corcept received $56,548,231.55 in revenue from Medicare Part D or about 35.5% of Corcept's total revenue for that year. The 10 states discussed *supra* where confidential witnesses have confirmed Corcept's off-label marketing scheme (California, Massachusetts, Nebraska, Nevada, New York, Ohio, Oklahoma, Pennsylvania, South Carolina, Texas and West Virginia), accounted for 42.69%, or $24,140,391.40, of total Medicare Part D revenue for 2017, equating to 15.16% of Corcept's total revenue in 2017. Unsurprisingly, as discussed below, South Carolina, where

Dr. Jerry Back and Dr. Joseph Mathews practice medicine, led the way with $7,993,890.39, or 14.1%, in Medicare Part D payments.

290. In 2018, Corcept received $104,791,706.1 from Medicare Part D or about 41% of Corcept's total revenue for the year. The 10 states discussed *supra* where confidential witnesses have confirmed Corcept's off-label marketing scheme, accounted for 47.1% or $49,391,787.32, of total Medicare Part D revenue for 2018, equating to 19.16% of Corcept's total revenue for the year.

291. Importantly, 15%-19% is the floor as it does not include revenue generated through private insurance reimbursement or cash payments for Korlym. Thus, given the widespread, uniform and pervasive marketing message, it can be inferred that a substantial portion of Corcept's revenue from private insurance reimbursement was the result of Corcept's off-label marketing of Korlym.

292. Moreover, a review of the Medicare Part D data demonstrates that a large percentage of Corcept revenue was generated from Korlym prescriptions written by non-Specialist Endocrinologists.[45,46] There has been a marked increase in prescriptions written by these non-Specialist Endocrinologists responsible for 11+ claims of Korlym since 2015. CW11 confirmed that this approach was a direct result of the off-label scheme implemented by Corcept. In addition to directly approaching these physicians with a consistent off-label message, changes to sales territories and sales quotas forced clinical specialists to expand their physician pool from solely Endocrinologists to include a growing number of Primary Care physicians.

293. In 2018, non-Specialist Endocrinologists accounted for 91.9% of the total physicians with 11+ claims of Korlym and 94.7% of the number of claims from physicians with at least 11 claims. Unsurprisingly, the revenue from these physicians has also dramatically increased. Revenue coming

[45] Medicare Part D does not disclose the name of a physician unless they are responsible for at least 11 claims of a drug in a given year. For example, there were 276 physicians who prescribed Korlym and had a Medicare Part D claim in 2017, but only 75 of them had 11+ claims.

[46] As used in these calculations, "Specialist Endocrinologists" are those Endocrinologists who either: (1) work at one of the top 25 Endocrinology hospitals based on U.S. News rankings; (2) work at one of the top 20 "Honor Roll" hospitals for 2019/2020 based on U.S. News rankings; (3) are specifically mentioned by the Cushing's Support & Research Foundation as a Cushing's specialist; or (4) work with one of the Endocrinologists who was listed by the Cushing's Support & Research Foundation as a Cushing's specialist. Non-Specialist Endocrinologists encompasses all other Endocrinologists. The non-specialist Endocrinologists may ordinarily treat other endocrinological conditions, such as thyroid disorders, diabetes and bone and lipid metabolism.

from non-Specialist Endocrinologists, i.e., community-based Endocrinologists, Internists, Family Medicine physicians etc., increased 2900% from 2014 to 2018:

Year	# of named prescribers	Non-Specialist Endocrinologists	% Non-Specialist Endocrinologist	# of Named Prescriber Claims	Non-Specialist Endocrinologists Claims	% Non-Specialist Endocrinologists Claims
2014	15	9	60%	216	128	59.2%
2015	20	16	80%	347	262	75%
2016	44	36	81.8%	714	597	83.6%
2017	75	65	88.7%	1576	1399	88.7%%
2018	135	124	91.9%	2943	2788	94.7%

294. In total, these 124 non-Specialist Endocrinologists accounted for 68% of all Korlym claims paid by Medicare Part D in 2018, despite representing only 30% of physicians who prescribed Korlym during that time period (indicating that these physicians are more likely to issue Korlym prescriptions to multiple patients).

Year	Total Revenue From Named Prescribers	Revenue from Specialist Endocrinologists	Revenue from Non-Specialist Endocrinologists	% Revenue from Non-Specialist Endocrinologists
2018	$76,620,384.05	$4,293,844.07	$72,326,539.98	94.3%
2017	$39,063,744.51	$4,955,468.50	$34,108,276.01	87.3%
2016	$15,786,294.62	$2,321,944.16	$13,464,350.46	85.3%
2015	$6,218,343.16	$1,567,124.17	$4,651,218.99	74.8%
2014	$3,446,912.62	$1,168,295.39	$2,278,617.23	66.1%

295. For example, Dr. Jerry Back, an Internal Medicine physician from North Charleston, South Carolina, had 115 Medicare Part D Korlym claims originate from his office in 2017 (accounting for nearly 5% of all Korlym claims submitted for Medicare reimbursement that year), the highest of any physician submitting Korlym claims to Medicare Part D in 2017. The sheer magnitude of Dr. Back's Korlym prescriptions demand scrutiny for several reasons.

296. Not only was Dr. Back the only physician with over 100 claims submitted to Medicare for Korlym in 2017 but, critically, Dr. Back is an Internal Medicine physician, ***not*** an Endocrinologist. Most Internists and Family Medicine physicians refer Cushing's Syndrome patients to an Endocrinologist, especially for the testing necessary to ***confirm*** a Cushing's Syndrome diagnosis, as set forth in the Diagnostic Guidelines.

297. Dr. Back presents himself as treating diabetic patients. As noted above, one of the pre-requisites for the FDA-approved use of Korlym is that the patient has type two diabetes or glucose intolerance in addition to endogenous Cushing's Syndrome. Thus, it is reasonable to infer that Dr. Back, at the direction of Corcept clinical specialists, is likely performing the DST on his patients with uncontrolled diabetes and prescribing Korlym if the DST is even borderline positive without any attempt to actually confirm an endogenous Cushing's Syndrome diagnosis and without any attempt to locate and surgically resect any causative tumor. This first-line reliance on Korlym constitutes an off-label use, as the drug is specifically approved only after a confirmed diagnosis and a failed surgery or confirmation that surgery is not an option for the patient.

298. Further, despite his physician profile claiming that "he is a provider of excellence in diabetes with more than 20 years of experience,"[47] Dr. Back submitted ***zero*** Korlym claims to Medicare Part D for the years of 2014 and 2015, before increasing that number to 19 in 2016 (with a total drug cost of $433,784.70) and then exploding that figure to 115 in 2017 (worth a total drug cost of $3,562,308.06 – ***nearly 2.5% of Corcept's total net product revenues for that year***).

299. As discussed above, Medicare Part D does not disclose the number of patients a specific physician has prescribed a drug to unless the figure is at least 11. From 2013 to 2016, there were no physicians who prescribed Korlym to at least 11 individuals in one year. However, as demonstrated in the chart below, in 2017 there were four such physicians, including Dr. Back, **none** of whom were Specialist Endocrinologists. Tellingly, as discussed below, that sole non-Specialist Endocrinologist, Dr. Joseph Mathews, was one of the highest recipients of honoraria payments made by Corcept to physicians:

Physician	**# of Patients**	**Specialty**
Jerry Back	23	Internal Medicine
Norman Crabb	19	Family Medicine
Joseph Mathews	13	Endocrinology
Roberto Pabalate	13	Family Medicine

[47] https://advancedcentersforim.com/physicians/profile/Dr-Jerry-G-Back-MD#

300. These numbers stand in stark contrast to Defendant Belanoff's assertion in a November 7, 2019 earnings call that "this is a disease where you're adding to your enrollment total by 1s and 2s everywhere you go."

301. Dr. Back was also one of the largest recipients of monetary benefits from Corcept's increased focus on Primary Care physicians. Dr. Back received only $154.38 in 2016 from Corcept in the form of food and beverage payments. However, in 2017, a year in which Dr. Back produced 115 Korlym claims according to Medicare Part D data, he received $55,454.60 from Corcept, with an additional $31,099.16 flowing to Dr. Back in 2018 from Corcept. This included $47,000 and $20,000 in honoraria payments from Corcept in 2017 and 2018, respectively.

302. Honoraria payments are similar to consulting fees but are generally reserved for a one-time short duration activity, such as payment for giving presentations to other physicians. Honoraria also differs from consulting fees in that the payments are generally provided for services which custom prohibits a price from being set. CW11 confirmed that such honoraria payments were made to speakers in order to facilitate the off-label marketing of Korlym to other physicians.

303. Dr. Back appears to be no stranger to breaking the ethical rules regarding receipt of payments from medical industry participants in exchange for using a company's product. According to a May 29, 2019 announcement by the Department of Justice, Dr. Back agreed to pay $92,506.30 as settlement for claims that he allegedly accepted illegal kickback payments from OK Compounding, L.L.C. in exchange for prescribing pain management creams compounded by that entity.

304. Dr. Back was not the only beneficiary of Corcept's new marketing strategy in 2017, particularly its focus on the use of honoraria payments to induce Korlym prescriptions.

305. Another major recipient was Dr. Joseph Mathews of Summerville, South Carolina, a non-Specialist Endocrinologist, who received $73,777 from Corcept in 2017, including $48,000 in honoraria payments. Dr. Mathews never received an honoraria payment from Corcept prior to 2017. According to Medicare Part D data, Dr. Mathews was the prescribing physician for 85 claims for Korlym, the second highest among Medicare Part D prescribers in 2017, second only to Dr. Back.

306. CW1 was aware that starting in 2017, there was a significant uptick in Korlym prescriptions from local physicians in CW1's area. CW1 could not believe that there could be so many

patients with true endogenous Cushing's Syndrome in such a small region, particularly given how rare the disease is. CW1 reached out to one of the doctors who Tyler Franklin said was treating around 30-40 patients with Korlym in 2018 to discuss CW1's concerns about his practice of prescribing Korlym after learning about several of his patients having adverse outcomes from being placed on Korlym, most of which did not have confirmed diagnoses of Cushing's Syndrome. In that lengthy conversation, the other physician brushed off CW1's concerns.

307. In total, Corcept increased its honoraria spending to $366,750 in 2017, a 322% increase from 2016. In fact, in 2017 Corcept's honoraria spending alone nearly exceeded all payments not associated with a research study to physicians in 2016 combined. Honoraria payments consisted of just 22.8% of Corcept's non-research study payments to physicians in 2016. That number jumped to 47.4% in 2017.

308. Upon information and belief, these honoraria payments were largely comprised of payments made to high-prescribing physicians to host informal marketing sessions or roundtable discussions (usually over dinner) at which the paid physician plays the role of Company spokesperson to market Korlym off-label.

309. PE sought to speak about Cushing's Syndrome on behalf of Corcept in 2012 or 2013 through their speakers' bureau but was told by Corcept that he could not speak because PE had not written enough Korlym prescriptions. The implication of this position by Corcept was that if the PE increased his Korlym prescriptions, he could receive payments for participating in their speakers' bureau.

310. Given the rarity of Endogenous Cushing's Syndrome, large clusters of affected individuals should be inherently few and far between. Additionally, one would expect that if there was a large cluster of the rare disease, it would be centered in a highly dense population. In fact, a study showed patients in rural areas saw a significantly higher number of physicians before getting their Cushing's Syndrome diagnosis, potentially indicating a less dense net of medical specialists familiar with the diagnostic features of Cushing's Syndrome. Cipoli DE, Martinez EZ, de Castro Md, Moreira AC. *Clinical judgment to estimate pretest probability in the diagnosis of Cushing's syndrome under a Bayesian perspective*. Arq Bras Endocrinol Metabol. 2012;56:633–637. However, the Medicare D

prescriber data for 2017 does not support this expectation. Between Dr. Back and Dr. Mathews, there were 200 claims spread between 36 patients for Korlym in 2017 in the area of South Carolina where Dr. Back and Dr. Mathews practice just 20 minutes apart from one another, indicating that the Cushing's Syndrome diagnoses are driven by these physicians, not a cluster of the disease.

311. Similar to physician data, Medicare Part D breaks down prescriptions on the state level. The data only shows the number of patients in a state if there are over 11 patients in the state. In 2017, there were 13 states with at least 11 patients on Korlym. Cushing's Syndrome has a prevalence of 10 – 15 per 1 million people. Importantly, as stated above, the FDA estimated that only a quarter (5,000 out of 20,000) of Cushing's Syndrome patients would qualify for treatment with Korlym under the Company's more expansive initial proposed indication. All of the states far exceed the expected number of Cushing's Syndrome patients based on their total Medicare population.

State	Number of People on Medicare[48]	Expected Number of Cushing's Patients	Expected Cushing's Patients Not Cured by Surgery	Actual Number of Patients Prescribed Korlym
California	5,915,868	59 - 88	15 - 22	32
Connecticut	649,953	6 - 10	2 - 3	22
Florida	4,239,320	42 - 63	11 - 16	21
Georgia	1,613,171	16 - 24	4 - 6	16
Illinois	2,146,998	21 - 32	5 - 8	29
Indiana	1,196,778	12 - 18	3 - 5	15
Maryland	978,671	9 - 14	2 - 3	12
Michigan	1,971,638	20 - 30	5 - 8	22
New York	3,457,888	35 - 52	9 - 13	18
North Carolina	1,858,980	19 - 28	5 - 7	24
Ohio	2,235,996	22 – 34	6 - 9	29
South Carolina	994,109	9 - 14	2 - 4	51
Texas	3,842,864	38 - 58	10 - 15	42

312. PE, a Specialist Endocrinologist, screens for endogenous Cushing's between 300 and 400 times per year. Of those 300 to 400 patients that PE screens, only approximately two to three result in a

[48]https://www.kff.org/medicare/state-indicator/total-medicare-beneficiaries/?currentTimeframe=1&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

Cushing's diagnosis. PE described the number of patients Drs. Back and Mathews claim qualify for treatment with Korlym as "astronomical."

313. Compounding the abnormality of Dr. Back and Dr. Mathews' increased prescription rate was the overall rapid increase in the number of physicians prescribing Korlym to address diabetes in patients without a confirmed endogenous Cushing's Syndrome diagnosis. The practice has become so prevalent that it caught the attention of two Endocrinologists, Dr. Eveline Waring and Dr. Beatrice Hull, who published a chapter titled "Inappropriate Use of Mifepristone to Treat Diabetes Mellitus" in Dr. Michael McDermott's 2019 book, *Management of Patients with Pseudo-Endocrine Disorders*..

314. In their chapter, Drs. Waring and Hull presented a case study regarding "a particularly difficult patient, with multiple comorbidities and a striking appearance consistent with Cushing's syndrome" who had been prescribed Korlym by her prior physician. Ultimately, Dr. Waring and Dr. Hull determined that, for this patient, "the indication for mifepristone use was arrived at in reverse: the patient presented with difficult-to-control metabolic syndrome (obesity, hypertension, diabetes, depression), and then the search for hypercortisolemia was undertaken, culminating in the patient being placed on mifepristone."

315. Assessing that a patient has diabetes and then working in reverse in an attempt to validate a Korlym prescription would be a clear off-label use, particularly as Korlym's FDA-approved label is unequivocal, including in its "Important Limitations of Use" just one provision: "Do not use for the treatment of type 2 diabetes mellitus unrelated to endogenous Cushing's syndrome."

316. Drs. Waring and Hull also summarized the issues with the initial screening tests generally used for Cushing's Syndrome, explaining why each of them, particularly used in isolation, potentially produces unreliable results:

> The majority of studies evaluating the diagnostic approach to autonomous cortisol secretion have been done in patients with adrenal incidentalomas. The overnight 1 mg dexamethasone suppression test (1 mg DST), 24h urinary free cortisol (UFC), midnight salivary cortisol (MSC), and ACTH measurement have all been studied as diagnostic tests for this condition with very variable results in sensitivity and specificity. **Subsequently, the definition of autonomous cortisol secretion varies, and there is no one reliable test to diagnose this condition, leading physicians to utilize multiple available tests to try to make an accurate diagnosis, but it also creates the situation where the interpretation of tests results can be interpreted "loosely" depending on physician personal bias and experience.**

317. Drs. Waring and Hull practice with the Carolina Endocrine Associates in North Charleston, South Carolina – the same town as Dr. Back and just minutes from Dr. Mathews – the two doctors responsible for 200 of the total 2,333 claims submitted for Medicare Part D reimbursement in 2017 and who received hundreds of thousands of dollars in remuneration from Corcept over the past few years.

318. In 2018, Ingleside, Texas became a new hotspot for Korlym activity, similar to Charleston, South Carolina's spike in 2017 but to a much larger degree. According to Medicare Part D data for 2018, three of the top six prescribers of Korlym were from Ingleside, Texas:

Physician	**Location**	**Beneficiary Count**
Norman Crabb	Ingleside, Texas	31
Robin Anderson	Chicago, Illinois	16
Jerry Back	North Charleston, South Carolina	15
Lena Rippstein	Ingleside, Texas	15
Roberto Pabalate	Decatur, Illinois	14
Candice Miller	Ingleside, Texas	13

319. Despite all these enrollment totals vastly outpacing Defendant Belanoff's assertion that Korlym is a drug that increases "by 1s and 2s," the real story here is Dr. Norman Crabb, NP Lena Rippstein, and NP Candice Miller (collectively, the "Ingleside Physicians"). The Ingleside Physicians accounted for 59 Medicare patients on Korlym in 2018 and are all located ***at the same office*** in Ingleside: 2713 Main Street, Ingleside, Texas 78362.[49] Note that Dr. Crabb is Doctor of Osteopathic Medicine (DO) reported to specialize in Family Medicine, Geriatric Medicine and Emergency Medicine. Lena Rippstein and Candice Miller are Nurse Practitioners (NP).

320. The population of San Patricio county, where Ingleside is located, and next-door neighbor Corpus Christi was roughly 380,000 people in 2018. Based on the expected incidence rate of endogenous Cushing's syndrome, this would yield *less than 1 expected patient* with endogenous

[49]https://www.healthgrades.com/physician/dr-norman-crabb-xf4pg;
https://www.healthgrades.com/providers/lena-rippstein-yc2lx;
https://www.healthgrades.com/providers/candice-miller-xynjg2y

Cushing's syndrome in the area, let alone a patient who would meet the FDA approved label of Korlym. The Ingleside Physicians prescription habits were so disproportionate, the Ingleside Physicians tied or exceeded every other states' ***total*** number of Medicare patients on Korlym in 2018:

Location	**Number of Beneficiaries**
The Ingleside Physicians	59
California	59
South Carolina	56
Florida	55
Ohio	51
New York	49
Illinois	48
Michigan	31
North Carolina	31
Indiana	26
Arizona	23
Connecticut	22
Georgia	19
Tennessee	14
New Jersey	11
Pennsylvania	11

321. In fact, the Ingleside Physicians accounted for 8.3% of all Medicare beneficiaries on Korlym in 2018, representing a total drug cost of over $7.3 million or roughly 7% of the total amount paid on Korlym claims.

322. The overall rapid increase in prescriptions of Korlym that drove the Company's revenues over the past several years unfortunately coincided with an increase in patient deaths while on Korlym. Korlym sales exploded in August of 2017 when Corcept switched from Dohmen to Optime. According to the FDA's Adverse Events Reporting System ("FAERS"), there were 17 reported deaths of patients on Korlym in 2017. In 2018, there were 40 deaths reported in the FAERS database. In 2019, a year with less rapid increase in prescriptions of Korlym, there were 19 deaths reported to FAERS. In total, there have been 103 deaths reported since 2012. In 17 of the deaths reported, Korlym was "used for [an] unknown indication."

323. Through Freedom of Information Act requests, Plaintiff received from the FDA individualized case reports for all instances where a patient on Korlym passed away from 2012 until 2018.

324. As demonstrated in the chart below, in 2017 the number of males who passed away on Korlym exceeded the number of females. This is anomalous because women are five times more likely to suffer from endogenous Cushing's Syndrome than men.

325. Despite this, since 2017, *i.e.*, when Corcept's massive off-label marketing push began, the number of men who died on Korlym (28) is almost equal to the number of women (31).

Year	Male Deaths	Female Deaths	Total
Unknown	4	8	12
2012	1	1	2
2013	2	4	6
2014	3	14	17
2015	5	8	13
2016	9	14	23
2017	15	12	27
2018	13	19	32

326. In summary, Defendants were specifically targeting physicians who were unfamiliar with the diagnosis and treatment of Cushing's Syndrome in an effort to get them to prescribe Korlym for off-label indications. Additionally, to help with the "exacting and intense" insurance approval process, Corcept created Optime to expedite insurance authorizations for Korlym. Corcept clinical specialists would also offer to fill out the required enrollment forms instead of the doctor or unilaterally fix the enrollment forms if they contained ICD 10 codes which would result in insurance reimbursements being denied. This led to a dramatic increase in sales in the first year of the agreement between Corcept and Optime.

327. Corcept did not disclose to investors that sales of Korlym, the Company's only revenue source, were dependent on unregulated, illicit off-label marketing.

G. Suspecting Off-Label Marketing and Prescriptions of Korlym, Insurance Providers Tighten Approval Standards to Require Physical Evidence of Cushing's Syndrome and Diagnosis by an Endocrinologist, Causing Corcept's Revenue Growth to Plummet

328. Becoming wise to the apparent off-label use of Korlym as evidenced by the skyrocketing prescription rate, in July 2018, insurance provider Blue Cross/Blue Shield of South Carolina (the very state in which Drs. Back and Mathews practice medicine) tightened its requirements for approving reimbursement for Korlym prescriptions.

329. In its bulletin announcing the new review process for Korlym, Blue Cross/Blue Shield of South Carolina stated that review of Korlym prescriptions was "previously conducted by CVS Caremark, [its] Pharmacy Benefit Manager (PBM) partner."[50]

330. According to CVS Caremark's "Specialty Guideline Management" for Korlym,[51] a twelve-month authorization for a Korlym prescription may be granted for members who meet the following criteria: (a) member has a diagnosis of Cushing's syndrome/disease; (b) member has type 2 diabetes mellitus or glucose intolerance; (c) Korlym is being prescribed to control hyperglycemia secondary to hypercortisolism; (d) Member has had surgery that was not curative OR member is not a candidate for surgery. *Importantly*, CVS Caremark's Korlym previous guidelines ***did not*** require any documentation proving a patient's satisfaction of the established criteria.

331. Presumably in response to rising Korlym claims, Blue Cross/Blue Shield of South Carolina changed its prior policy to now require documentation to support a Korlym prescription, including: (1) A1C lab results showing a clinical response to therapy for those seeking a coverage continuation; (2) documentation of surgical history and response; and (3) if the patient is not a surgical candidate, documentation of previous medication therapy failures, including doses and dates of all drugs tried to date, and laboratory tests (including dates obtained) of serum and urinary cortisol levels to assess efficacy of the previous regimens.

332. Blue Cross/Blue Shield of South Carolina is hardly the only insurance company to scrutinize the rising number of Korlym prescriptions, with Independence Blue Cross based in

[50] https://www.bluechoicesc.com/providers/news/2018/pharmacy-new-review-process-prescription-drugs-korlym-and-xyrem

[51] https://www.caremark.com/portal/asset/Korlym_Policy.pdf

Philadelphia, Pennsylvania modifying its Korlym policy effective January 1, 2019 to require documentary evidence of *all* of the following criteria: (1) Hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's Syndrome who have type 2 diabetes mellitus or glucose intolerance; and (2) that the patient has failed surgery or is not a candidate for surgery; and (3) that Korlym is being prescribed by or in consultation with an endocrinologist.

333. Highmark Blue Cross/Blue Shield ("Highmark") is based in Pittsburgh, Pennsylvania and insures patients in Pennsylvania, West Virginia, and Delaware. On May 4, 2018 Highmark revised its policy[52] to require trial and failure of one diabetes medication before a patient receives Korlym.

334. These changes in the Korlym prescription approval processes by private insurance companies and state authorization boards coincided with a drastic decline in Corcept's quarter over quarter revenue growth. After posting quarter over quarter revenue growth of at least 75% in each of the first four quarters with Optime as its specialty pharmacy, Corcept's third quarter revenue growth in Q3 2018 was just 50.7%. The revenue growth continued to fall into 2019 to a low of 12.4% in Q1 2019 as the insurance companies became wise to Corcept and Optime's scheme and it became more difficult for Optime to secure insurance approval for Korlym prescriptions.

Quarter	Revenue (in thousands)	Quarter over Quarter % Increase
Q3 2017	$42,763	96.8%
Q4 2017	$53,280	123.8%
Q1 2018	$57,659	108.9%
Q2 2018	$62,312	75.2%
Q3 2018	$64,445	50.7%
Q4 2018	$66,831	25.5%
Q1 2019	$64,829	12.4%

335. Insurance companies have continued to crackdown on the off-label prescriptions of Korlym. For example, the Oklahoma Health Care Authority ("OHCA") administers two health programs for the state, SoonerCare and Insure Oklahoma. SoonerCare is Oklahoma's Medicaid program. Insure

[52]https://content.highmarkprc.com/Files/Region/PA-WV/SpecialBulletins/sb-pa-wv-3rd-qtr-formulary-update-070318.pdf

Oklahoma assists qualifying adults and small business employees in obtaining health care coverage for themselves and their families.

336. The Drug Utilization Review Board ("DUR Board") is a subsection of OHCA. The DUR Board advises OHCA about the appropriate and optimal use of pharmaceuticals for Oklahoma Medicaid recipients. The DUR Board holds monthly meetings where they discuss certain drugs and the drug's efficacy, side effects, current prior authorization criteria, and recommendations to the board, among other topics.

337. In January 2020, the DUR Board discussed Korlym. The DUR Board was given an introduction on Korlym, a product summary of Korlym, and market news and updates regarding Korlym. The College of Pharmacy then recommended prior authorization of Korlym that included seven requirements, and two conditions for the length of authorization/reauthorization, before Medicaid could approve Korlym. Six of the seven requirements are in direct response to things on the FDA-approved label for Korlym, such as that female members must not be pregnant. However, the 7th requirement has to do with who can prescribe Korlym. The College of Pharmacy recommended to only allow prior authorization of a Korlym prescription on the condition that "Korlym must be prescribed by, or in consultation with, an endocrinologist (or be an advanced care practitioner with a supervising physician who is an endocrinologist)."

338. In August 2020, the Eastern Oregon Coordinated Care Organization ("EOCCO") similarly made changes to the Prior Authorization for Korlym. The EOCCO now requires patients to have undergone two additional types of medical therapy before a patient will be approved for Korlym. The two other types of treatment had to have been "ineffective, not tolerated, or contraindicated" before EOCCO will approve Korlym prescriptions. The EOCCO made these changes based, in part, on the Endocrine Society Clinical Practice Guideline.

339. The insurance companies above were hardly the only insurance companies changing their requirements for approving Korlym; Wellmark Blue Cross and Blue Shield, which operates in Iowa and South Dakota (April 2020), BlueCross BlueShield Arizona (August 2020), AllWays Health Partners in

Massachusetts (July 2020), and Blue Cross Blue Shield of Michigan (December 2020) have all recently made changes to their prior authorization requirements for Korlym.[53]

V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

340. As set forth in the chart attached hereto as Exhibit A and incorporated by reference into this paragraph, throughout the Class Period, Defendants made materially false and misleading statements about the Company and Korlym which materially altered the total mix of information in the market.

341. These statements were made by the Individual Defendants in, among other sources, Company press releases, SEC filings, presentations and during earnings conference calls. In accordance with the Court's preferences articulated in its November 20, 2020 Motion to Dismiss Order at 8, 24-32, Plaintiff has organized the alleged false statements into the following five categories:

1) the aim and outcome of physician education programs (Statements 1, 7, 11, 16, 21, 25, 27);
2) whether Corcept's marketing was in line with the FDA-approved label for Korlym (Statements 2, 8, 12, 17, 22, 28);
3) Corcept's compliance with FDA regulations regarding off-label marketing (Statements 3 9, 13, 18, 23, 29);
4) The basis for Corcept's revenue growth (Statements 4,5, 6, 10, 14, 15,19, 20, 24); and
5) The percentage of patients who were prescribed Korlym for on-label uses (Statement 26).

342. Further, each category of statement and constituent statement identified in Exhibit A was additionally false and misleading by omission as Defendants failed to disclose the pervasive off-label marketing scheme.

VI. THE TRUTH IS REVEALED IN TWO PARTIAL DISCLOSURES

343. On January 25, 2019, SIRF released the SIRF Report alleging that Corcept has been reimbursing physicians through honoraria payments in exchange for them agreeing to prescribe Korlym for off-label uses in an effort to boost Korlym sales. For example, the SIRF Report highlighted the

[53] Prior versions of these prior authorization requirements are not currently available, but it is reasonable to infer that the changes were similar to the other insurance changes described above.

relationship between Corcept and Dr. Hanford Yau, an Endocrinologist at the Veterans Administration Medical Center in Orlando, Florida. In 2016, Dr. Yau received $13,524.27 from Corcept, none of which was defined as honoraria. Dr. Yau had received $12,300 from Corcept as a consulting fee and the rest was reimbursement for travel and food expenses. In 2017, Dr. Yau received $95,139.66, of which $77,000 was defined as honoraria. This represented a 603% increase in total compensation from Corcept to Dr. Yau from 2016 to 2017.

344. The SIRF Report also identified a connection between Dr. Yau receiving more money from Corcept and the Orlando Veteran's Administration Medical Center, where Dr. Yau worked, prescribing Korlym. The Orlando Veterans Administration Medical Center became a large client of Corcept in 2017. The VA clinic wrote 50 prescriptions to new patients alone in 2017. According to the SIRF Report, these 50 patients accounted for up to 9.1% of Corcept's 2017 revenue.

345. The SIRF Report found these numbers to be suspicious because endogenous Cushing's Syndrome is five times more likely to affect women than men. However, the Orlando VA Medical Center has a patient base that is historically 91 percent male. The SIRF Report hypothesized that the only way to reach these numbers required the Endocrinology clinic, and specifically Dr. Yau, to prescribe Korlym off-label to their patients.

346. The SIRF Report also brought to light the increasing number of patient deaths signaling off-label marketing and use. As reported in the FDA's FAERS, the number had dramatically increased in recent years and that 17 of the 103 deaths reported in the FAERS mentioned Korlym being "***used for [an] unknown indication***," i.e., likely off-label.

347. The SIRF Report also questioned the geographic clustering of supposed endogenous Cushing's diagnoses, as the analyzed data skewed not towards areas with heavier populations with pituitary disorder clinics affiliated with prominent university medical centers, but instead towards smaller communities, lending credence to the report's allegations that these physicians in smaller communities with limited patient populations could be prescribing the drug to individuals solely with diabetes and not a true endogenous Cushing's Syndrome diagnosis.

348. Following the release of the SIRF Report, the Company's share price fell $1.52, or more than 11%, to close at $12.29 per share on January 25, 2019, on unusually heavy trading volume.

349. After the market closed on January 31, 2019, the Company issued a press release announcing its fourth quarter and full-year 2018 preliminary selected financial results. Therein, and likely due to the increased scrutiny of its illicit sales practices, the Company forecasted a slowdown in sales of Korlym, projecting full-year 2019 revenue of $285 million to $315 million, well below the $328 million expected by analysts.

350. On this news, the Company's share price fell $1.15, or more than 10%, to close at $10.08 per share on February 1, 2019, on unusually heavy trading volume.

VII. POST-CLASS PERIOD EVENTS

351. In the wake of the Class Period and the partial disclosures exposing the truth about Corcept's off-label marketing, the Company has struggled to recapture the growth levels it enjoyed at the outset of its relationship with Optime.

352. On February 5, 2019, shortly after the market opened, Blue Orca published a report adopting the SIRF Report's allegations and alleging that Optime, Corcept's "sole specialty pharmacy and exclusive distributor[,] is actually an undisclosed related party" and that the relationship "creates a material risk that [Corcept] is using its captured pharmacy to boost sales, hide losses, or engage in other financial shenanigans." The Blue Orca Report detailed the extreme revenue increases posted by Corcept after it switched specialty pharmacies and the potential regulatory risks of using a captured pharmacy. The report requested that, at a minimum, Corcept restate its financials to consolidate its specialty pharmacy.

353. In conjunction with the release of its report, Blue Orca posted a video on YouTube of a call between a Blue Orca employee and Optime.[54] On that call, multiple Optime representatives identified themselves as employees of Corcept. An edited version of the transcript is as follows:

> Optime Representative: Optime Care, this is XXXX.
>
> Blue Orca: Hi, I'm looking for Corcept Therapeutics please.
>
> Optime Representative: Yes, you have reached it, is there anyone in particular you need to speak with.

[54] https://www.youtube.com/watch?v=C0ktvZiZiYc

Blue Orca: I'm a physician in the Austin area, an endocrinologist, and I was wondering if there is a Corcept sales rep that covered the area?

[….]

Optime Representative: Sir, I'm going to transfer you over to XXXX and XXXX is one of our care coordinators and he can find a sales rep in your area for you.

…(call transferred internally)

Optime Representative #2: Thank you for holding, this is XXX, how can I help you?

Blue Orca: Hi, is this Corcept?

Optime Representative #2: It Is.

354. Importantly, the call shows that Optime is working as a sales arm of Corcept. Both representatives of Optime identified themselves as working for Corcept. The second Optime representative then put the Blue Orca representative in touch with the regional sales manager of Corcept to help set up a meeting regarding Korlym. The regional sales manager provided contact information for a sales representative in the area.

355. In response to the SIRF Report, Corcept released a Form 8-K on February 5, 2019. The Form 8-K was supposedly intended to "help investors ground their analysis in the facts." Therein, Corcept falsely stated that "literally, ninety-nine percent of the Korlym we sell goes to patients whose diagnosis matches Korlym's FDA-approved label." Additionally, Defendants refuted the claim that there are not enough patients available to support Corcept's growth stating, in contradiction to their years of prior statements to the FDA and the public, that there are "probably several times more than 10,000 patients [in the United States with Cushing's Syndrome] than are required to account for our revenue."

356. On May 9, 2019, Corcept announced its lowest quarter over quarter growth since Korlym was approved by the FDA, coming in at just 12.4%. This was the third consecutive quarter posting the lowest quarter over quarter revenue growth since Korlym was approved by the FDA, likely due to being unable to induce as many unsuspecting physicians to prescribe Korlym and the tightening of insurance company approval procedures for Korlym prescriptions.

357. On this news, the Company's share price fell $0.49, or more than 4%, to close at $10.83 per share on May 10, 2019.

358. While Corcept's quarter over quarter growth rebounded slightly in the second and third quarter of 2019, to 16% and 26.5% respectively, these quarters were still the second and fourth lowest quarter over quarter growth numbers since the FDA approved Korlym. In the three quarters after the SIRF report was published, Corcept posted three of its four lowest quarter over quarter revenue growths since the FDA approved Korlym.

359. Corcept is also locked in legal battles with both Teva and Sun Ltd. regarding potential generic versions of Korlym. On May 7, 2019, Teva filed for a post-grant review of Corcept's recently issued '214 use patent[55] before the US Patent and Trademark Office ("USPTO"). On November 20, 2019, the USPTO announced it will hear arguments from Teva regarding Corcept's '214 patent.

360. On this news, Corcept's share price fell $3.68, or more than 22%, to close at $13.22 per share on November 20, 2019 on unusually heavy trading volume.

361. This massive drop in stock price when the USPTO granted **review** of one of Corcept's patents indicates the Defendants' fear of a potential generic entering the market was well-founded. In anticipation of new market players entering the endogenous Cushing's Syndrome arena, Defendants perpetuated the scheme detailed above to increase the stock price to lessen the impact.

362. On November 8, 2019, Corcept filed a lawsuit in the Superior Court of the State of California, County of San Mateo, captioned as *Corcept Therapeutics, Inc. v. Doe*, 19-civ-06658, against a John Doe for defamation and trade libel. The Company alleges that, on August 19, 2019, John Doe posted on Cafepharma.com, an online message board for pharmaceutical professionals, asserting that Corcept "sells off label big time" and "patient deaths have escalated." The Company has since voluntarily dismissed that action.

VIII. ADDITIONAL SCIENTER ALLEGATIONS

363. As alleged herein, each of the Individual Defendants acted with scienter in that they knew

[55] The Company's '214 patent, filed by the Company with the USPTO on June 19, 2017, is directed to methods of reducing the dose of mifepristone for patients also taking a CYP3A inhibitor, such as ketoconazole.

or recklessly disregarded that the public statements and documents issued and disseminated in the name of the Company were materially false and misleading, knew or acted with deliberate recklessness in disregarding that such statements and documents would be issued and disseminated to the investing public, and knowingly and substantially participated and/or acquiesced in the issuance or dissemination of such statements and documents as primary violators of the federal securities laws.

364. The Individual Defendants had the opportunity to commit and participate in the wrongful conduct complained of herein. Each was a senior executive officer and/or director of Corcept and, thus, controlled the information disseminated to the investing public in the Company's press releases and SEC filings. As a result, each could falsify the information that reached the public about the Company's business and performance.

365. Throughout the Class Period, each of the Individual Defendants acted intentionally or recklessly and participated in and orchestrated the fraudulent schemes alleged herein to conceal the true nature and extent of the Company's off-label marketing scheme. Such actions allowed Corcept to inflate the Company's stock price. The Individual Defendants' scienter may be imputed to Corcept as the Individual Defendants were among Corcept's most senior management and were acting within the scope of their employment.

A. <u>The Individual Defendants' Knowledge and/or Recklessness</u>

1. Former Corcept Employees Confirm Defendants Directed Corcept's Sales Force to Engage in a Pervasive Companywide Scheme to Market and Sell Korlym Off-Label Using a Uniform Marketing Message

366. At least fifteen confidential witnesses—CWs 1-14 and PE—all confirmed that Corcept used the same uniform off-label marketing message across all its regions in which the Company's clinical specialists told physicians to use Korlym as a treatment for non-Cushing's indications, such as obesity, poorly controlled diabetes and subclinical Cushing's. The clinical specialists also instructed physicians to use a single DST to diagnose Cushing's syndrome and even if the test results were in a "grey area" or below in some cases, to immediately begin treatment with Korlym as a first line treatment. CWs 11-14 stated this message was pushed by Burke and Defendant Maduck before, during and after the Class Period during weekly, quarterly and annual meetings and during one-on-one meetings.

367. At least five confidential witnesses, PE, CW3, CW7, CW9, and CW11 confirmed that Corcept clinical specialists also instructed physicians to use Korlym as a "bridge to surgery" in patients awaiting surgery for adrenal or pituitary tumors—also a direct violation of the FDA-approved label.

368. Corcept clinical specialists communicated these off-label messages to physicians orally during office visits and through marketing materials they gave to physicians promoting off-label use of Korlym.

369. Defendants' pervasive marketing scheme violated the FDA-approved label because it promoted the use of Korlym in a manner and for indications not approved by the FDA.

2. Defendants Assisted and/or Engaged in the Off-Label Marketing Scheme by Accompanying Clinical Specialists to Visit Physicians

370. According to CW11, Defendants Belanoff was heavily involved in the sales process. CW11 recalled that, at least twice, Defendant Belanoff would accompany him on the road to meet with "important" physicians about prescribing Korlym. On these visits, Defendant Belanoff made off-label representations to all the physicians. CW11 asked Defendant Belanoff about the off-label marketing and Defendant Belanoff responded "I can say what I want" because he was the CEO and a physician. According to CW11, Defendant Belanoff did this with all the clinical specialists.

371. CW12 recalled Defendant Belanoff riding with Balzanti, who believed Korlym could be prescribed to anyone whose DST result came back greater than 0, "one or two times."

3. Defendants Were Present During Company Sales Meetings Where Off-Label Studies and the Successes of High-Performing Clinical Specialists Known Throughout the Company to be Marketing Korlym Off-Label Were Discussed and Touted

372. According to CWs 11, 12, 13 and 14, Corcept held Annual National Sales Meetings, typically in Las Vegas, Nevada or Phoenix, Arizona. CWs 11, 12, 13 and 14 stated that Defendant Maduck always attended the sales meetings, and Defendant Belanoff attended some of the sales meetings or one of the days of the meetings.

373. According to CWs 11, 12 and 13, high performers at the Company, like Carl Balzanti and Tyler Franklin, were lauded and given an opportunity to discuss their success at the Annual National Sales Meetings. Corcept also had Medical Science Liaison's explain to all the clinical specialists case

studies showing examples of "mild" or "subclinical" Cushing's Syndrome and explain how Korlym could be used to treat these patients.

374. CW14 further recalled that CW14 attended regional sales meetings with Defendant Maduck, Tom Burke and the other Regional Sales Managers where they discussed Corcept's performance, the successes of top-performing clinical specialists such as Tyler Franklin and Carl Balzanti, and why Franklin and Balzanti were so much more successful. CW14 was told that CW14's clinical specialists should reach out to Balzanti and Franklin to learn how they were able to achieve such high sales and the other clinical specialists should follow what Balzanti and Franklin did. At these meetings, Burke and Defendant Maduck told the regional managers that the clinical specialists needed to find a physician who was willing to prescribe Korlym where the DST was below the 1.8 guidelines. This of course, is what Balzanti and Franklin had done, Franklin's largest customers being Drs. Back and Mathews.

4. Defendants Closely Monitored and Tracked Each Korlym Prescription Prior to and During the Class Period Through Internal Company Reports and at Company Meetings

375. In addition to joining clinical specialists to visit physicians, Defendant Belanoff and Defendant Maduck closely monitored and tracked each Korlym prescription that came in. Indeed, according to CW11, the Individual Defendants, along with other senior management, would wait by the fax machine when a prescription was coming in and celebrate each enrollment form that came in with a round of "high fives." Defendants Belanoff and Maduck would even send congratulatory emails to the clinical specialists the same day that the enrollment forms would arrive.

376. CW12 similarly stated that new prescriptions were tracked at Corcept on a daily basis and that Defendants watched the fax waiting for a new prescription to come in. CW13 further recalled that Defendant Maduck received weekly reports detailing each clinical specialist's pipeline and that the regional managers had a weekly call with Maduck where they would go over each region's projections and discuss the "successes" of prescriptions achieved.

377. In addition, according to CW13 and CW14, at each Annual National Sales Meeting, Defendants displayed a Ranking Report of all clinical specialist from most enrollments to least for all attendees to see. Tyler Franklin was always at the top of the list.

378. Defendant Belanoff confirmed the CW accounts, admitting during a November 2, 2017 earnings call conference call that "[w]e know where are they all – *essentially, every single tablet goes*."

379. Further, according to CW 11, Defendant Belanoff would occasionally be the one to flag incorrect ICD-10 codes on enrollment forms and then send the forms to Dr. Moraitis to "fix" the forms to guarantee insurance reimbursements.

380. Accordingly, at all times relevant to this Action, Defendants had access to internal company information regarding in the off-label marketing scheme and were closely monitoring and tracking the Korlym prescriptions as they came into the company.

5. Defendants' Admission they knew the Basis for Each Korlym User's Prescription, the Identity of Each User, and His or Her Prescribing Physician Supports Scienter

381. Because Korlym, through its active ingredient mifepristone, is an abortifacient, it is subject to tight FDA restrictions regarding its prescription. Thus, as the Individual Defendants admit, they knew every patient on Korlym and the indication for which it was prescribed, among other information. As Defendant Belanoff stated on the November 2, 2017 earnings call in response to a question regarding the potential patient transition from Korlym to any newly approved second-generation Corcept drug offering:

> **It's intended so that there will be very tight control of where Korlym tablets are. We know where are they all – *essentially, every single tablet goes.*** And because relacorilant is not the abortion pill, I think that portion of the equation really changes tremendously. In addition to that, while we're not expecting relacorilant to have any better efficacy than Korlym because Korlym has superb efficacy, taking away the progesterone side effects, particularly for women who are the majority of patients with Cushing's syndrome, things get much, much easier for them and for their doctors in prescribing the medication.

382. Defendant Belanoff, again, acknowledged Corcept's tight control over the distribution of Korlym based on its pharmacological properties when, during an earnings call on May 8, 2018, he stated, "Because its active ingredient is the same as the abortion pills, Korlym's distribution is tightly controlled."

383. On this same call, Defendant Belanoff invoked the stringent distribution controls when discussing the possibility of Korlym's use for more widespread conditions: "The observation [is] that Korlym reverses fatty liver disease in patients with Cushing's syndrome. But despite its demonstrated

promise, Korlym's abortifacient properties which necessitate tightly controlled distribution, disqualify it as a treatment for these widespread conditions."

384. In another example, on an earnings call dated May 1, 2017, Defendant Robb stated, "because ***we sell directly to patients***, we have actually pretty - very good insight into what sort of discounts from our full price that we expect to see."

385. Moreover, during the Class Period, Defendant Maduck, Corcept's Senior Vice President of Commercial, confirmed the Company's insight into the scope of Korlym's end-users, stating on an earnings call held on November 1, 2018, "So 99% of our Korlym patients are on label – prescription, sorry, are on-label and we continue to see favorable insurance reimbursement." Plaintiff alleges this statement was false because the majority, or at least over half of Korlym prescriptions were off label. *See* False Statement Chart, Statement No. 26.

386. Further, the Company, again, invoked this statistic in its February 5, 2019 "White Paper" wherein it refuted the SIRF Report and Blue Orca Report, as filed as an exhibit to a Form 8-K signed by Defendant Robb. In this "white paper" response (the heading of which listed defendant Robb as a contact person), the Company stated:

> **In fact,** we do not. ***Literally, ninety-nine percent (99%) of the Korlym we sell goes to patients whose diagnosis matches Korlym's FDA-approved label***. Insurance companies require proof of this diagnosis before agreeing to cover the cost of Korlym. Patients who do not have a properly documented diagnosis of Cushing's syndrome rarely receive reimbursement.
>
> * * *
>
> **Do you promote for diagnoses other than Cushing's syndrome?** No. We only promote Korlym for its approved use. Literally, ninety-nine percent (99%) of the Korlym we sell goes to patients whose diagnosis matches Korlym's FDA-approved label. Our vigilance is matched by insurance companies, which in most cases insist on comprehensively reviewing a patient's medical records to confirm the diagnosis of Cushing's syndrome before paying for the drug.

387. Thus, by Defendants' own admission, the Company tracked Korlym's patient population to determine on-label versus off-label usage and thus, would have been aware of Corcept's aggressive off-label marketing practices, as well as the impact such off-label marketing had on Korlym prescription trends.

388. With such clear insight into the end-users of Korlym, Defendants either knew of and

endorsed, or recklessly disregarded the massive increased prescription rates in small geographic clusters like the North Charleston, South Carolina area where Drs. Back and Mathews practice medicine or Ingleside, Texas where the Ingleside Physicians practice medicine.

389. Additionally, the Company's services agreement with Dohmen required Dohmen to provide Corcept with an itemized invoice every month for the services provided and six daily financial reports. It is reasonable to infer that Optime is under a similar obligation, particularly as the Company's direct-to-customer sales model has not shifted and with Corcept's demonstrated control over its specialty pharmacy (including assisting in the creation of the pharmacy's processes by copying those employed by Dohmen).

390. Moreover, the direct-to-customer sales model necessarily requires the Company to know both the prescribing physician and the prescribed indication of the patient receiving Korlym, as well as general inventory levels of Korlym at all times, supporting an inference of knowledge or reckless disregard of the Company's off-label marketing trends based on the sharp increase in off-label prescriptions of Korlym that these reports would have necessarily shown.

391. Accordingly, at all times relevant to this Action, the Company and the Individual Defendants knew or had access to and recklessly disregarded internal Company information that showed Korlym was being prescribed off-label as a result of the Company's pivot in sales strategies.

6. CWs Confirm that Corcept's Quarter-Over-Quarter Revenue Growth Was Driven by Off-Label Marketing of Korlym to Treat Subclinical Cushing's Patients and Patients with Other Non-Cushing's Diagnoses Such as Uncontrolled Diabetes

392. CWs 11, 12 and 13 confirmed that prior to and during the Class Period, Corcept's substantial sales growth was mainly driven by prescriptions to subclinical Cushing's patients resulting from Corcept's off-label marketing of Korlym. CW11 estimated approximately 60% of Corcept's annual sales came from prescriptions resulting form off-label marketing of Korlym to physicians. According to CW14, approximately 50% of the Korlym prescriptions came from three physicians—Drs. Jerry Back, Norman Crabb, and Robin Anderson. As alleged herein, these three physicians were well known prescribers of Korlym for off-label subclinical indications and were paid handsomely by Corcept for doing so through purported honoraria payments.

393. Moreover, the astronomical increase in Corcept's revenues during the first four quarters with Optime as a specialty pharmacy further supports Defendants' knowledge or reckless disregard for Corcept's pervasive off-label marketing practices. Korlym is used to treat a rare disease with an FDA-approved label that limits treatable population to less than 5,000 patients.

394. Yet, as demonstrated in the chart below, while Defendant Belanoff asserted that Cushing's Syndrome "is a disease where you're adding to your enrollment total by 1s and 2s everywhere you go," Corcept was somehow able to report near or over 100% quarter-over-quarter revenue growth for the first year Optime was acting as its specialty pharmacy, until insurance companies began tightening their approval requirements in mid-2018, as discussed above (*see* Section IV.G, *supra*).

Quarter	Revenue (in thousands)	Quarter over Quarter % Increase
Q3 2017	$42,763	96.8%
Q4 2017	$53,280	123.8%
Q1 2018	$57,659	108.9%
Q2 2018	$62,312	75.2%
Q3 2018	$64,445	50.7%
Q4 2018	$66,831	25.5%
Q1 2019	$64,829	12.4%

395. In context of their total revenue for the year, the growth is even more alarming:

Fiscal Year	Revenue (in thousands)	Year over Year increase
2016	81,321	61.7%
2017	159,201	95.8%
2018	251,247	57.8%
2019	306,486	21.99%

396. A drug that can only be prescribed for a limited subset of a rare disease affecting only 20,000 patients in the United States could not experience such massive revenue growth in a short period of time absent off-label prescriptions.

397. As Defendants Belanoff and Maduck "high fived" and sent congratulatory emails after every Korlym enrollment, they were aware or recklessly disregarded situations such as the Ingleside Physicians prescribing Korlym to 59 Medicare patients in 2018 alone.

398. CW14 confirmed that the "impossible" sales numbers were a frequent topic of conversation at the quarterly regional managers meetings. CW14 and other regional managers would consistently question Burke and Defendant Maduck about how it was possible for these physicians to be prescribing so much Korlym without going off-label. In response, Maduck and Burke told clinical specialists they just needed to find physicians who were willing to prescribe Korlym when the DST came back below the 1.8 medical guidelines. CW14 stated that in order to find such physicians, the clinical specialist would first have to present the idea that patients with a DST below 1.8 could still benefit from being treated with Korlym—e.g., off-label marketing.

399. Thus, Defendants either knew or recklessly disregarded that these revenue numbers were not the result of prescriptions increasing by "1s and 2s".

7. Defendant Maduck, Corcept's Senior Vice President of Commercial and a Company Executive Officer, Was Aware of Corcept's Off-Label Marketing Scheme through His Responsibilities Overseeing Corcept's Sales Staff and Korlym's Marketing Practices

400. During the Class Period, Defendant Maduck was one of just four executive officers for the Company, along with Defendants Belanoff and Robb, and Dr. Robert S. Fishman, the Company's former Chief Medical Officer ("CMO") who submitted his resignation from the Company on November 13, 2018, less than two weeks after Maduck's false statement that 99% of all Korlym prescriptions "are on-label."

401. Further, Defendant Maduck, as Corcept's head of commercial operations, was directly responsible for overseeing the sales staff and the Company's education and training programs. Defendant Maduck's oversight over Korlym's marketing practices is evidenced by the comments made by Defendant Belanoff during various earnings calls during the Class Period, including his reference to Maduck as the individual who "runs the whole Cushing's syndrome franchise" on November 2, 2017, and his lauding of Maduck's work on February 22, 2018 when he stated, "I would like to introduce you to a person who runs our Cushing's syndrome franchise, Sean Maduck, who's really done a fabulous job in really ***educating really about the people, about the disease throughout the country***."

402. Corcept clinical specialists received marketing materials that they were instructed to provide to physicians promoting off-label use of Korlym. Defendant Maduck, as head of commercial operations, would have to have been aware of the marketing materials provided to his sales staff

403. Thus, it is reasonable to infer that Defendant Maduck, as the head of sales and marketing for Corcept responsible for overseeing such activities, and who admittedly "educat[ed] people" (including physicians) "throughout the country" about Cushing's was aware of Corcept's off-label marketing practices.

404. Moreover, as one of just three to four Corcept executive officers during the Class Period (two of whom were, at all relevant times, Defendants Belanoff and Robb), Maduck would have regularly reported on the Company's marketing strategies to the other Individual Defendants. Further, given the small size of the Company and the executive management team, it is reasonable to infer that the other Individual Defendants had access to the same information upon which Maduck based his false statement that 99% of all Korlym prescriptions "are on-label," as well as general information related to Korlym prescription trends and marketing.

8. Korlym is Corcept's Only FDA-Approved Drug and Revenue Source

405. As set forth above, Corcept's ***only source of revenue*** during the Class Period came from its sales of Korlym, representing the Company's "core operations."

406. Defendants acknowledged the importance of Korlym in the Company's SEC filings, stating, *inter alia*, "We anticipate that for the foreseeable future our ability to generate meaningful revenue and fund our commercial operations and development programs **will be solely dependent on the successful commercialization of Korlym**."

407. Defendant Belanoff further stated on an earnings call held May 1, 2017 that "the best way to think of Corcept" is as "a **self-funding company** with a vibrant clinical platform."

408. Further, the Company's direct-to-customer distribution model illuminates the importance of Corcept's relationship with prescribing physicians and its specialty pharmacy. Unlike other pharmaceutical companies who sell their drugs to wholesale drug distributors, which then supply large chain pharmacies, Corcept only distributes Korlym directly to patients through its specialty pharmacy, Optime. Importantly, under this model, Optime never takes title to Korlym and acts only as the conduit

to the end-patient. This means that at any moment, Defendants have complete transparency into the end-users of Korlym, including the basis for each prescription.

9. Corcept's Failure to Follow Professional Society Guidelines Supports an Inference of Scienter

409. As discussed above, the Endocrine Societies have very specific diagnosis and treatment guidelines regarding Cushing's Syndrome. The Diagnosis Guidelines provide that a non-Endocrinologist clinician may perform the initial screen for Cushing's Syndrome and, in the event this initial test is abnormal, a further evaluation by an Endocrinologist (including the performance of a second screening test to either confirm the initial test or identify a false positive) is recommended to confirm or exclude an endogenous Cushing's Syndrome diagnosis. Additionally, the Diagnosis Guidelines go in depth on the limitations of the four recommended tests for Cushing's Syndrome and stress the need for confirmatory testing.

410. Yet confidential witnesses have all confirmed that the marketing message Corcept's clinical specialists were actually using ignored the guidelines and, rather, instructed them to employ a single test to screen for Cushing's Syndrome—the single 1-mg overnight Dexamethasone suppression test—and if it came back even close to positive, they should immediately prescribe Korlym and use it as a diagnostic tool for Cushing's Syndrome.

411. The Defendants, whose only product is for Cushing's Syndrome, either knew or recklessly disregarded the proper diagnostic guidelines for Cushing's Syndrome in an effort to induce physicians to improperly diagnose patients as having Cushing's Syndrome in an effort to increase Korlym sales.

10. Defendants' Payments to Physicians Who Prescribe the Most Korlym Prescriptions Supports Scienter

412. CW11 confirmed that Corcept used honoraria payments to speakers as a means to facilitate off-label marketing of Korlym.

413. Indeed, to induce physician speakers to market Korlym for off-label uses during dinners and other engagements, Corcept paid them significant sums, which increased by 322% to $366,750 in 2017. Corcept's honoraria spending alone in 2017 almost exceeded all payments not associated with a

research study to physicians in 2016 combined. Honoraria payments consisted of just 22.8% of Corcept's non-research study payments to physicians in 2016. That number jumped to 47.4% in 2017.

414. That these honoraria payments were made to physicians who had the most Korlym prescriptions is no coincidence. As previously discussed, Drs. Back and Mathews were two of the largest prescribers of Korlym in 2017, prescribing the drug to at least 23 patients and 13 patients, respectively. Drs. Back and Mathews were also second and third in receiving honoraria payments in that time frame, receiving $47,000 and $48,000, respectively. Notably, Tyler Franklin, who was known throughout Corcept as marketing Korlym off-label and obtaining massive bonuses as a result, was the clinical specialist for both Back and Mathews. CW11 estimates that approximately 90% of Franklin's Corcept sales were for off-label prescriptions of Korlym.

415. Drs. Back and Mathews were only behind Dr. Hanford Yau who received $77,000 in honoraria payments in 2017. According to the SIRF Report, Dr. Yau prescribed Korlym to 27 patients in 2017.

416. Thus, this massive increase in Corcept's spending to physicians who prescribe the most Korlym supports an inference of Defendants' knowledge and/or recklessness with respect to the off-label marketing.

11. Corcept's Limited Number of Sales Regions and Clinical Specialists Supports Scienter

417. The limited number of just six sales regions in which the Company operates and a small number of clinical specialists covering these regions further supports Defendants' actual knowledge or recklessness related to the off-label marketing scheme.

418. On a November 1, 2018 earnings call, Defendant Maduck stated, "In terms of our prescribing, as everybody may remember, we discussed this on previous calls, we have 6 sales regions that are comprised of 40 clinical specialists that are evenly distributed across the country in those regions."

419. Further, the Company's overall relatively small size,[56] including the small salesforce tasked with promoting Korlym, further lends to an inference that the Individual Defendants knew or were reckless in not knowing of the off-label marketing scheme and relationship with Optime. According to the Company's Annual Report on Form 10-K for the period-ending December 31, 2018 filed with the SEC on February 26, 2019, Corcept had 166 employees.

420. With such a small number of sales force members, the Individual Defendants either knew, or had the ability to know and recklessly disregarded, the off-label marketing strategies being pushed across the entire country.

12. Defendants' Awards to Clinical Specialists Supports Their Knowledge of the Clinical Specialists' Off-Label Marketing

421. Further, the Company clearly monitored the performance of its individual sales team members, bestowing upon them various accolades and awards. Indeed, Tyler Franklin in South Carolina, alone, received recognition as the Clinical Specialist of the Year and membership in Corcept's "President's Club" in 2016, 2017, and 2018. CW11 recalled Franklin received a $1 million dollar bonus in 2017, which based on CW11's experience could only be possible if 90% of Franklin's sales were off-label.[57]

422. Thus, where Defendant Belanoff asserted in a November 7, 2019 earnings call that "this is a disease where you're adding to your enrollment total by 1s and 2s everywhere you go," any sales team member whose yearly numbers increased by the dozens (as was necessarily the case for Tyler Franklin based on Drs. Back and Mathews' drastic increase in Medicare Part D claims in 2017) should have, and did, draw the attention of Corcept executive management, lending to an inference that the Company was either aware of the off-label marketing push among its sales staff or recklessly disregarded it.

[56] According to the Company's Annual Report on Form 10-K for the period-ending December 31, 2017 filed with the SEC on February 28, 2018, Corcept had 136 employees. According to the Company's Annual Report on Form 10-K for the period-ending December 31, 2016 filed with the SEC on March 6, 2017, Corcept had 106 employees.

[57] According to CW11, Defendants Maduck and Belanoff set the sales quotas along with Tom Burke and the Individual Defendants and the Board approved the commissions paid to clinical specialists who met their quarterly sales quotas.

13. The Temporal Proximity of Corcept's Chief Medical Officer's Departure and Defendants' False Statements Regarding On-Label Use Supports an Inference of Scienter

423. As set forth above, on November 1, 2018, Defendant Maduck asserted that "99% of [the Company's] Korlym patients are on label" – a false and misleading statement given that the Company's growth had been driven by an off-label marketing scheme that encouraged non-Endocrinologists to prescribe Korlym without a confirmed endogenous Cushing's Syndrome diagnosis and in the absence of any surgical intervention (or evaluation for surgical suitability).

424. On November 19, 2018, the Company filed with the SEC a Form 8-K, announcing that, on November 13, 2018, the Company's CMO Dr. Robert S. Fishman tendered his resignation, effective January 31, 2019. Dr. Fishman was the CMO of Corcept from September 2015 through January 31, 2019.

425. The suspicious timing of Fishman's resignation and Defendant Maduck's false statement regarding purported on-label prescriptions supports an inference of scienter.

426. As CMO, Dr. Fishman was one of just four executive officers for the Company (alongside Defendants Belanoff, Robb, and Maduck). Further, at the time of his resignation, Fishman had not yet reached retirement age and was just 56 years old, further illustrated by the fact that Dr. Fishman has continued to work in pharmaceutical space since his departure from the Company, first as chief medical officer of Xoc Pharmaceuticals, Inc. from February 2019 to October 2020, and then assuming the same role as Chief Medical officer at 4D Molecular Therapeutics from October 2020 to present. Dr. Fishman's departure from the Company also does not appear to have been based on any inability to perform in his role, as he held the position of CMO for more than three years and during that period he received base salary increases approved by the Compensation Committee of the Corcept Board of Directors (3% increase in 2016, 5.5% increase in 2017, and 4% increase in 2018), equity grants, and discretionary cash bonuses, including one in February 2019 (the month *after* his departure from Corcept) of more than $200,00 based on the Company's achievement of its "significant clinical, commercial, and financial goals."

427. Further, Dr. Fishman's departure appears to have been wholly unexpected as there was no succession plan in place at the time of the November announcement. The circumstances of Dr.

Fishman's ultimate departure in January 2019 are particularly suspicious given that a replacement had not yet been named, and would not be named until March 18, 2019 when the Company announced the hiring of Dr. Andreas Grauer, an outside hire who had previously been Vice President of Global Development at Amgen Inc.

B. The Individual Defendants' Motive to Commit Fraud

1. The Individual Defendants Were Motivated to Conduct the Alleged Fraud in Order to Capitalize on the Company's Market Exclusivity before its Expiration

428. As alleged herein, Korlym was designated as an "Orphan Drug" by the FDA in 2007. One of the benefits of having orphan status is seven years of marketing exclusivity for the drug from the date the FDA approves it. Korlym's marketing exclusivity as a result of its orphan status expired on February 17, 2019.

429. Korlym's underlying drug, mifepristone, was developed in 1980 and, as such, its underlying composition of matter patents covering its structure have expired. This left Corcept open to potential generic competitors when its market exclusivity period expired. In anticipation of this, Teva submitted a new drug application for a generic version of Korlym in early 2018. Sun Ltd. also filed a generic drug application in June of 2019. Corcept has since been locked in litigation with both companies, claiming they are violating Corcept's method of use patents.

430. Defendants were aware of and relied on the advantages of having an Orphan Drug market exclusivity period. According to the Company's Annual Report on Form 10-K for each fiscal year between 2012 and 2017, "to protect our market for Korlym, [Corcept] re[lies] on the exclusive marketing rights conferred as a benefit of orphan drug designation and marketing exclusivity in the United States."

431. With the market exclusivity period coming to a close in February 2019, the Defendants needed to employ new strategies to maximize profits from Korlym prior to the period's expiration, while also "protecting" their market share to fend off potential generic competitors by indoctrinating non-Endocrinologists for off-label indications – physicians other companies entering the market would not target in fear of regulatory blowback.

2. The Individual Defendants Were Motivated to Commit the Alleged Fraud in Order to Continue Funding Operations and the Development of Relacorilant

432. Corcept derives 100 percent of its revenue from sales of Korlym. As the Company stated in its annual report, "[Corcept's] ability to generate revenue and fund our commercial operations and development programs is entirely dependent on the sale of Korlym." Defendant Belanoff stated on the Q1 2017 earning call on May 1, 2017 that Corcept's "goal really has been… to be self-funding."

433. Defendant Belanoff further stated "the best way to think of Corcept" is as "a self-funding company with a vibrant clinical platform that's in development and the growth of our commercial revenue matches it quite well."

434. According to Defendant Belanoff on the Q2 2017 earnings call on August 1, 2017, Corcept's research and development projects included the "Cushing's Syndrome business conducting Phase 2 and Phase 3 trials of [Corcept's] proprietary selective cortisol modulator 125134 in both Cushing's Syndrome and solid tumor cancers, conducting the Phase 1 and Phase 2 trials of CORT125281 for castration-resistant prostate cancer, and the Phase 1 trial of Cost 118335 and advancing into the clinic additional next-generation cortisol modulators."

435. Defendant Belanoff stated on an investor call on August 1, 2017 that "as [Corcept's] studies get further along they become more expensive" and to "expect increasing costs as we get deeper into the studies."

436. There was a sharp increase in Corcept's Research and Development Spending in 2017 and 2018. After staying between $14 million and $24 million for five years between 2011 and 2016, research and development spending hit $40.4 million in 2017, before almost doubling in 2017 to $75.2 million.

Year	Research and Development Spending (in millions)
2018	$75.2
2017	$40.4
2016	$23.8
2015	$15.4
2014	$18.4
2013	$20.5
2012	$14.1

2011	$21

437. The Individual Defendants knew of the increasingly high research and development costs Corcept was expected to (and did) incur in 2017 and 2018. The Individual Defendants felt pressure to keep Corcept as a "self-funding" company. This led the Individual Defendants to implement the aforementioned off-label marketing strategy for Korlym and install Optime as Corcept's specialty pharmacy as a means of generating revenue to sustain Corcept's operations.

C. Corporate Scienter is Additionally Supported by the Actions of Corcept's Employees

438. In addition to the inference of Corcept's scienter stemming from the above-alleged scienter of Individual Defendants Belanoff, Robb, and Maduck, Corcept's corporate scienter is further evidenced by the actions of its employees.

439. As set forth above, Corcept's efforts to clandestinely prop up Optime and manufacture a breach of its contract with Dohmen for the purpose of facilitating its off-label marketing scheme create an inference of the Company's knowledge.

440. As set forth in Dohmen's complaint against Corcept, on April 12, 2017, Amy Hanstein, Corcept's Cost Accounting Manager sent an email to Tina Pheasant, Vice President of IT Pharmacy Services for Optime, in which Hanstein requested modification to Optime's mock-up reports. In this email, Hanstein revealed that she "tried to bring this up on our call approximately a month ago, but you said this would have to be a phase 2, because you were only copying the existing reports." As such, it is clear that Corcept and Optime employees were maneuvering to transition the Company's specialty pharmacy business – an essential portion of Corcept's business (given its reliance on a specialty pharmacy) that was necessarily dictated from the Company's senior-most executives – to Dohmen as early as March 2017.

441. Further, Individual Defendants Robb and Maduck were each personally involved in the meetings between Corcept and Dohmen related to Dohmen's termination. On July 12, 2017, the CEO of Dohmen's parent company met with Defendants Robb and Maduck in San Francisco, California, seeking to address Corcept's claim of a breach.

442. A subsequent follow-up meeting between Dohmen President Dan Johnson and Defendant Maduck occurred on July 18, 2017 in Denver, Colorado.

443. This direct participation in the Dohmen/Optime transition by the Company's senior executives supports an inference of corporate scienter.

444. Moreover, Tom Burke, VP of Sales who reported directly to Defendant Maduck throughout the Class Period, participated in every aspect of the off-label scheme. Burke instructed regional sales managers and clinical specialists to target and find physicians who were willing to prescribe Korlym as a first line treatment for patients whose DST score was in the grey area or even below without further testing and as a pre-treatment to surgery. Burke also attended and was the primary speaker at the Annual National Sales Meetings and quarterly management meetings where sales discussing the Company's new directive to target such patients and encouraged clinical specialists to get sales like Balzanti and Franklin, two clinical specialists widely known to achieve high sales through off-label marketing.

445. Additionally, the actions of Corcept's sales staff promoting off-label use of Korlym supports the Company's scienter. Across the country, Corcept's sales staff was uniformly pushing non-Endocrinologists to rely on a single DST screening test among their patients to validate a Korlym prescription despite the fact that clearly established Diagnosis Guidelines call for multiple confirmatory tests and that the DST itself is prone to yielding incorrect results given the targeted patient population and interference from other medications.

446. Thus, the scienter of Corcept related to the alleged off-label marketing scheme and interplay of that scheme with the transition to Optime, can be inferred.

IX. LOSS CAUSATION

447. At all relevant times, the market for Corcept securities was open, well-developed, and efficient. During the Class Period, Defendants named in this Action materially misled the investing public by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make their statements, as set forth herein, not false and/or misleading, thereby inflating the price of Corcept securities. These material misstatements and omissions concerned the sales and profitability of the Company's only source of revenue, Korlym. Defendants' materially false or misleading statements and omissions of material fact, alleged above in Section V, caused the price of

Corcept's securities to be artificially inflated, and/or maintained such artificial inflation during the Class Period, operating as a fraud or deceit upon Plaintiff and other Class Period purchasers of Corcept securities.

448. Plaintiff and other members of the Class purchased or otherwise acquired Corcept securities relying upon the integrity of the market of Corcept and market information related to the Company and have been damaged thereby.

449. As Defendants' misrepresentations and fraudulent conduct were disclosed and became apparent to the market, the artificial inflation in the price of Corcept's securities was removed, and the price of Corcept shares fell.

450. The first corrective disclosure occurred on January 25, 2019, when SIRF published the SIRF Report revealing for the first time that Corcept used off-label marketing messages to induce physicians to prescribe Korlym for off-label indications and paid such physicians for prescribing Korlym off label. The SIRF Report further revealed that Corcept's off-label marketing spanned Company-wide and that Corcept's revenue growth was largely driven by off-label prescriptions.

451. The author of the SIRF Report, Roddy Boyd, is an investigative journalist who has been identified by the Huffington Post as one of the twenty-five "Most Dangerous People in Financial Media" because "he's one of the few out there with the patience and the eye for detail that this type of work requires."[58]

452. Mr. Boyd's perceived credibility to investors in Corcept is further bolstered by his professional credentials, which can be found in the "About Us" section of the website for The Foundation of Financial Journalism (formerly SIRF).[59] According to the SIRF website, Mr. Boyd has taught investigative reporting at the University of North Carolina at Chapel Hill, regularly leads seminars at Investigative Reporters & Editors conferences on financial statement analysis and fraud detection and has authored financial analysis books. In fact, the SIRF website boasts that Mr. Boyd's work "has prompted numerous regulatory, civil and criminal actions."

[58] https://www.huffpost.com/entry/best-financial-journalists_b_1605584?slideshow=true&guccounter=1#gallery/5bb2c63ce4b0480ca65bce38/12

[59] *See* https://ffj-online.org/about-us.

453. An archived version of the "About Us" section of SIRF's website from December 2018 further sets SIRF apart from other journalists:

> Our foundation produces substantive investigative reporting without fear or favor. These investigations bring to life important stories that are going untold, illuminating the many ways investors, consumers and market stakeholders are regularly misled. We accomplish this through carefully mining corporate legal and financial filings– such as a skillfully buried footnote inside a quarterly report, or an overlooked exhibit in a forgotten legal claim–which, when coupled with ample shoe leather reporting, presents the clearest possible picture of our subject.
>
> The hallmark of the foundation's reporting is a commitment to accuracy, the breadth of our news gathering and the clarity of our presentation. In doing this work, our goal is to conduct the foundation's business to meet or exceed the highest standards of non-profit governance and ethical journalism. To that end, apart from truth and increased knowledge, our work will be free of agenda. The completed investigations are published free of charge, without advertisements or sponsors.
>
> We are funded solely through the tax-deductible contributions of individual donors and foundations, none of whom derive any professional or economic benefit from this support. No one, apart from the foundation's employees and our legal advisors, has any input to editorial decisions. The foundation's employees, directors and advisors will never benefit financially from the price movements in the securities or derivatives of companies mentioned in our journalism.[60]

454. Neither SIRF, nor Roddy Boyd have any financial interest in Corcept.[61]

455. As revealed in the SIRF Report, Corcept employed a pervasive, Company-wide scheme to market Korlym to physicians for off-label use and then compensated those physicians who prescribed Korlym off-label through substantial honoraria payments. In support of its findings, the SIRF Report conducted a detailed examination of data obtained from a variety of sources, including the FDA's Adverse Events Reporting System (FAERS), Medicare Part D coverage data, the U.S. government's Open Payments database, and documents obtained through a privately submitted non-public FOIA request to the Office of Veteran's Administration.

456. The FDA FAERS data is only available through letter request and it takes weeks to receive a response. The FDA FAERS data contains medical analysis of over 146 patients who suffered

[60] Available at https://web.archive.org/web/20181211223520/http://sirf-online.org/about-us/

[61] *Id*. ("The foundation's employees, directors and advisors will never benefit financially from the price movements in the securities or derivatives of companies mentioned in our journalism.").

from an adverse event on Korlym. The FAERS data lists all drugs the patient was on, a list of additional diseases the patient has, and a medical/event narrative explaining the issue with the patient, generally written by the physician or the prescribing company.

457. The FAERS data is not understandable by the average investor. Rather, it requires a degree of expert knowledge about how the FAERS works and the specific condition being reported on (here Cushing's Syndrome). Moreover, to interpret the data and understand that it demonstrates off-label use of Korlym, an investor would have first had to research Cushing's Syndrome and the Korlym label to understand the narrow indication for which Korlym was actually approved, that Cushing's Syndrome is more prevalent in women than men and that an "unknown" diagnosis meant that the patient was put on Korlym without having a confirmed Cushing's Syndrome diagnosis. These analyses and facts, among others, are not easily understood by the average investor and require significant additional research and expertise to understand.

458. Moreover, the Open Payments data contained over 6,000 individual entries for each year during the Class Period for payments made by Corcept to physicians. The Medicare data similarly contained millions of data points for over one hundred physicians.

459. By analyzing the Open Payments and Medicare data and then cross-checking them with the FOIA data, the SIRF Report uncovered that Corcept had compensated a specific Florida doctor, Hanford Yau, $95,139.66 in 2017 after Dr. Yau's VA clinic prescribed Korlym to 50 new patients in just one year—well beyond the likely number of Cushing's Syndrome cases in such a small geographical area, particularly given the rarity of Cushing's Syndrome and the narrow Korlym FDA label. Given the sharp uptick in both prescriptions and payments to Dr. Yau, and that the Endocrinology clinic at which he worked saw primarily male patients (with Endogenous Cushing Syndrome more prevalent in females), the SIRF Report concluded that this physician was helping Corcept push its off-label message in exchange for the speaker's bureau payments.

460. The SIRF Report also uncovered a pattern of geographic clustering of supposed Cushing's Syndrome diagnoses in rural communities with small populations where, given the rarity of Cushing's Syndrome, these communities should have only had one to two such diagnoses annually, as well as numerous reported deaths in patients on Korlym with no Cushing's Syndrome diagnoses.

461. Corcept's off-label marketing scheme was not plausibly understood by the market until the SIRF Report analyzed and pieced together data from thousands of entries across several databases to uncover Corcept's widespread off-label marketing. By conducting this original analysis that has not been done before, SIRF's analysis is itself new information. Given SIRF's expert analysis and detailed investigation and analysis, it served as an authoritative source for investors.

462. Indeed, not a single analyst report issued, nor any analyst commentary or questions during Corcept's quarterly earnings calls during the Class Period made any mention of off-label marketing, the FOIA FAERS data, Corcept's excessive payments to physicians or the Medicare or Open Payments data. Nor did Corcept in any of its public statements ever direct investors to look to any of these sources for additional information.

463. Upon the news disclosed for the first time in the SIRF Report, Corcept's share price fell $1.52, or more than 11%, to close at $12.29 per share on January 25, 2019, on unusually heavy trading volume. The temporal connection between the release of the SIRF Report and the stock drop is evident, as the financial media attributed the decline to the SIRF Report's investigative findings.[62]

464. On January 31, 2019, the Company forecasted a sharp slowdown in sales of Korlym in 2019 likely due to insurance companies tightening approval guidelines after getting wind of the off-label marketing and physicians starting to become wise to Defendants' improper marketing tactics. On this news, the Company's share price fell $1.15, or more than 10%, to close at $10.03 per share on February 1, 2019, on unusually heavy trading volume.

465. As a result of their purchases of Corcept stock during the Class Period at artificially inflated prices, Plaintiff, and the other Class members suffered economic loss, i.e., damages, under the federal securities laws. The timing and magnitude of the price decline in Corcept stock negate any inference that the loss suffered by Plaintiff and the other Class members was caused by changed market conditions, macroeconomic or industry factors, or Company specific facts unrelated to the Defendants' fraudulent conduct.

[62] *See, e.g.*, The Motley Fool, Here's Why Corcept Therapeutics Stock Fell as Much as 18.5% Today, Jan. 25, 2019 (available at https://www.fool.com/investing/2019/01/25/heres-why-corcepttherapeutics-fell-as-much-as-185.aspx).

X. PRESUMPTION OF RELIANCE

466. At all relevant times, the market for Corcept securities was efficient for the following reasons:

(a) Corcept common stock met the requirements for listing, and was listed and actively traded on the Nasdaq, a highly efficient and automated market;

(b) As a regular issuer, Corcept filed periodic reports with the SEC and Nasdaq;

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

(d) Corcept was followed by four to five securities analysts employed by major brokerage firms (including Bank of America Merrill Lynch, Piper Jaffray Companies, Ladenburg Thalmann & Co. Inc., and Stifel, Nicolaus & Company, Incorporated, and B. Riley FBR, Inc.) who participated in the Company's Class Period earnings calls and wrote reports which were distributed to those brokerage firms' sales force and certain customers and each of these reports was publicly available and entered the public marketplace;

(e) Corcept had approximately 113.4 million and 114.7 million shares outstanding as of August 2, 2017 and February 5, 2019, respectively, with an average of 1.6 million shares trading daily on the Nasdaq;

(f) During the Class Period, Corcept common stock averaged a weekly trading volume of 7.5 million shares, translating to an average weekly turnover of 6.5% of the outstanding shares;

(g) On January 25, 2019, the day the SIRF Report was released, approximately 7.6 million shares were traded - 4.7 times the normal daily average;

(h) On February 1, 2019, the day after Corcept revised their projected earnings for the fiscal year, approximately 6.1 million shares were traded - 3.8 times the normal daily average;

(i) During the Class Period, the Company was eligible to register and sell its common stock pursuant to a Form S-3 shelf registration statement and, in fact, did so just prior to the commencement of the Class Period on May 5, 2017;

(j) During the Class Period, the Company's public float ranged from 79.8% to 84.5%, indicating market efficiency; and

(k) The presence of a major activist short-seller like Blue Orca supports a finding of market efficiency where there did not exist barrier to investors shorting the Company's stock during the Class Period.

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

468. Further, to the extent that the Defendants concealed or improperly failed to disclose material facts with regard to the Company, Plaintiff is entitled to a presumption of reliance in accordance with *Affiliated Ute Citizens v. United States*, 406 U.S. 128, 153 (1972).

XI. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR AND BESPEAKS CAUTION DOCTRINE

469. The statutory safe harbor and/or bespeaks caution doctrine applicable to forward-looking statements under certain circumstances does not apply to any of the materially false or misleading statements pleaded in this Complaint.

470. None of the statements complained of herein was a forward-looking statement. Rather, each was a historical statement or a statement of purportedly current facts and conditions at the time such statement was made.

471. To the extent that any of the false or misleading statements alleged herein can be construed as forward-looking, any such statement was not accompanied by meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statement. As alleged above in detail, then-existing facts contradicted Defendants' statements regarding,

inter alia, (i) the target physician demographic of the Company's marketing efforts; (ii) the aim of the Company's physician education programs and the resulting awareness they purportedly raised; (iii) the indication targeted in the Company's marketing, namely, that the Company's efforts were in line with the FDA-approved label for Korlym; (iv) the Company's compliance with FDA-regulations regarding "off-label" marketing; (v) the basis for the Company's revenue growth, as connected to broader prescription trends in its Korlym franchise, Corcept's only commercial product and profit source; (vi) the Company's controls over the processes and activities of its specialty pharmacy, Optime; (vii) the landscape with respect to insurance reimbursements for Korlym; and (viii) the percentage of Korlym patients who meet with FDA-approved indication and can be considered "on-label." Given the then-existing facts contradicting Defendants' statements, any generalized risk disclosures made by Corcept were not sufficient to insulate Defendants from liability for their materially false or misleading statements.

472. To the extent that the statutory safe harbor does apply to any forward-looking statement pleaded herein, Defendants are liable for any such statement because at the time such statement was made, the particular speaker actually knew that the statement was false or misleading.

XII. CLASS ACTION ALLEGATIONS

473. Plaintiff brings this action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of a class of all persons or entities that purchased or otherwise acquired Corcept securities during the Class Period, seeking to pursue remedies under the Exchange Act (the "Class").

474. Excluded from the Class are Corcept and its subsidiaries and affiliates, and their respective officers and directors at all relevant times, and any of their immediate families, legal representatives, heirs, successors, or assigns, and any entity in which any Defendant has or had a controlling interest.

475. Because Corcept had between 113.4 million and 114.7 million shares of common stock outstanding during the Class Period, and because its securities were actively traded on the NASDAQ, the members of the Class are so numerous that joinder of all Class members is impracticable. While the exact number of Class members is unknown at this time and can only be ascertained through discovery,

Plaintiff believes that there are, at a minimum, thousands of Class members. Members of the Class may be identified from records maintained by Corcept or its transfer agent and may be notified of the pendency of this action by mail, using forms of notice customarily used in securities class actions.

476. Plaintiff's claims are typical of those of the members of the Class, as all Class members have been similarly affected by Defendants' wrongful conduct as alleged herein.

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

478. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. These common questions include:

a) Whether Defendants violated the federal securities laws as alleged herein;

b) Whether Defendants' statements to the investing public during the Class Period misrepresented material facts about Corcept's business and operations;

c) Whether the price of Corcept's securities was artificially inflated during the Class Period; and

d) The extent to which members of the Class have sustained damages and the proper measure of damages.

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

XIII. COUNTS

COUNT I
For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against Corcept and the Individual Defendants

480. Plaintiff realleges each allegation as if fully set forth herein.

481. This claim is brought under §10(b) of the Exchange Act, 15 U.S.C. § 78j(b) and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5, against Corcept and the Individual Defendants (the "Count I Defendants").

482. The Count I Defendants (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material fact and/or omitted material facts necessary to make the statements made not misleading; and (c) engaged in acts, practices and a course of business which operated as a fraud and deceit upon Plaintiff and the Class, in violation of §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

483. The Count I Defendants individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or the mails, engaged and participated in a continuous course of conduct to conceal non-public, adverse material information about the Company's financial condition as reflected in the misrepresentations and omissions set forth above.

484. The Count I Defendants each had actual knowledge of the misrepresentations and omissions of material facts set forth herein or acted with reckless disregard for the truth by failing to ascertain and to disclose such facts even though such facts were available to them, or deliberately refrained from taking steps necessary to discover whether the material facts were false or misleading.

485. As a result of the Count I Defendants' dissemination of materially false and misleading information and their failure to disclose material facts, Plaintiff and the Class were misled into believing that the Company's statements and other disclosures were true, accurate, and complete.

486. Corcept is liable for the acts of the Individual Defendants and other Company personnel referenced herein under the doctrine of *respondeat superior*, as those persons were acting as the officers, directors, and/or agents of Corcept in taking the actions alleged herein.

487. Plaintiff and the Class purchased Corcept securities, without knowing that the Count I Defendants had misstated or omitted material facts about the Company's financial performance or prospects. In so doing, Plaintiff and the Class relied directly or indirectly on false and misleading statements made by the Count I Defendants, and/or an absence of material adverse information that was known to the Count I Defendants or recklessly disregarded by them but not disclosed in the Count I Defendants' public statements. Plaintiff and the Class were damaged as a result of their reliance on the Count I Defendants' false statements and misrepresentations and omissions of material facts.

488. At the time of the Count I Defendants' false statements, misrepresentations and omissions, Plaintiff and the Class were unaware of their falsity and believed them to be true. Plaintiff

and the Class would not otherwise have purchased Corcept securities had they known the truth about the matters discussed above.

489. By virtue of the foregoing, the Count I Defendants have violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

490. As a direct and proximate result of the Count I Defendants' wrongful conduct, Plaintiff and the Class have suffered damages in connection with their purchase of Corcept securities.

COUNT II
For Violations of Section 20(a) of the Exchange Act
Against Corcept and the Individual Defendants

491. Plaintiff realleges each allegation as if fully set forth herein.

492. This claim is brought under §20(a) of the Exchange Act, 15 U.S.C. § 78t, against Corcept and the Individual Defendants (the "Count II Defendants").

493. Each of the Count II Defendants, by reason of their status as senior executive officers and/or directors of Corcept, directly or indirectly, controlled the conduct of the Company's business and its representations to Plaintiff and the Class, within the meaning of §20(a) of the Exchange Act. The Count II Defendants directly or indirectly controlled the content of the Company's SEC statements and press releases related to Plaintiff and the Class' investments in Corcept securities within the meaning of §20(a) of the Exchange Act. Therefore, the Count II Defendants are jointly and severally liable for the Company's fraud, as alleged herein.

494. The Count II Defendants controlled and had the authority to control the content of the Company's SEC statements and press releases. Because of their close involvement in the everyday activities of the Company, and because of their wide-ranging supervisory authority, the Count II Defendants reviewed or had the opportunity to review these documents prior to their issuance or could have prevented their issuance or caused them to be corrected.

495. The Count II Defendants knew or recklessly disregarded the fact that Corcept's representations were materially false and misleading and/or omitted material facts when made. In so doing, the Count II Defendants did not act in good faith.

496. By virtue of their high-level positions and their participation in and awareness of Corcept's operations and public statements, the Count II Defendants were able to and did influence and

control Corcept's decision-making, including controlling the content and dissemination of the documents that Plaintiff and the Class contend contained materially false and misleading information and on which Plaintiff and the Class relied.

497. The Count II Defendants had the power to control or influence the statements made giving rise to the securities violations alleged herein, and as set forth more fully above.

498. As set forth herein, the Count II Defendants each violated §10(b) of the Exchange Act and Rule 10b-5, thereunder, by their acts and omissions as alleged herein. By virtue of their positions as controlling persons, the Individual Defendants are also liable pursuant to §20(a) of the Exchange Act.

499. As a direct and proximate result of the Count II Defendants' wrongful conduct, Plaintiff and the Class suffered damages in connection with their purchase of Corcept securities.

XIV. PRAYER FOR RELIEF

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

A. Declaring this action to be a proper class action pursuant to Rule 23 of the Federal Rules of Civil Procedure and certifying Plaintiff as a representative of the Class;

B. Awarding Plaintiff and the members of the Class damages, including interest;

C. Awarding Plaintiff reasonable costs and attorneys' fees; and

D. Awarding such other relief as the Court may deem just and proper.

XV. JURY DEMAND

In accordance with Fed. R. Civ. P. 38(b), Plaintiff demands a jury trial of all issues involved, now, or in the future, in this action.

Dated: December 21, 2020

Respectfully submitted,

LEVI & KORSINSKY, LLP

/s/Shannon L. Hopkins

Adam M. Apton (SBN 316506)
Adam C. McCall (SBN 302130)
388 Market Street, Suite 1300
San Francisco, CA 94111
Tel: (415) 373-1671
Email: aapton@zlk.com
Email: amccall@zlk.com

Shannon L. Hopkins (admitted *pro hac vice*)
Sebastiano Tornatore (admitted *pro hac vice*)
Michael J. Keating
(to be admitted *pro hac vice*)
1111 Summer Street, Suite 403
Stamford, CT 06905
Tel: (203) 992-4523
Email: shopkins@zlk.com
Email: stornatore@zlk.com

Counsel for Lead Plaintiff the Ferraro Family Foundation, Inc. and James L. Ferraro

PROOF OF SERVICE

I hereby certify that on December 21, 2020, a copy of the foregoing was filed electronically and served by mail on anyone unable to accept electronic filing. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic Filing. Parties may access this filing through the Court's CM/ECF System.

/s/Shannon L. Hopkins
Shannon L. Hopkins