UNITED STATES DISTRICT COURT

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

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' THIRD AMENDED COMPLANT

This case is a putative securities class action against Corcept Therapeutics Incorporated ("Corcept"); its Chief Executive Officer, Joseph K. Belanoff; its Chief Financial Officer, Charles Robb; and its Vice President of Commercial Sean Maduck (collectively, "Defendants"). Lead Plaintiff Ferraro Family Foundation, Inc. and James L. Ferraro ("Plaintiffs") bring this suit on behalf of "all other persons similarly situated who purchased or otherwise acquired Corcept securities between August 2, 2017 and January 31, 2019, inclusive (the 'Class Period')." Third Amended Complaint, at 1, ECF No. 127 ("TAC").

Before the Court is Defendants' motion to dismiss. ECF No. 130 ("Mot."). Having considered the submissions of the parties, the relevant law, and the record in this case, the Court GRANTS in part and DENIES in part Defendants' motion to dismiss.

I. BACKGROUND

A. Factual Background

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." TAC at ¶ 38. Defendant Joseph K. Belanoff ("Belanoff") is a co-founder of Corcept and has served as Chief Executive Officer ("CEO") and Director of Corcept since 1999, and President of Corcept since 2014. *Id.* at ¶ 39. Defendant Charles Robb ("Robb") has been Corcept's Chief Financial Officer since 2011. *Id.* at ¶ 40. Defendant Sean Maduck ("Maduck") was Corcept's Vice President ("VP") of Sales and Marketing from 2012 to 2016 and has been Corcept's Senior VP of Commercial since 2016. *Id.* at ¶ 41.

1. Orphan Drug Designation and FDA Approval

In July of 2007, the Food and Drug Administration ("FDA") granted Corcept orphan drug designation for its mifepristone drug, Korlym, which treats endogenous Cushing Syndrome. This designation conferred Corcept with market exclusivity, among other benefits, under the Orphan Drug Act of 1983. *Id.* at ¶ 59. In April of 2011, Corcept submitted a New Drug Application ("NDA") for Korlym to the FDA, which sought regulatory approval for the use of Korlym as a general treatment for all forms of endogenous Cushing's syndrome. *Id.* at ¶ 74. In February of 2012, the FDA approved the use of Korlym "to treat Endogenous Cushing Syndrome in patients with hyperglycemia who have type 2 diabetes or glucose intolerance and who have failed or are ineligible for surgery." *Id.* at ¶ 75. Korlym is approved only to treat endogenous Cushing Syndrome and currently generates 100% of Corcept's revenue. *Id.* at ¶ 63. There are two recognized forms of Cushing Syndrome, exogenous and endogenous. Endogenous Cushing

Syndrome is far more rare, and treatment requires surgery, radiation, or medications. *Id.* at ¶ 60–61. Treatment is usually provided by an endocrinologist: a physician who specializes in conditions that affect the body's adrenals and other glands. There are an estimated 20,000 people in the United States with Cushing's Syndrome. *Id.* at ¶ 67.

When it approved Corcept's NDA for Korlym, the FDA required Corcept to "'establish a distribution program through a central pharmacy' where 'physicians can submit their prescriptions . . . to have Korlym delivered directly to the patient.'" *Id.* at ¶ 112 (quoting from FDA's summary review). Corcept entered into an agreement with Dohmen Life Sciences Services, LLC ("Dohmen") in May of 2013 to provide this service. *Id.* at ¶ 115. Per the terms of the service agreement, Dohmen distributed Korlym to patients and recorded inventory levels. *Id.* at ¶ 116. Dohmen was also responsible for providing Corcept with a monthly itemized invoice for services provided and six financial reports each day. *Id.* at ¶ 120.

2. Corcept's Expiring Market Exclusivity

Due to Korlym's Orphan Drug Designation, Corcept had seven years of market exclusivity for Korlym, which expired in February of 2019. *Id.* at ¶ 128. Plaintiffs allege that due to Korlym's expiring market exclusivity, which would bring inexpensive generics onto the market, Defendants began to push "off-label" use of Korlym to physicians in order to generate revenue in order to sustain Corcept until its next drug could be developed. *Id.* at ¶ 136. Furthermore, Corcept reported in its December 31, 2017 10-K and June 30, 2019 10-Q filings with the Securities and Exchange Commission ("SEC") that other pharmaceutical companies had applied for FDA approval to manufacture generic versions of Korlym. *Id.* at ¶¶ 128–129. Plaintiffs allege that Corcept is now engaged in litigation with other pharmaceutical drug makers regarding the manufacturing of generic versions of Korlym. *Id.* at ¶ 130.

Plaintiffs allege that in reaction to this looming loss of market exclusivity, Defendants began to aggressively market Korlym to specialist endocrinologists. *Id.* at ¶ 131. When that proved insufficient, Defendants began to market Korlym to "less knowledgeable non-Specialist

Endocrinologists and [Primary Care Physicians] such as Internal Medicine physicians (also known as Internists) and Family Medicine physicians." *Id.* at ¶ 136. Plaintiffs also allege that Defendants ended their specialty pharmacy agreement with Dohmen and entered into a new specialty pharmacy agreement with Optime Care, LLC ("Optime"), in order to better conduct this new marketing campaign for Korlym. *Id.* at ¶ 138. Optime's co-founders and CFO are all former Dohmen employees. *Id.* at ¶ 139. Plaintiffs allege that the service agreement between Corcept and Optime was structured in such a way as to allow Corcept to "exert control over Optime, treating Optime as its ministerial arm while providing strict-day-to-day oversight on any project it sees fit." *Id.* at ¶ 147.

In order to market Korlym, Plaintiffs allege that Corcept makes payments to physicians to promote awareness and adoption of Korlym. Although Plaintiffs generally use the broad term "payments" when discussing Corcept's marketing practices, it appears that there are three forms of payments to which Plaintiffs are referring. One is essentially reimbursement for food and beverage expenses incurred at informal dinners that physicians can hold to discuss their use of Korlym with other medical professionals. *See, e.g., id.* ¶ 19. Another form of payment is "honoraria payments." Plaintiffs allege that these honoraria payments are "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." *Id.* at ¶ 308. Finally, there are "consulting fees." Plaintiffs distinguish honoraria payments from consulting fees by explaining that honoraria payments "are generally reserved for a one-time short duration activity" and "are generally provided for services which custom prohibits a price from being set." *Id.* at ¶ 302. Throughout the TAC, Plaintiffs sometimes clarify to which form of payment they are referring, but in other instances they do not. *See, e.g., id.* at ¶ 272.

Regardless of the specific form that these payments took, Plaintiffs allege that Corcept transitioned from making payments primarily to the small number of endocrinologists who specialize in Cushing's Syndrome to non-specialist endocrinologists and primary care physicians.

Id. at ¶¶ 271–273. In 2013, for example, of the 298 physicians to which Corcept made payments, 203 were endocrinologists. *Id.* at ¶ 272. In 2018, by contrast, 2438 physicians received payments from Corcept, of which only 1072 were endocrinologists. *Id.* at ¶ 273. Plaintiffs point to a series of other changes in the composition and distribution of physician payments that they allege support this general trend. *Id.* at ¶¶ 274–282. Plaintiffs allege that this increase illustrates Defendants' campaign to target non-specialist endocrinologists and primary care physicians. *Id.* ¶ 282. This approach was vital to increasing Korlym's revenue, Plaintiff argue, because non-specialist endocrinologists and primary care physicians were perceived by Corcept as "unlikely to have the same in-depth understanding of endogenous Cushing's Syndrome as Specialist Endocrinologists" and thus "would be more susceptible to prescribing Korlym as a first-line therapy, even in preference to surgical intervention." *Id.* at ¶ 281–282.

3. Corcept's Alleged Off-Label Marketing Scheme

Plaintiffs allege that the growth in prescriptions for Korlym was also driven by an illegal off-label marketing scheme. *Id.* at ¶ 10. As background, the FDA approves a drug or medical device for specific uses, sometimes referred to as "on-label" uses. *See* 21 U.S.C. §§ 355(d), 360e(e)(1)(A). Once the product is approved, physicians may also prescribe the product for "off-label" uses, meaning uses not approved by the FDA. *See In re Gilead Sciences. Sec. Litig.*, 536 F.3d 1049, 1051 (9th Cir. 2008). Nonetheless, under current FDA regulations, "pharmaceutical manufacturers are generally prohibited from promoting off-label uses of their products if the off-label marketing is false or misleading, or if it evidences that a drug is intended for such off-label use and is therefore 'misbranded.'" *Polansky v. Pfizer, Inc.*, 822 F.3d 613, 615 (2d Cir. 2016) (citing 21 C.F.R. § 201.128).

Relying on ten physician confidential witnesses ("CWs 1–10"), Plaintiffs' Expert ("PE"), and four former Corcept employees ("CWs 11–14"), Plaintiffs allege that Corcept began to aggressively market Korlym for off-label use, both as a (1) treatment for "patients that did not have a confirmed Cushing's diagnosis and instead, had a general Cushingoid appearance,

subclinical Cushing's Syndrome, 'Pre-Cushing's,' [or] poorly controlled diabetes;" and (2) "as a first-line therapy with no consideration of surgery or as a bridge to surgery." *Id.* at ¶ 173. Marketing Korlym in this manner constitutes off-label promotion, Plaintiffs argue, because it markets Korlym in a manner that contradicts 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." *Id.*

Plaintiffs allege that "Corcept's clinical specialists [] employ[ed] a 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 Syndrome." *Id.* at ¶ 217. "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." *Id.* at ¶ 13 n.2. Plaintiffs further allege that Corcept's clinical specialists instructed physicians, including Plaintiffs' CWs, to screen for Cushing's Syndrome with a single 1-mg overnight Dexamethasone suppression test ("DST"), which Plaintiffs allege is an off-label use of Korlym because "DST is unreliable as a standalone test for diagnosing Cushing's Syndrome." *Id.* at ¶¶ 13–16.

Plaintiffs provide examples of this alleged off-label marketing scheme for each of their ten physician CWs. *Id.* at ¶¶ 219–260. These physician CWs statements are described in turn:

- CW1, "an Endocrinologist practicing in the Southeastern United States with decades of experience," describes a Corcept clinical specialist, Tyler Franklin, who visited CW1's office frequently between 2017 and 2019. *Id.* at ¶ 135, 219. 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." *Id.* at ¶ 219. CWI also recalls attending a dinner talk by a local internal medicine physician who had received $80,000 in honoraria payments from Corcept in 2017 and 2018. CW1 recalls that the physician "claimed 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." *Id.* at ¶ 220.
- CW2, "a family medicine physician from Oklahoma," recalls a Corcept clinical specialist coming into CW2's office beginning in 2018. CW2 recalls the clinical specialist advising CW2 to look for patients with poorly controlled diabetes who were

obese and had hypertension, and to perform a DST on those patients. The clinical specialist told CW2 that if "the DST was positive, then CW2 should immediately start the patients on Korlym." *Id.* at ¶ 221. CW2 also recalls being instructed by the clinical specialist to "'close [CW2's] eyes' and not just look for physical symptoms of Cushing's Syndrome because 'anyone could have it.'" *Id.* at ¶ 222. "CW2 recalls prescribing Korlym to two patients based on the Corcept rep's off-label marketing message." *Id.* at ¶ 224.

- CW3, "an Endocrinologist practicing in Nebraska for over 15 years," recalls a Corcept clinical specialist visiting the office between 2017 and 2018 who recommended "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." *Id.* at ¶ 228. CW3 further recalls that in late 2018 or early 2019, the clinical specialist began "recommending CW3 use Korlym 'proactively' to 'pre-treat' patients with adrenal masses, prior to surgery." *Id.* at ¶ 230.
- CW4, "an Endocrinologist practicing in Pennsylvania for over 15 years," recalls being visited by a Corcept clinical specialist from September 2019 until February 2020 who "promot[ed] using a single DST on obese diabetic patients and then, if the DST was positive or in the grey area, to start the patient on Korlym." *Id.* at ¶ 233. The clinical specialist further pushed this marketing of Korlym at other events CW4 attended in February of 2020. *Id.* at ¶ 235.
- CW5, "an Endocrinologist from New York practicing for over 10 years," had similar experiences with the same clinical specialist between 2017 and 2018. CW5 recalls that the clinical specialist "instructed CW5 to use a single DST on CW5's patients suffering from diabetes and/or obesity," and "if the test was even borderline then to put the patients on Korlym." *Id.* at ¶ 239.
- CW6, "an Endocrinologist practicing in West Virginia with over 20 years of experience," described a Corcept clinical specialist telling CW6 "to use Korlym as a diagnostic tool to confirm a Cushing's diagnosis after a single mildly abnormal DST." *Id.* at ¶ 241. These conversations took place between the summer of 2019 and October of 2019. After CW6 complained about this conduct, a regional sales manager from Corcept visited CW6's office to "explain[] to CW6 that the sales rep.'s marketing was purportedly consistent with the Korlym FDA-approved label." *Id.* at ¶ 241.
- CW7, "an Endocrinologist from New York, practicing for over 6 years," was visited by a Corcept clinical specialist for several years. The clinical specialist 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" and to use "Korlym as a 'bridge' for those awaiting surgery." *Id.* at ¶ 243. The clinical specialist also provided CW7 with DST samples and offered to fill out insurance paperwork to get Korlym approved. *Id.* at ¶ 244.
- CW8, "an Endocrinologist from Texas practicing for over nine years," recalls that beginning in 2016 or early 2017, a Corcept clinical specialist began "to focus on trying to get CW8 to screen all diabetic and obese patients with the DST," and if the result was positive, to put the patient on Korlym. *Id.* at ¶ 247. CW8 recalls the clinical specialist also "inserting case studies into promotional materials that also promoted Korlym for off-label use," and offering to fill out insurance paperwork on CW8's behalf. *Id.* at ¶ 247–251.

- CW9, "an Endocrinologist from Ohio practicing for over twenty years," recalls a clinical specialist who instructed CW9 "to test obese and diabetic patients with a single DST and if the test result was even borderline positive, to put the patient on Korlym right away." *Id.* at ¶ 252. The clinical specialist also suggested using Korlym "as a bridge to surgery." *Id.* at ¶ 254.
- CW10, "a family medicine physician from California practicing for over 20 years," recalls that a Corcept clinical specialist visited CW10's office between March 2017 and October 2017. *Id.* at ¶ 219. The clinical specialist "essentially promoted Korlym as the new treatment for diabetes," and "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." *Id.* at ¶ 257. CW10 also recalls the clinical specialist "giving CW10 a tear sheet that promoted Korlym as a front-line therapy for diabetic patients." *Id.*

Plaintiffs also provide the allegations of four former Corcept employees who contend that Corcept deployed an off-label marketing scheme during their time at the company. *Id.* at ¶ 173. Below, the Court provides examples of this alleged off-label marketing scheme for each of the former employee CWs. *Id.* at ¶¶ 175–203.

- CW11 is 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." *Id.* at ¶ 177. According to CW11, beginning "in early 2016 [VP of Sales Tom] 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." *Id.* at ¶ 176. CW11 refused to market Korlym off-label, and "went to Defendant Belanoff [CEO] and Burke [VP of Sales] to raise concerns about Corcept's off-label marketing and was told by Burke to 'sit down and shut up.'" *Id.* Finally, CW11 alleges that three Corcept clinical specialists were let go during the Class Period for refusing to promote Korlym off-label. *Id.* at ¶¶ 192–194.
- CW12 is 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." *Id.* at ¶ 177. In 2015, CW12 was told by a manager to mirror what a colleague, Carl Balzanti [top-performing clinical specialist], was doing in order to increase sales of Korlym. *Id.* "CW12 recalled numerous meetings with Balzanti about promoting Korlym off-label." *Id.* at ¶ 179. CW12 alleges that Balzanti "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 . . . could be put on Korlym immediately." *Id.* at ¶ 178. CW12 alleges that Balzanti spoke with CW12 about marketing Korlym off-label on several other occasions. *Id.* CW12 also recalls that "Defendant Maduck [VP of Commercial] and others would hold Balzanti and [Tyler] Franklin up as the examples on conference calls and at meetings and say how great they have done." *Id.* at ¶ 183. Moreover, CW12 alleges that CW12 attended a meeting of clinical specialist at which VP of Sales

"Burke told the clinical specialists that 'the goal is to stop making Cushing's Syndrome sound as rare as it is.'" *Id.* at ¶ 184.

- CW13 is a "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." *Id.* at ¶ 188. CW13 alleges 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?" *Id.* CW13 alleges that during a June 2016 sales meeting that Defendant Maduck attended, "a medical science liaison ('MSL') 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." *Id.* at ¶ 190. Moreover, CW13 alleges that during CW13's employment, Defendant Maduck, Tom Burke and other Corcept management pushed clinical specialists like CW13 to find physicians who were willing to prescribe Korlym as a first-line treatment when patient's DST results were in the "grey area" and that Corcept's strategy was to "go to rural areas and find someone" who would be receptive to Korlym. *Id.* at ¶ 195.
- CW14 is 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." *Id.* at ¶ 198. CW14 was aware that physicians were prescribing Korlym even when the DST was below the "1.8 guideline, including as low as 0.7, and that this was happening 'a lot.'" *Id.* at ¶ 198. CW14 alleges that "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." *Id.* at ¶ 200.

Plaintiffs allege that Corcept's off-label marketing scheme was furthered by providing clinical specialists with marketing materials to distribute to physicians that promoted off-label use of Korlym. *Id.* at ¶ 200. For example, CW12 alleges 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." *Id.* at ¶ 205. CW12 also alleges that Corcept distributed case studies to clinical specialists that promoted off-label use of Korlym to utilize when meeting with physicians. *Id.*

Plaintiffs also allege that insurance providers suspected that there were a growing number of off-label prescriptions of Korlym. Accordingly, insurers began to tighten their requirements for approving Korlym, beginning in 2018. *Id.* at ¶¶ 328. Plaintiffs allege that insurers who tightened their review process for Korlym include Blue Cross/Blue Shield of South Carolina; Independence

Blue Cross of Philadelphia; Highmark Blue Cross/Blue Shield of Pittsburgh; Oklahoma Health Care Authority; Eastern Oregon Coordinated Care Organization; Wellmark Blue Cross and Blue Shield of Iowa and South Dakota; BlueCross BlueShield of Arizona; AllWays Health Partners of Massachusetts; and Blue Cross Blue Shield of Michigan. *Id.* at ¶¶ 328–339. Plaintiffs allege that as a result of these changes to Korlym's prescription approval process by various private insurance companies, "[a]fter 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." *Id.* at ¶ 334.

Finally, Plaintiffs allege that the rapid increase in prescriptions for Korlym coincided with an increase in patient deaths while using Korlym. According to Plaintiffs "there were 17 reported deaths of patients on Korlym in 2017. In 2018, there were 40 deaths reported . . . . In 2019, a year with less rapid increase in prescriptions of Korlym, there were 19 deaths reported . . . . In total, there have been 103 deaths reported since 2012." *Id.* at ¶ 322.

4. Defendants' Alleged Materially False and Misleading Statements

Plaintiffs allege that throughout the Class Period, Defendants made 29 false or misleading statements. *Id.* at ¶ 341; Exhibit A: Statements Alleged to Have Been False and Misleading, ECF No. 127-1 ("Ex. A"). Plaintiffs argue that Defendants' false and misleading statements fall into five categories: (1) the aim and outcome of Corcept's physician education programs; (2) whether Corcept's marketing was in line with the FDA-approved label for Korlym; (3) Corcept's compliance with FDA regulations regarding off-label marketing; (4) the basis for Corcept's revenue growth; and (5) the percentage of patients who were prescribed Korlym for on-label use. *Id.* These false or misleading statements were allegedly made in Defendants' company press releases, Securities and Exchange Commission ("SEC") filings, and earning conference calls and presentations. *Id.* Following Plaintiffs' organization of the allegedly false and misleading statements, the Court outlines the five categories of statements below.

a. Speaker and Education Programs (Statements # 1, 7, 11, 16, 21, 25, 27)

Plaintiffs allege that Defendants made the following statement in Corcept's Form 10-Q, filed with the SEC on August 2, 2017:

> Because a large percentage of the people who suffer from Cushing's Syndrome remain undiagnosed or are inadequately treated, we have developed and continue to refine and expand programs to educate the medical community and patients about diagnosis of this syndrome and to increase awareness regarding the role of cortisol modulators to treat the disease.

Ex. A at 2. Plaintiffs allege that Defendants made this statement, or a nearly identical statement, on six subsequent occasions. *Id.* at 22, 35, 52, 69, 83, 89.

b. Marketing and Promotional Materials (# 2, 8, 12, 17, 22, 28)

Plaintiffs allege that Defendants made the following statement in Corcept's Form 10-Q, filed with the SEC on August 2, 2017:

> In the United States, we market Korlym for treatment of 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 and provide promotional materials and training programs to physicians regarding the use of Korlym for this indication.

Id. at 5. Plaintiffs allege that Defendants made this statement, or a nearly identical statement, on five subsequent occasions. *Id.* at 25, 38, 55, 72, 92.

c. Compliance with FDA-Regulations (# 3, 9, 13, 18, 23, 29)

Plaintiffs allege that Defendants made the following statement in Corcept's Form 10-Q, filed with the SEC on August 2, 2017: "Although we believe our marketing materials and training programs for physicians do not constitute 'off-label' promotion of Korlym, the FDA may disagree." *Id.* at 9. Plaintiffs allege that Defendants made this statement, or a nearly identical statement, on five subsequent occasions. *Id.* at 29, 42, 59, 76, 96.

d. Korlym Revenue and Sales Growth (# 4, 5, 6, 10, 14, 15, 19, 20, 24)

Plaintiffs allege that Defendants made the following statement in an earnings call on November 2, 2017:

> The strong growth in Korlym revenue . . . was sustained by the same trends in medical practice that I have described in previous calls: growing awareness amongst physicians of Korlym's efficacy, the increasing frequency with which physicians are

> screening for and treating patients with hypercortisolism and our commercial organization[']s focus[] on the endocrinologists who treat most patients with hypercortisolism.

Id. at 12 (second and third alterations in original). Plaintiffs allege that Defendants made a similar statement regarding the basis for Korlym's growth on eight occasions. *Id.* at 15, 19, 32, 45, 49, 62, 65, 79.

e. On-Label Use of Korlym (# 26)

Plaintiffs allege that Defendants made the following statement during an earnings call on November 1, 2018: "99% of our Korlym patients are on label – prescription, sorry, are on-label and we continue to see favorable insurance reimbursement." *Id.* at 86.

In sum, Plaintiffs allege that Defendants made 29 false and misleading statements during the Class Period. Plaintiffs allege that these statements were false and misleading because, contrary to Defendants' statements, Corcept was engaged in a company-wide off-label marketing scheme, which targeted non-specialist endocrinologists and primary care physicians. Opp. at 8–12. Plaintiffs further allege that Defendants' statements were false and misleading because Defendants' off-label marketing scheme was the true basis for Corcept's revenue growth, and Defendants' marketing scheme failed to comply with FDA regulations regarding the promotion of Korlym. *Id.*

5. Alleged Partial Disclosures

On January 25, 2019, the Southern Investigative Reporting Foundation ("SIRF") released a 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 sales." TAC at ¶ 343. The SIRF Report also questioned the prescription practices of several individual doctors; the rise in the number of deaths in patients using Korlym; and the geographic clustering of supposed endogenous Cushing diagnoses. *Id.* at ¶¶ 343–347. Following the release of the SIRF Report, Corcept's share price declined by $1.52 and closed the day of January 25, 2019 at $12.29. *Id.* at ¶ 348.

After the market closed on January 31, 2019, Corcept issued a press release that announced

fourth quarter and full-year 2018 preliminary selected financial results. *Id.* at ¶ 349. Corcept forecasted, Plaintiffs allege, 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." *Id.* On February 2, 2019, Corcept's share price declined by $1.15 and closed the day at $10.08. *Id.* at ¶ 350.

B. Procedural Background

On March 14, 2019, a Corcept shareholder filed the instant case captioned *Nicholas Melucci v. Corcept Therapeutics Incorporated, et al.*, N.D. Cal. Case No. 19-CV-01372. On October 7, 2019, the Court appointed Plaintiffs Ferraro Family Foundation, Inc. and James L. Ferraro (collectively, "Plaintiffs") as lead plaintiffs and Levi & Korinsky, LLP as lead counsel. ECF No. 82.

On December 6, 2019, Plaintiffs filed a First Amended Class Action Complaint. ECF No. 91 ("FAC"). On January 27, 2020, Defendants filed a motion to dismiss the FAC. ECF No. 95. On March 12, 2020, the Court granted the parties' stipulation to allow Plaintiffs to file a Second Amended Complaint and denied Defendants' pending Motion to Dismiss as moot. ECF No. 99.

On March 20, 2020, Plaintiffs filed a Second Amended Class Action Complaint. ECF No. 100 ("SAC"). On May 11, 2020, Defendants filed a motion to dismiss the SAC. ECF No. 105. On June 25, 2020, Plaintiffs filed an opposition. ECF No. 108. On July 27, 2020, Defendants filed a reply. ECF No. 109. On October 26, 2020, the Court granted Defendants' motion to dismiss Plaintiffs' SAC with leave to amend. ECF No. 124.

On December 21, 2020, Plaintiffs filed a Third Amended Complaint. ECF No. 127 ("TAC"). On February 19, 20201, Defendants filed the instant motion to dismiss Plaintiffs' TAC. ECF No. 130 ("Mot."). The same day, Defendants filed a request for judicial notice. ECF No. 132. On April 20, 2021, Plaintiffs filed an opposition. ECF No. 135 ("Opp."). On June 4, 2021, Defendants filed a reply. ECF No. 138 ("Reply").

C. Request for Judicial Notice

In connection with their motion to dismiss, Defendants request judicial notice of six documents, which include (1) *Corcept Therapeutics: The Company That Perfectly Explains the Health Care Crisis* ("SIRF Report") ("Exhibit A"); (2) Corcept Form 8-K and Ex. 99.1, dated January 31, 2019 ("Exhibit B"); (3) Redline Comparing Plaintiffs' Second Amended Complaint with Plaintiffs' Third Amended Complaint ("Exhibit C"); (4) FDA Label for Korlym ("Exhibit D"); (5) FDA Adverse Event Reporting System ("FAERS") Data ("Exhibit E"); and (6) Transcript for the November 2, 2017 Corcept Earnings Call for Q3 2017 ("Exhibit F"). ECF No. 132 ("RJN").

The Court may take judicial notice of matters that are either "generally known within the trial court's territorial jurisdiction" or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Public records, including judgments and other publicly filed documents, are proper subjects of judicial notice. *See, e.g.*, *United States v. Black*, 482 F.3d 1035, 1041 (9th Cir. 2007). Moreover, courts may consider materials referenced in the complaint under the incorporation by reference doctrine, even if a plaintiff failed to attach those materials to the complaint. *Knievel v. ESPN*, 393 F.3d 1068, 1076 (9th Cir. 2005). However, to the extent any facts in documents subject to judicial notice are subject to reasonable dispute, the Court will not take judicial notice of those facts. *See Lee v. City of Los Angeles*, 250 F.3d 668, 689 (9th Cir. 2001), *overruled on other grounds by Galbraith v. County of Santa Clara*, 307 F.3d 1119 (9th Cir. 2002).

Defendants argue that Exhibits B, C, D, and E are properly subject to judicial notice because they are court filings, SEC filings, documents from government data repositories, and the FDA label for Korlym. RJN at 2–3. Plaintiffs do not object to judicial notice being taken of these documents. Defendants argue that Exhibits A and F are properly incorporated by reference in Plaintiffs' complaint because they form the basis of Plaintiffs' claims and are referenced throughout the complaint. *Id.* Plaintiffs question the extent to which Exhibit F is referenced throughout the TAC and argue that if notice is taken of this document, it should not be for the

truth of its contents. Opp. at 23 n.15.

The Court finds that Exhibits B, C, D, and E are the proper subject of judicial notice because they are SEC filings, court filings, and documents found on government websites. *See In re Yahoo! Inc. Customer Data Sec. Breach Litig.*, 2017 WL 3727318, at *10 (N.D. Cal. Aug. 30, 2017) ("[B]oth SEC filings and documents on government websites are proper subjects of judicial notice."). The Court also finds that Exhibits A and F are the proper subject of incorporation by reference because they are referenced throughout Plaintiffs' TAC and form the basis of Plaintiffs' claims. *See United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003) ("Even if a document is not attached to a complaint, it may be incorporated by reference into a complaint if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim."). However, to the extent any facts in these documents are subject to reasonable dispute, the Court will not take judicial notice of those facts. *See Lee*, 250 F.3d at 689. As such, the Court GRANTS Defendants' request for judicial notice and incorporation by reference of Exhibits A–F in support of the motion to dismiss.

II. LEGAL STANDARD

A. Motion to Dismiss

Pursuant to Federal Rule of Civil Procedure 12(b)(6), a defendant may move to dismiss an action for failure to state a claim upon which relief may be granted. Because Plaintiffs have brought their claims as a federal securities fraud action, Plaintiffs are not subject to the notice pleading standards under Federal Rule of Civil Procedure 8(a)(2), which require litigants to provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Instead, Plaintiffs must "meet the higher, [more] exacting pleading standards of Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act (PSLRA)." *Or. Pub. Emp. Ret. Fund v. Apollo Group Inc.*, 774 F.3d 598, 603–04 (9th Cir. 2014).

Under Federal Rule of Civil Procedure 9(b), "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Plaintiffs must include

"an account of the time, place, and specific content of the false representations" at issue. *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007) (internal quotation marks omitted). Rule 9(b)'s particularity requirement "applies to all elements of a securities fraud action." *Apollo Group*, 774 F.3d at 605.

"PSLRA imposes additional specific pleading requirements, including requiring plaintiffs to state with particularity both the facts constituting the alleged violation and the facts evidencing scienter." *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 877 (9th Cir. 2012). In order to properly allege falsity, "a securities fraud complaint must . . . specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." *Id.* (internal quotation marks and alteration omitted). In addition, in order to "adequately plead scienter under the PSLRA, the complaint must state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* (internal quotation marks omitted).

For purposes of ruling on a Rule 12(b)(6) motion, the Court "accept[s] factual allegations in the complaint as true and construe[s] the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). Nonetheless, the Court is not required to "'assume the truth of legal conclusions merely because they are cast in the form of factual allegations.'" *Fayer v. Vaughn*, 649 F.3d 1061, 1064 (9th Cir. 2011) (quoting *W. Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981)). Mere "conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss." *Adams v. Johnson*, 355 F.3d 1179, 1183 (9th Cir. 2004). Furthermore, "'a plaintiff may plead [him]self out of court'" if he "plead[s] facts which establish that he cannot prevail on his . . . claim." *Weisbuch v. Cty. of L.A.*, 119 F.3d 778, 783 n.1 (9th Cir. 1997) (quoting *Warzon v. Drew*, 60 F.3d 1234, 1239 (7th Cir. 1995)).

B. Leave to Amend

Under Rule 15(a) of the Federal Rules of Civil Procedure, leave to amend "shall be freely granted when justice so requires," bearing in mind "the underlying purpose of Rule 15 to facilitate

decision on the merits, rather than on the pleadings or technicalities." *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (en banc) (internal quotation marks and alterations omitted). Generally, leave to amend shall be denied only if allowing amendment would unduly prejudice the opposing party, cause undue delay, or be futile, or if the moving party has acted in bad faith. *Leadsinger, Inc. v. BMG Music Publ'g*, 512 F.3d 522, 532 (9th Cir. 2008).

III. DISCUSSION

Plaintiffs allege two causes of action: (1) violation of § 10(b) of the Exchange Act and Rule 10b-5 against Corcept and the Individual Defendants, and (2) violation of § 20(a) of the Exchange Act against Corcept and the Individual Defendants. TAC at ¶¶ 480–499. The Court addresses each cause of action in turn.

A. Claim One: Violation of § 10(b) of the Exchange Act and Rule 10b-5

"To plead a claim under section 10(b) and Rule 10b-5, Plaintiffs must allege: (1) a material misrepresentation or omission; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." *Apollo Group*, 774 F.3d at 603.

Defendants do not contend that Plaintiffs have failed to allege the following three elements: (1) the connection between the misrepresentations or omissions and the purchase or sale of a security, (2) reliance, or (3) economic loss. Thus, the Court does not address them.

However, Defendants do contend that Plaintiffs' claim should be dismissed because Plaintiffs have failed to allege the remaining three elements: (1) material misrepresentations; (2) scienter; and (3) loss causation. The Court discusses each element in turn.

1. False or Misleading Statements

Plaintiffs allege that during the Class Period, Defendants made a number of false or misleading statements in Corcept's 10-Qs, Company Press Releases, earnings calls, and 10-Ks. TAC at ¶ 341; Ex. A at 2–92. Defendants argue that Defendants' statements are not actionable because, among other things, they are true and not misleading, and not accompanied by sufficient

allegations of an off-label marketing scheme. Mot. at 12–13. The Court first addresses Defendants' challenge to the adequacy of Plaintiffs' pleading of an off-label marketing scheme. The Court then addresses Plaintiffs' allegations regarding the falsity of Defendants' statements.

a. Plaintiffs' Allegations Regarding Defendants' Off-Label Marketing Scheme

Plaintiffs allege that "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 [other physicians] . . ." TAC at ¶ 31. Defendants argue that Plaintiffs' allegations are insufficient to show that Corcept engaged in a widespread off-label marketing scheme, and therefore, Plaintiffs have failed to plead material misrepresentations or omissions. Mot. at 4. The Court first considers whether Plaintiffs have adequately alleged an off-label marketing scheme. The Court then turns to whether each category of statements is materially false and misleading as a result.

Plaintiffs allege four general categories of facts to support their claim that Defendants were engaged in an off-label marketing scheme: (1) statements from Plaintiffs' confidential witnesses ("CWs"); (2) Corcept's physician education programs; (3) diagnosis rates of Cushing's Syndrome; and (4) insurance reimbursement practices for Korlym. Each category of evidence could be sufficient standing alone to demonstrate that Plaintiffs have adequately alleged that Defendants were engaged in an off-label marketing scheme. If no one category of evidence is sufficient, the Court will consider the allegations holistically. *See In re Gilead Sciences Securities Litigation*, 2005 WL 181885, at *9 (N.D. Cal. Jan. 26, 2005) (considering allegations of off-label marketing scheme as a whole). Below the Court addresses each category of evidence in turn. Even though the Court finds that one category adequately alleges an off-label marketing scheme, the Court nonetheless also considers Plaintiffs' allegations as a whole.

i. Statements of Physician and Former Employee CWs

Plaintiffs first argue that the statements of their ten physician CWs, PE, and four former employee CWs establish that Defendants were engaged in an off-label marketing scheme.

Plaintiffs contend that these CWs confirm that "Corcept clinical specialists aggressively marketed Korlym for off-label use." TAC at ¶ 173. This off-label marketing scheme involved promoting Korlym to physicians "(1) to treat patients that did not have a confirmed Cushing's diagnosis and instead, had a general Cushingoid appearance, subclinical Cushing's Syndrome, 'Pre-Cushing's,' [or] poorly controlled diabetes; and (2) as a first-line therapy with no consideration of surgery or as a bridge to surgery, in contradiction of the FDA label." *Id.* Plaintiffs argue that the statements of their CWs establish that Corcept's off-label marketing scheme was "pervasive and extended across the country into each of the Company's six sales regions." *Id.* at ¶ 174. Defendants argue that the CW statements are insufficient to plead a plausible off-label marketing scheme because they are unreliable and insufficient to establish an off-label marketing scheme during the Class Period. Mot. at 4–8.

In the Court's November 20, 2020 Order granting Defendants' motion to dismiss, the Court found that Plaintiffs' statements from ten physician CWs and PE were insufficient to plausibly plead an off-label marketing scheme. ECF No. 124, at 18. Specifically, the Court found that Plaintiffs "failed to adequately allege that Corcept sales representatives were directed to market Korlym off-label. Rather, Plaintiffs have adequately alleged only that a handful of individual sales representatives engaged in off-label marketing to the CWs and PE." *Id.* Plaintiffs largely repeat the same allegations from their ten physician CWs and PE, and so the Court does not restate the inadequacy of those CWs allegations standing alone. However, Plaintiffs now provide allegations from four former employee CWs that Plaintiffs allege establish that Corcept directed clinical specialists—who Plaintiffs previously called "sales representations"—to market Korlym off-label to physicians. Opp. at 4–5. The Court begins by explaining briefly how courts in this circuit (1) evaluate the legal sufficiency of confidential witness statements; and (2) evaluate allegations regarding an off-label marketing scheme. The Court then considers the sufficiency of Plaintiffs' allegations regarding the former employee CWs.

To satisfy the PSLRA's pleading requirements, Plaintiffs' CW statements must satisfy two

tests. "First, the [CWs] must be 'described with sufficient particularity to establish their reliability and personal knowledge.' Second, the [CWs'] statements must 'themselves be indicative of' the elements in question; here, falsity and materiality." *Huang v. Higgins*, 2019 WL 1245136, at *6 (N.D. Cal. Mar. 18, 2019) (quoting *Zucco Partners v. Digimarc Corp.*, 552 F.3d 981, 995 (9th Cir. 2009)).

For each of the former employee CWs, Plaintiffs have provided "each witness's job description and responsibilities," which courts in this circuit generally require to determine reliability and personal knowledge. *In re Quality Sys.*, 865 F.3d 1130, 1145 (9th Cir. 2017). Each of the four CWs worked for Corcept, although only CW13 and CW14 worked for Corcept during the Class Period, which is between August 2, 2017 and January 31, 2019. *See* TAC at ¶¶ 175–203. CW11 and CW12 both worked for Corcept prior to the beginning of the Class Period. *Id.* (explaining that CW11 worked for Corcept between 2012 and 2016 and CW12 worked for Corcept between 2014 and 2016).

In cases from this circuit where courts have determined that an off-label marketing scheme was plausibly alleged, plaintiffs have pled facts illustrating that sales representatives were instructed by managers or other members of the firm leadership to engage in off-label marketing. For example, in *In re Gilead Sciences Securities Litigation*, the court found an off-label marketing scheme where confidential witnesses alleged that they personally "attended various meetings at which Gilead's sales and marketing team received specific instructions to market Viread off-label." 2005 WL 181885, at *8. Plaintiffs in that case alleged that confidential witnesses attended three meetings where sales and marketing staff were instructed to market off-label. *Id.* Plaintiffs also alleged that confidential witnesses "were in the room when specific instructions were given to sales and marketing personnel to utilize off-label information to push sales of Viread." *Id.*

Similarly, in *In re Amgen Inc. Securities Litigation*, the court found that an off-label marketing scheme was plausibly alleged where confidential witness sales representatives described receiving instructions from their district and regional sales managers to engage in off-

label marketing, and there "was evidence that Amgen's marketing scheme emanated from its national office." 544 F. Supp. 2d 1009, 1033 (C.D. Cal Feb. 1, 2008). Moreover, "[a]ccording to CW#2, a former Amgen interim district sales manager in Houston, Amgen ostensibly repudiated off-label promotion . . . but provided its sales staff with 'color coded spreadsheets, Power Point presentations and unpublished study results,' to insure they 'were prepared to discuss any off-label topic.'" *Id.* (internal citations removed).

By contrast, in *Huang v. Higgins*, the court found that plaintiffs' confidential witness statements failed to plausibly allege a company-wide off-label marketing scheme. 2019 WL 1245136, at *6–8. Specifically, after evaluating plaintiffs' allegations that confidential witness former employees alleged off-label marketing, the court found that the former employees "[did] not provide the details of any individual meetings, nor allege that they received specific instructions to market NUCYNTA for off-label uses. Further, Plaintiffs do not allege corroborating evidence akin to the FDA warning letters in *Gilead*." *Id.* at *8. The court thus found that plaintiffs had failed to allege a company-wide off-label marketing scheme.

Plaintiffs' allegations in the instant case fall closer to the sufficient allegations in *In re Gilead* and *In re Amgen* than the insufficient allegations in *Higgins*. The Court restates the most important of the former employees CWs statements below.

Specifically, CW11, a clinical sales specialist in the region comprised of Ohio, Kentucky, and Tennessee from November 2012 through July 2016, recalls that "in early 2016 [VP of Sales Tom] 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." *Id.* at ¶ 176. CW11 refused to market Korlym off-label, and "went to Defendant Belanoff [CEO] and Burke [VP of Sales] to raise concerns about Corcept's off-label marketing and was told by Burke to 'sit down and shut up.'" *Id.* CW11 also recalls that on at least two occasions, Defendant Belanoff accompanied CW11 to meet with important physicians regarding Korlym. On these visits, "Defendant Belanoff made off-label representations to all the

physicians." *Id.* ¶ 370. Finally, CW11 alleges that three Corcept clinical specialist were let go during the Class Period for refusing to promote Korlym off-label. *Id.* at ¶¶ 192–194.

CW12, a clinical specialist in the Pacific Northwest region from July 2014 to August 2016, recalls being told by a Corcept manager to mirror what a colleague, Carl Balzanti [top-performing clinical specialist], was doing in order to increase sales of Korlym. *Id.* at ¶ 177. Furthermore, "CW12 recalled numerous meetings with Balzanti about promoting Korlym off-label." *Id.* at ¶ 179. CW12 alleges that Balzanti "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 . . . could be put on Korlym immediately." *Id.* at ¶ 178. CW12 alleges that Balzanti talked with CW12 about marketing Korlym off-label on several other occasions. *Id.* CW12 also recalled that "Defendant Maduck [VP of Commercial] and others would hold Balzanti and [Tyler] Franklin [top-performing clinical specialist] up as the examples on conference calls and at meetings and say how great they have done." *Id.* at ¶ 183. In his role as VP of Commercial, Maduck oversaw the company's sales staff and education programs. *Id.* at ¶ 401.

CW13, a clinical sales specialist in the Philadelphia region from September 2016 until February 2019 and the Florida region until July 2019, alleges 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?" *Id.* at ¶ 188. CW13 alleges that during a June 2016 sales meeting that VP of Commercial Maduck attended, "a medical science liaison ("MSL") 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." *Id.* at ¶ 190. Moreover, CW13 alleged that during CW13's employment, Defendant Maduck [VP of Commercial], Tom Burke [VP of Sales] and other Corcept management pushed clinical specialists liked CW13 to find physicians who were willing to prescribe Korlym as a first-line treatment when DST results were in the "grey area" and that Corcept's strategy was to "go to rural areas and find someone" who

would be receptive to prescribing Korlym. *Id.* at ¶ 195.

CW14, a Regional Manager on the East Coast from April 2016 to May 2019, was aware that physicians were prescribing Korlym even when the DST was below the "1.8 guideline, including as low as 0.7, and that this was happening 'a lot.'" *Id.* at ¶ 198. CW14 alleges that "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." *Id.* at ¶ 200.

Plaintiffs' former employee CWs also allege that Corcept's off-label marketing scheme was furthered by providing clinical specialists with marketing materials that promoted off-label use of Korlym to distribute to physicians. *Id.* at ¶ 200. For example, CW12 alleges 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." *Id.* at ¶ 205. CW12 also alleges that Corcept distributed case studies to clinical specialists to use when meeting with physicians that promoted off-label use of Korlym. *Id.*

Moreover, even if these former employee CW statements were insufficient on their own to adequately plead an off-label marketing scheme, statements made by Plaintiffs' ten physician CWs and PE provide further support to Plaintiffs' allegations. For example, Plaintiffs allege that CW1-10 and PE received instructions from Corcept's clinical specialists to use a single DST as a diagnostic tool to screen for Cushing's Syndrome. *Id.* at ¶¶ 219–260. If the patient was positive, or borderline positive, the clinical specialist instructed the physician to start the patient on Korlym. *Id.* Plaintiffs also allege that CW3, CW7, and CW9 were all instructed by Corcept clinical specialists to use Korlym as a "bridge to surgery" or "pre-surgery" for patients, in conflict with the FDA-approved label for Korlym. *See* TAC at ¶¶ 230, 243, 254. Finally, Plaintiffs note that CW8 and CW10 recount that tear sheets or case studies promoting off-label use of Korlym were given to them by clinical specialists. *See id.* at ¶¶ 251, 257.

Finally, although Defendants argue that the marketing practices alleged by Plaintiffs do not

constitute off-label promotion of Korlym under the FDA label, Mot. at 11, the Court notes that whether these practices constitute off-label promotion of Korlym is a factual dispute that is not appropriately resolved on a motion to dismiss. *See Dahlia v. Rodriguez*, 735 F.3d 1060, 1076 (9th Cir. 2013) (stating that a court's "task is not to resolve any factual dispute" on a Rule 12(b)(6) motion). As such, the Court assumes that these practices constitute off-label promotion of Korlym for the purpose of ruling on the motion to dismiss. *Manzarek*, 519 F.3d at 1031 (explaining that on a 12(b)(6) motion the court "accept[s] factual allegations in the complaint as true and construe[s] the pleadings in the light most favorable to the nonmoving party.").

ii. Corcept's Physician Education Programs

Plaintiffs next allege that Defendants were engaged in an off-label marketing scheme as evidenced by Corcept's increased spending through a marketing strategy that targeted non-specialist endocrinologists and primary care physicians. Due to Korlym's Orphan Drug Designation, Corcept's market exclusivity for Korlym would expire in February of 2019 and inexpensive generics would then be available on the market. *Id.* at ¶¶ 128, 136. Defendants were therefore incentivized to increase the number of prescriptions for Korlym while Corcept remained the exclusive producer of the drug. As such, beginning roughly in early 2014, Defendants allegedly began to aggressively target non-specialist endocrinologists and primary care physicians. *Id.* at ¶ 274. For example, Plaintiffs allege that in 2013, out of the 298 physicians who received payments from Corcept, 203 were endocrinologists. TAC at ¶ 272. By 2018, out of the 2438 physicians who received payments from Corcept, only 1072 were endocrinologists. *Id.* at ¶ 273. For context, the Class Period runs from August 2, 2017 to January 31, 2019.

Plaintiffs further allege that the total number of payments made, the total number of physicians paid, and the total amount of payments to physicians all increased dramatically between 2013 and 2018. For example, Corcept increased its honoraria spending to $366,750 in 2017, a 322% increase from 2016. *Id.* at ¶ 307. Plaintiffs allege that payment figures show that Defendants were increasingly focused over time on marketing Korlym to both non-specialist

endocrinologists and primary care physicians. *Id.* at ¶ 274. Plaintiffs explain that Defendants targeted non-specialist endocrinologists because non-specialist endocrinologists were "more susceptible to Corcept's off-label marketing messaging regarding Korlym" and "would be more susceptible to prescribing Korlym as a first-line therapy." *Id.* at ¶ 281–282.

However, Plaintiffs have failed to allege any statements by Defendants or Corcept employees that demonstrate that the purpose or intent of Corcept's physician education programs were to advance or promote off-label use of Korlym. The TAC alleges that "CW11 confirmed that [] honoraria payments were made to speakers in order to facilitate the off-label marketing of Korlym to other physicians." *Id.* at ¶ 281. However, Plaintiffs provide no evidence of how CW11 knew this or the basis for CW11's bare allegation. Thus, these allegations alone are insufficient to establish an off-label marketing scheme. However, as explained below, the Court considers these allegations in combination with Plaintiffs' other evidence to find that Plaintiffs have adequately alleged an off-label marketing scheme.

iii. Diagnosis Rates of Cushing's Syndrome

Third, Plaintiffs allege that Defendants' off-label marketing scheme is confirmed by diagnosis rates of particular physicians. Specifically, Plaintiffs allege that two physicians—Dr. Jerry Back in North Charleston, North Carolina and Dr. Joseph Mathews in Sommerville, South Carolina—exemplify Defendants' off-label marketing scheme. TAC at ¶¶ 19–22.

Dr. Back is an internal medicine doctor who specializes in diabetes patients. Dr. Back had 115 Medicare Part D claims for Korlym in 2017, but he submitted only 19 Medicare Part D claims for Korlym in 2016 and zero in 2014 and 2015. *Id.* at ¶ 19. Plaintiffs compare these numbers with Dr. Back's payments from Defendants: $154.38 in payments from Defendants for food and drinks in 2016, to $55,454 in payments from Defendants in 2017 ($47,000 of which were honoraria payments). *Id.* Plaintiffs allege that "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 Syndrome diagnosis." *Id.* at ¶ 297.

Plaintiffs draw a similar inference from the practice of Dr. Mathews, an endocrinologist from South Carolina. Dr. Mathews received $73,777 from Corcept in 2017 and made 85 Medicare Part D claims for Korlym in 2017, second only to Dr. Back. *Id.* at ¶¶ 21, 305.

As the Court explained in its November 20, 2020 Order granting Defendants' motion to dismiss, these allegations are insufficient on their own to demonstrate that Dr. Back and Dr. Mathews were prescribing Korlym off-label at the suggestion of Corcept clinical specialists. ECF No. 124, at 21. Specifically, the Court stated that "Plaintiffs essentially require the Court to infer from Dr. Back's increase in Medicare Part D claims and increased payments from Defendants that Dr. Back is being directed by Defendants to prescribe Korlym off-label." *Id.* at 22. The Court again notes that standing alone, these allegations are insufficient to demonstrate that Defendants were engaged in a widespread off-label marketing scheme. Specifically, these allegations do not show that Corcept management directed clinical specialists to engage in off-label marketing to Dr. Back and Dr. Mathews. *See Higgins*, 2019 WL 1245136, at *6–8 (finding that Plaintiffs failed to adequately allege an off-label marketing scheme in part because there were no allegations that sales representatives were instructed to market off-label). Nonetheless, as explained below, the Court considers these allegations in combination with Plaintiffs' other evidence to find that Plaintiffs have adequately alleged an off-label marketing scheme.

iv. Insurance Reimbursement

Finally, Plaintiffs allege that insurance reimbursement practices of particular insurance companies confirm that Defendants were engaged in an off-label marketing scheme. Specifically, Plaintiffs allege that seven healthcare insurers and two state health authorities— Blue Cross/Blue Shield of South Carolina; Independence Blue Cross of Philadelphia; Highmark Blue Cross/Blue Shield of Pittsburgh; Oklahoma Health Care Authority; Eastern Oregon Coordinated Care Organization; Wellmark Blue Cross and Blue Shield of Iowa and South Dakota; BlueCross BlueShield of Arizona; AllWays Health Partners of Massachusetts; and Blue Cross Blue Shield of

Michigan—all modified their policies with respect to reimbursing claims for Korlym prescriptions between May of 2018 and December of 2020. TAC at ¶¶ 330–339. In each case, the insurer tightened requirements for Korlym prescriptions. Plaintiffs allege that these changes to insurance prescription approval processes account for Defendants' decline in revenue growth, which had grown 75% quarter over quarter previously, but declined in Q3 of 2018 to just 50.7%. *Id.* at ¶ 334. In Q1 of 2019 it fell to just 12.4%. *Id.* However, as Defendants argue, Plaintiffs have done little more than allege a connection between these insurance providers tightening their reimbursement policies and Defendants' declining growth. Thus, although these allegations are insufficient on their own to plead an off-label marketing scheme, the Court considers them in combination with Plaintiffs' other evidence.

v. Totality of Allegations

Taken as a whole, Plaintiffs' allegations with respect to Defendants' conduct are sufficient at the motion to dismiss stage to allege that Defendants engaged in an off-label marketing scheme. As in *In re Amgen*, Plaintiffs in this case provide sufficient allegations that Corcept's marketing scheme was directed by Corcept managers and leadership. 544 F. Supp. 2d at 1033 (explaining sufficiency of off-label marketing allegations). Moreover, as in *In re Amgen*, Corcept managers allegedly provided clinical specialists with tear sheets and case studies to assist in the promotion of off-label uses of Korlym to physicians. *Id.* (explaining that Amgen "provided its sales staff with 'color coded spreadsheets, Power Point presentations and unpublished study results," to insure they 'were prepared to discuss any off-label topic.'").

Furthermore, Plaintiffs provide examples of meetings both before and during the Class Period in which Corcept managers and company leadership either encouraged clinical specialists to promote Korlym off-label or to follow the guidance and advice of top sales staff who were flagrantly promoting Korlym off-label to physicians. *See, e.g.*, TAC at ¶¶ 188, 195, 200; *see also In re Gilead*, 2005 WL 181885, at *8 (finding off-label marketing scheme where confidential witnesses attended three meetings where sales and marketing staff were instructed to market off-

label). CW11 even alleges that on three different visits with physicians, Defendant Belanoff [CEO] directly made off-label representations as part of the sales visit. *Id.* at ¶ 370 (explaining that on three visits "Defendant Belanoff made off-label representations to all the physicians."). These allegations are bolstered by the allegations of Plaintiffs' ten physician CWs and PE, each of whom report that Corcept clinical specialists marketed Korlym off-label during the Class Period. *Id.* at ¶¶ 219–260.

Accordingly, in light of Plaintiffs' allegations, the Court finds that Plaintiffs have adequately alleged at the motion to dismiss stage that Corcept engaged in an off-label marketing scheme of Korlym.

b. Adequacy of Allegations of Falsity

Having found that Plaintiffs sufficiently alleged an off-label marketing scheme, the Court now turns to Defendants' argument that Plaintiffs have failed to allege actionable false or misleading statements. To assert a claim under the PSLRA, Plaintiffs must plead with particularity the element of falsity. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009). "The PSLRA has exacting requirements for pleading 'falsity.'" *Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1070 (9th Cir. 2008).

To satisfy these "exacting requirements," Plaintiffs must plead "specific facts indicating why" the statements at issue were false or misleading. *Id*; *see also Ronconi v. Larkin*, 253 F.3d 423, 434 (9th Cir. 2001) ("Plaintiffs' complaint was required to allege specific facts that show" how statements were false). Moreover, to be actionable, statements must be false "at [the] time by the people who made them." *Id.* at 430. "The fact that [a] prediction proves to be wrong in hindsight does not render the statement untrue when made." *In re VeriFone Sec. Litig.*, 11 F.3d 865, 871 (9th Cir. 1993).

The Court now addresses the five categories of statements that Plaintiffs allege are actionable. Specifically, the Court addresses statements related to: (1) the aim and outcome of Corcept's physician education programs; (2) whether Corcept's marketing was in line with the

FDA-approved label for Korlym; (3) Corcept's compliance with FDA regulations regarding off-label marketing; (4) the basis for Corcept's revenue growth; and (5) the percentage of patients who were prescribed Korlym for on-label use. The Court addresses each of these categories of statements in turn. One category of false or misleading statements is sufficient to state a claim under Plaintiffs' § 10(b) and Rule 10b-5 cause of action.

i. Speaker and Education Programs for Physicians

Plaintiffs first challenge Defendants' statements related to Corcept's speaker and education programs for physicians. Ex. A at 2, 22, 35, 52, 69, 83, 89. Specifically, Plaintiffs challenge the following statements:

> Because a large percentage of the people who suffer from Cushing's Syndrome remain undiagnosed or are inadequately treated, we have developed and continue to refine and expand programs to educate the medical community and patients about diagnosis of this syndrome and to increase awareness regarding the role of cortisol modulators to treat the disease.

See e.g., *id.* at 2. Plaintiffs argue that these statements were false "because the Company's purported expanded programs were not to educate the medical community on the diagnosis of endogenous Cushing's Syndrome but rather . . . Corcept specifically instructed its clinical specialists to target physicians with patients who had diabetes, obesity, cushingoid appearance or other 'unknown' causes of elevated cortisol levels and tell those physicians to rely on a single screening test (the DST) . . . to prescribe Korlym." *Id.* Plaintiffs further argue that Defendants' statements were false because multiple CWs recount experiences with a Corcept clinical specialist who instructed them to use Korlym off-label. *Id.* Plaintiffs also argue that Defendants increased their honoraria payments to physicians by 322% in 2017 in order to encourage physicians to essentially act as Corcept spokespersons. *Id.* at 3.

Even taking Plaintiffs' factual allegations as true, the Court finds that Plaintiffs have failed to plead "specific facts indicating why" the statements at issue were false. *Metzler*, 540 F.3d at 1070. Specifically, even accepting as true Plaintiffs' allegations regarding an off-label marketing scheme, Plaintiffs have failed to indicate what was false and misleading about Defendants'

statements that Corcept had "developed and continue to refine and expand programs to educate the medical community and patients about diagnosis of this syndrome and to increase awareness regarding the role of cortisol modulators to treat the disease." Ex. A. at 2. Defendants' statements are generic and vague with regards to their claims regarding Corcept's efforts to educate physicians and patients about Cushing's Syndrome. As such, Plaintiffs' allegations regarding Defendants' off-label marketing scheme do not render Defendants' generic statements regarding Corcept's education efforts false when made. Thus, under the exacting pleading requirements for falsity under the PSLRA, Plaintiffs have not adequately demonstrated what was false or misleading about Defendants' challenged statements. *See Metzler*, 540 F.3d at 1070 (explaining that Plaintiffs must provide "specific facts indicating why" the statements at issue were false when made); *Apollo Group*, 774 F.3d at 603–04 (explaining that in a securities case, plaintiffs must "meet the higher, [more] exacting pleading standards of Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act (PSLRA).").

Accordingly, the Court finds that Statements 1, 7, 11, 16, 21, 25, 27 are not actionable.

ii. Marketing and Promotional Materials

Plaintiffs next argue that Defendants' statements related to the marketing and promotion of Korlym were false and misleading. Ex. A at 5, 25, 38, 55, 72, 92. Specifically, Plaintiffs challenge Defendants' statements that:

> In the United States, we market Korlym for treatment of 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 and provide promotional materials and training programs to physicians regarding the use of Korlym for this indication.

See, e.g., *id.* at 5. Plaintiffs argue that these statements were materially false and misleading when made "because Defendants did not market Korlym for on-label use." *Id.* Instead, Plaintiffs allege, "Corcept specifically instructed its clinical specialists to target physicians with patients who had diabetes, obesity, cushingoid appearance or other 'unknown' causes of elevated cortisol levels and tell those physicians to rely on a single screening test (the DST) with a high probability of a false

positives [sic] as a basis to prescribe Korlym immediately upon any indication of mild hypercortisolism (below the 1.8 Endocrinology guidelines) in disregard for the FDA-label and well-established clinical diagnosis protocols." *Id.* Defendants argue that Plaintiffs have failed to allege that Plaintiffs' challenged statements are false and misleading because Plaintiffs have failed to allege a widespread off-label marketing scheme or that any Corcept clinical specialists were instructed to market Korlym off-label. Mot. at 12–13.

The Court has already found that Plaintiffs have adequately alleged an off-label marketing scheme and that some Corcept clinical specialists were instructed to market Korlym off-label. *See* Section III(A)(1)(a), *supra*. Accordingly, the Court finds that Defendants' arguments lack merit. Furthermore, Plaintiffs have alleged "specific facts indicating why" Defendants' statements were false or misleading when made. *Metzler*, 540 F.3d at 1070. Specifically, Plaintiffs allege on the basis of their CWs statements that Corcept clinical specialist were encouraged and directed by Corcept managers and leadership to promote Korlym off-label to physicians across the country. *See* Section III(A)(1)(a), *supra*. The off-label marketing scheme that Corcept allegedly employed directly conflicts with the representations made to investors by Defendants in Statements 2, 8, 12, 17, 22, and 28. Accordingly, the Court finds that Statements 2, 8, 12, 17, 22, and 28 are actionable.

iii. Compliance with FDA Regulations for Off-Label Promotion

Plaintiffs next argue that Defendants' statements related to Corcept's compliance with FDA regulations for off-label promotion of Korlym are false and misleading. Specifically, Plaintiffs challenge Defendants' statements that "[a]lthough we believe our marketing materials and training programs for physicians do not constitute 'off-label' promotion of Korlym, the FDA may disagree." Ex A at 9, 29, 42, 59, 76, 96. Plaintiffs allege these statements were materially false and misleading because "Corcept did not market Korlym for on-label use" and Corcept "specifically instructed its clinical specialists to target physicians with patients who had diabetes, obesity, cushingoid appearance or other 'unknown' causes of elevated cortisol levels and tell those

physicians to rely on a single screening test (the DST) with a high probability of a false positives [sic] as a basis to prescribe Korlym immediately upon any indication of mild hypercortisolism . . . in disregard for the FDA-label." *Id.* at 9.

Because Defendants' statements were expressions of opinion, the challenged statements are actionable only if (1) the speaker "does not honestly hold the stated belief and the belief is objectively incorrect," or (2) if the statements "omit[] material facts about the issuer's inquiry into or knowledge concerning a statement of opinion and those facts conflict with what a reasonable investor would take from the statement itself." *City of Dearborn Heights Act 245 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 615 (9th Cir. 2017) (internal quotation marks omitted) (quoting *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 188 (2015)).

Plaintiffs argue that although "Defendants' statement is framed as an opinion or belief, any purported belief lacked any reasonable basis given the pervasive and uniform sales pitch used across the country by Corcept's relatively small sales staff." Ex. A at 10. Plaintiffs further argue that Defendants' statement of opinion was false or materially misleading because Defendants "[did] not honestly hold the stated belief and the belief is objectively incorrect." *City of Dearborn Heights*, 856 F.3d at 615.

The Court agrees with Plaintiffs' arguments. The Court has found that Plaintiffs adequately alleged that Corcept utilized an off-label marketing scheme and that some Corcept clinical specialists were instructed and encouraged to market Korlym off-label to physicians. *See* Section III(A)(1)(a), *supra*. Thus, Defendants' statements were objectively incorrect because Defendants were engaged in an off-label marketing scheme for Korlym to physicians.

Furthermore, Plaintiffs have adequately alleged that Defendants did not honestly believe the statement that Corcept's "marketing materials and training programs for physicians do not constitute 'off-label' promotion of Korlym." Ex A at 9. Specifically, Plaintiffs have alleged that Corcept's CEO, Defendant Belanoff, accompanied CW11 on sales visits to physicians' offices and

on those visits Belanoff marketed Korlym off-label to physicians. TAC at ¶ 370. When CW11 questioned Belanoff regarding these off-label promotions of Korlym, Belanoff stated, "I can say what I want." *Id.* CW11 later raised concerns to Belanoff and VP of Sales Burke regarding Korlym's off-label marketing practices and Burke told CW11 to "sit down and shut up." *Id.* at ¶ 176. Furthermore, CW11 recalls that during the Class Period, three Corcept employees were let go for raising concerns regarding off-label promotion of Korlym or for refusing to promote Korlym off-label. *Id.* at ¶¶ 192–194. Accordingly, the Court finds that Plaintiffs have adequately alleged that Defendants did not honestly believe their statements that "[a]lthough we believe our marketing materials and training programs for physicians do not constitute 'off-label' promotion of Korlym, the FDA may disagree." Ex. A at 9.

In sum, with respect to Statements, 9, 13, 18, 23, and 29, the Court agrees with Plaintiffs that even as statements of opinion, Defendants "[did] not honestly hold the stated belief and the belief is objectively incorrect." *City of Dearborn Heights*, 856 F.3d at 615. Accordingly, the Court finds that Statements 3, 9, 13, 18, 23, and 29 are actionable.

iv. Corcept's Revenue and Sales Growth

Plaintiffs next argue that Defendants made false and misleading statements regarding Corcept's revenue and sales growth. Specifically, Plaintiffs challenge Defendants' statement that:

> The strong growth in Korlym revenue . . . was sustained by the same trends in medical practice that I have described in previous calls: growing awareness amongst physicians of Korlym's efficacy, the increasing frequency with which physicians are screening for and treating patients with hypercortisolism and our commercial organization[']s focus[] on the endocrinologists who treat most patients with hypercortisolism.

Ex. A at 12 (second and third alterations in original). Plaintiffs allege that Defendants made a similar statement regarding the basis for Korlym's growth on eight occasions. *Id.* at 15, 19, 32, 45, 49, 62, 65, 79. Plaintiffs argue first that these statements were false when made because "the increase in revenue from Korlym was the direct result of Corcept promoting Korlym to non-specialist Endocrinologists and Primary Care Physicians, for off-label uses." *Id.* at 12 (emphasis in original). Second, Plaintiffs argue that Defendants' statements were false because "Defendants

were focusing their marketing on unsuspecting non-Specialist Endocrinologists and other physicians, not Specialist Endocrinologists." *Id.* (emphasis in original).

Plaintiffs' allegations in the TAC do not render Defendants statements false or misleading. First, Plaintiffs argue that Defendants' statement were false when made because "the increase in revenue from Korlym was the direct result of Corcept promoting Korlym to non-specialist Endocrinologists and Primary Care Physicians, for off-label uses." *Id.* at 12. However, even assuming that Plaintiffs' allegation is true, the Court does not find that this allegation renders Defendants' statements false. Defendants' statements attribute Korlym's growth in revenue to "growing awareness amongst physicians of Korlym's efficacy." *Id.* However, Defendants' statements say nothing about whether physicians are prescribing Korlym for on-label or off-label use. Defendants merely state that physicians are increasingly realizing Korlym's "efficacy." Once a product is approved by the FDA, physicians may prescribe the product for "off-label" use. *See In re Gilead*, 536 F.3d at 1051. Thus, Defendants' off-label marketing scheme does not render Defendants' challenged statements false when made because those statements do not claim that physicians were prescribing Korlym only for on-label use.

Second, Plaintiffs argue that Defendants' statements were false because "Defendants were focusing their marketing on unsuspecting non-Specialist Endocrinologists and other physicians, not Specialist Endocrinologists." Ex. A at 12 (emphasis in original). However, Defendants' statements do not mention Special Endocrinologists or non-Specialist Endocrinologists, a distinction that Plaintiffs appear to have invented for the purpose of their complaint. Rather, Defendants' statements refer only to Corcept's "focus[] on the endocrinologists who treat most patients with hypercortisolism." Even accepting as true that Corcept began to focus its marketing on so-called "non-specialist" endocrinologists, that does not demonstrate that Corcept was not focused on "the endocrinologists who treat most patients with hypercortisolism." Furthermore, Plaintiffs have failed to identify any other allegations in the TAC that render Defendants' statements false or misleading.

Accordingly, the Court finds that Statements 4, 5, 6, 10, 14, 15, 19, 20, and 24 are not actionable.

v. On-Label Use of Korlym

Plaintiffs next argue that Defendants made a false and misleading statement regarding on-label use of Korlym. Specifically, Plaintiffs challenge Defendants statement that "99% of our Korlym patients are on label – prescription, sorry, are on-label and we continue to see favorable insurance reimbursement." Ex. A at 86. Plaintiffs argue that this statement was materially false and misleading because "it was unmoored from reality: the Company's off-label marketing scheme had resulted in non-Specialist endocrinologists prescribing Korlym to a myriad of patients without confirmed endogenous Cushing's diagnoses." *Id.* Plaintiffs further argue that this statement was false because CW11 alleges that at least 60% of Korlym prescriptions were off label during CW11's tenure at Corcept [2012 to 2016]. Opp. at 12. The Court addresses each argument in turn.

First, even accepting as true CW11's allegation that during CW11's tenure at Corcept 60% of prescriptions were off-label, CW11's allegation does not demonstrate the falsity of Defendants' statement that "99% of our Korlym patients are on label – prescription, sorry, are on-label and we continue to see favorable insurance reimbursement." Defendants' statement was made in 2018, roughly two years after CW11 left Corcept. CW11's allegations regarding the percentage of prescriptions of Korlym that were off-label between 2012 and 2016 does not prove the falsity of Defendants' statement two years later regarding the percentage of Korlym prescriptions that were on-label. "[A] temporal mismatch between a CW's statement and a Defendant's statement results in a failure to plead with particularity 'the reason or reasons why the statement is misleading.'" *Brodsky v. Yahoo! Inc.*, 592 F. Supp. 2d 1192, 1201 (N.D. Cal. 2008) (quoting 15 U.S.C. §78u-4(b)(1)).

Second, Plaintiffs argue that Statement 26 was false when made because Corcept was engaged in a widespread off-label marketing scheme for Korlym. Specifically, Plaintiffs allege

that Corcept's "off-label marketing scheme had resulted in non-Specialist endocrinologists prescribing Korlym to a myriad of patients without confirmed endogenous Cushing's diagnoses, as Korlym prescriptions were based only on a single DST result, even if those results were only borderline abnormal or well below the guidelines of 1.8." Ex. A at 86. Plaintiffs further allege that Plaintiffs' ten physician CWs were all subject to off-label marketing from Corcept clinical specialists during the Class Period. *Id.* CW14 further alleges that during the Class Period physicians prescribed Korlym even when the DST was below the "1.8 guideline, including as low as 0.7, and that this was happening 'a lot.'" TAC at ¶ 198. Finally, CW14 alleges that "Maduck [VP of Commercial] and Burke [VP of Sales] 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." *Id.* at ¶ 200.

Defendants argue in opposition that Plaintiffs' allegations are insufficient to demonstrate falsity because Plaintiffs have not adequately alleged that Korlym prescriptions based on only a single DST result are "off label." Mot. at 13.

However, as the Court has already explained, see *supra* Section III(A)(1)(a)(i), whether these practices constitute off-label promotion of Korlym is a question of fact that is not appropriately decided on a motion to dismiss. *See Dahlia*, 735 F.3d at 1076 (stating that a court's "task is not to resolve any factual dispute" on a Rule 12(b)(6) motion). At this stage, the Court must assume the truth of Plaintiffs' allegations regarding off-label promotion of Korlym and construe the pleadings in the light most favorable to Plaintiffs. *See Manzarek*, 519 F.3d at 1031 (explaining that on a 12(b)(6) motion the court "accept[s] factual allegations in the complaint as true and construe[s] the pleadings in the light most favorable to the nonmoving party.").

Accepting as true Plaintiffs' allegations regarding Corcept's off-label marketing scheme and the allegations of Plaintiffs' ten physician CW and four former employee CWs, the Court finds that Plaintiffs have adequately alleged the falsity of Defendants' statement that "99% of our Korlym patients are on label – prescription, sorry, are on-label and we continue to see favorable

insurance reimbursement." Ex. A at 86. Thus, given the widespread nature of Corcept's off-label marketing scheme and the reports of Plaintiffs' CWs that physicians were prescribing Korlym off-label at the suggestion of Corcept clinical specialist, the Court finds that Plaintiffs have adequately alleged that Statement 26 was false or misleading when made. *Metzler*, 540 F.3d at 1070 (falsity is demonstrated by pleading "specific facts indicating why" statement was false when made). As such, the Court finds that Statement 26 is actionable.

In summary, the Court finds that Plaintiffs have adequately alleged that Statements 2, 3, 8, 9, 12, 13, 17, 18, 22, 23, 26, 28, and 29 were false or misleading when made. The Court further finds that Plaintiffs have failed to adequately allege that Statements 1, 4-7, 10, 11, 14-16, 19-21, 24, 25, and 27 were false or misleading when made. Accordingly, the Court GRANTS Defendants' motion to dismiss Plaintiffs' § 10(b) and Rule 10b-5 cause of action with respect to Statements 1, 4-7, 10, 11, 14-16, 19-21, 24, 25, and 27. The Court previously dismissed these statements with leave to amend. *See* ECF No. 124. at 47. The Court warned that failure to cure the deficiencies identified in the Court's order and in Defendants' motion to dismiss would result in dismissal of Plaintiffs' deficient claims with prejudice. *Id.* The Court thus finds that leave to amend as to Statements 1, 4-7, 10, 11, 14-16, 19-21, 24, 25, and 27 would be futile. See *Leadsinger*, 512 F.3d at 532. Accordingly, the Court dismisses with prejudice Plaintiffs' § 10(b) and Rule 10b-5 claim with respect to Statements 1, 4-7, 10, 11, 14-16, 19-21, 24, 25, and 27.

The Court now turns to Defendants' arguments regarding scienter and loss causation with respect to Statements 2, 3, 8, 9, 12, 13, 17, 18, 22, 23, 26, 28, and 29.

2. Scienter

In order to survive a motion to dismiss, Plaintiffs' complaint must also create a strong inference of scienter. *See* 15 U.S.C. § 78u–4(b)(2) ("[The complaint must] state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind."). With respect to the strong inference requirement, the Ninth Circuit has stated that "[a] strong inference of scienter must be more than merely plausible or reasonable—it must be cogent and at

least as compelling as any opposing inference of nonfraudulent intent." *Reese v. Malone*, 747 F.3d 557, 569 (9th Cir. 2014), *overruled on other grounds by City of Dearborn Heights*, 856 F.3d at 605.

As to the meaning of "scienter," the Ninth Circuit has held that a plaintiff's complaint must show that "the defendants made false or misleading statements either intentionally or with deliberate recklessness." *Zucco*, 552 F.3d at 990–91 (internal quotation marks omitted). "[F]acts showing mere recklessness or a motive to commit fraud and [the] opportunity to do so" are insufficient. *Id.* "To meet this pleading requirement, the complaint must contain allegations of specific contemporaneous statements or conditions that demonstrate the intentional or the deliberately reckless false or misleading nature of the statements when made." *Ronconi*, 253 F.3d at 432 (internal quotation marks and citation omitted). When an omission is at issue, "plaintiff must plead a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Zucco*, 552 F.3d at 991 (internal quotation marks omitted).

In the Ninth Circuit, courts generally first determine "whether any of the plaintiff's allegations, standing alone, [are] sufficient to create a strong inference of scienter." *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1056 (9th Cir. 2014). If none of the allegations are sufficient standing alone, the court "then consider[s] the allegations holistically to determine whether they create a strong inference of scienter taken together." *Id.* Under this holistic review, scienter is adequately pled if "all of the facts alleged, taken collectively, give rise to a strong inference of scienter." *Police Retirement Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1061–62 (9th Cir. 2014).

Here, Plaintiffs argue that they have adequately pled scienter through (1) a core operations theory; (2) particularized facts demonstrating scienter for Individual Defendants, and (3) various CW statements and other evidence when viewed holistically. Defendants argue that Plaintiffs

have failed to adequately allege scienter because (1) Plaintiffs fail to plead direct evidence of scienter, (2) Plaintiffs' scienter allegations fail under a holistic review, and (3) Plaintiffs' core operations allegations are insufficient.

The Court first addresses Plaintiffs' core operations theory allegations. Because the Court finds that these allegations are dispositive, the Court does not reach Plaintiffs' alternative arguments in support of scienter.

a. Core Operations Theory

Plaintiffs first argue that they have adequately pled a strong inference of scienter through a core operations theory. A core operations theory may be used to impute to a company's key officers knowledge of "facts critical to a business's 'core operations' or an important transaction." *S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 783 (9th Cir. 2008). This theory may be used where the allegations in the complaint (1) "when read together, raise an inference of scienter that is cogent and compelling, thus strong in light of other explanations"; (2) "are particular and suggest that defendants had actual access to the disputed information"; or (3) "in rare circumstances where the nature of the relevant fact is of such prominence that it would be absurd to suggest that management was without knowledge of the matter." *Intuitive Surgical*, 759 F.3d at 1062 (quoting *S. Ferry LP*, F.3d at 785–86). Plaintiffs rely on the second and third of these theories.

Plaintiffs argue that the core operations theory supports a strong inference of scienter because "Defendants had access to the off-label prescription and patient data (including the tracking of this data for clinical specialist commission payments and sending of congratulatory emails)." Opp. at 14. Furthermore, Plaintiffs argue that "[g]iven that Korlym comprised 100% of Corcept's revenue, it would be absurd to suggest that Defendants were unaware of Corcept's off-label marketing scheme, particularly where it emanated from senior leadership." *Id.* Defendants argue that Plaintiffs cannot adequately plead "scienter under such theory because the TAC does not adequately allege a company-wide off-label marketing scheme for Korlym." Mot. at 22.

First, Defendants' argument lacks merit because the Court finds that Plaintiffs have adequately allegedly an off-label marketing scheme. *See* Section III(A)(1)(a), *supra*.

Second, the Court agrees with Plaintiffs that this is one of the circumstances in which a core operations theory is sufficient to plead a strong inference of scienter because "the nature of the relevant fact is of such prominence that it would be 'absurd' to suggest that management was without knowledge of the matter." *Reese*, 747 F.3d at 576. Plaintiffs have alleged that Korlym accounts for 100% of Corcept's revenue and therefore any company-wide off-label marketing scheme would be of such prominence that "it would be 'absurd' to suggest that management was without knowledge" of Corcept's widespread off-label marketing scheme. *Id.*

The Court notes that Belanoff has served as CEO and Director of Corcept since 1999, and President of Corcept since 2014. TAC ¶ 39. Robb has served as Corcept's Chief Financial Officer since 2011. *Id.* at ¶ 40. Maduck was Corcept's VP of Sales and Marketing from 2012 to 2016 and has been Corcept's Senior VP of Commercial since 2016. *Id.* at ¶ 41. Each is a key member of Corcept's management team and is intimately involved in the operation of the company and the sale of Korlym. Belanoff, for example, assured investors on a call by stating that "[i]t'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." *Id.* at ¶ 381. Defendants were also involved in the marketing of Korlym. Belanoff allegedly accompanied clinical specialists on physician sales calls and Maduck was responsible for overseeing the company's sales staff and education programs. *Id.* at ¶¶ 370, 401. These allegations are sufficient to establish that Defendants were engaged in the core operation of the company. *See S. Ferry LP*, 542 F.3d at 785 (explaining that information about the management structure of a company may create a strong inference of scienter "in conjunction with detailed and specific allegations about management's exposure to factual information within the company").

Furthermore, Plaintiffs allege that ten physician CWs received unfirm off-label marketing messages from Corcept clinical specialists during the Class Period. *Id.* at ¶¶ 366–369. Plaintiffs

also allege that Corcept leadership and managers, including Maduck, openly pushed clinical specialist to market Korlym off-label to physicians, and that Corcept's top-performing clinical specialists were flagrantly promoting Korlym off-label to boost sales numbers. *Id.* at ¶¶ 195, 200, 373.

The Court therefore agrees with Plaintiffs that given that Korlym represented 100% of Corcept's revenue and Corcept allegedly employed a widespread off-label marketing scheme to promote Korlym, "it would be 'absurd' to suggest that management was without knowledge of the" off-label marketing scheme. *Reese*, 747 F.3d at 576; *see also Di Donato v. Insys Therapeutics, Inc.*, 2017 WL 3268797,*15 (D. Ariz. Aug. 1, 2017) (inferring scienter under a core operations theory where Subsys accounted for 98% of the company's revenue, noting "it is absurd to think [the CFO] knew about Subsy's anomalous market dominance but did not know how the company had pulled off the feat."). As such, the Court finds that "all of the facts alleged, taken collectively, give rise to a strong inference of scienter." *Intuitive Surgical*, 759 F.3d at 1061–62.

Accordingly, the Court finds that Plaintiffs have adequately alleged a strong inference of scienter for Defendants Belanoff, Robb, and Maduck under a core operations theory as to Statements 2, 3, 8, 9, 12, 13, 17, 18, 22, 23, 26, 28, and 29. Defendants do not challenge Plaintiffs' allegations regarding Corcept's corporate scienter. *See* TAC at ¶ 446.

3. Loss Causation

Finally, the Court addresses Defendants' arguments regarding loss causation. To prevail, a securities fraud plaintiff must ultimately "prove that the defendant's misrepresentation was a substantial cause of his or her financial loss." *Loos v. Immersion Corp.*, 762 F.3d 880, 887 (9th Cir. 2014). "At the pleading stage, however, the plaintiff need only allege that the decline in the defendant's stock price was proximately caused by a revelation of fraudulent activity rather than by changing market conditions, changing investor expectations, or other unrelated facts." *Id.* The Ninth Circuit has clarified that "[t]o prove loss causation, plaintiffs need only show a causal connection between the fraud and the loss, by tracing the loss back to the very facts about which

the defendant lied." *Mineworkers' Pension Scheme v. First Solar Incorporated*, 881 F.3d 750, 753 (9th Cir. 2018) (internal citations and quotation marks omitted). "The burden of pleading loss causation is typically satisfied by allegations that the defendant revealed the truth through 'corrective disclosures' which caused the company's stock price to drop and investors to lose money." *Lloyd v. CVB Fin. Corp.*, 811 F.3d 1200, 1209 (9th Cir. 2016) (internal quotation marks omitted). To be corrective, the disclosure must "relate back to the misrepresentation and not to some other negative information about the company." *In re Nuveen Funds/City of Alameda Sec. Litig.*, 2011 WL 1842819, at *10 (N.D. Cal. May 16, 2011) (internal quotation marks omitted).

Plaintiffs argue that the following allegations adequately plead loss causation: (1) Defendants made materially false and misleading statements that inflated the price of Corcept securities, and (2) "[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." TAC at ¶ 449.

As the Court noted in its November 20, 2020 Order granting Defendants' motion to dismiss, these allegations indicate that Plaintiffs rely on a market revelation of fraud theory of loss causation, whereby a plaintiff's loss is demonstrated by "allegations that the defendant revealed the truth [of the fraud] through correct disclosures which caused the company's stock price to drop and investors to lose money." *Lloyd*, 811 F.3d at 1209 (internal citations and quotation marks removed). Under a market revelation of fraud theory, a plaintiff alleges that they purchased securities on the basis of defendant's misstatements or other fraudulent conduct. When the truth regarding the fraud or misstatement is finally revealed through a "corrective disclosure," such as a press release, SEC filing, or some other announcement, the disclosure of the truth causes the stock price to drop, thereby causing the plaintiff to lose money. *See In re Bofl Holding, Inc. Sec. Litig.*, 977 F.3d 781, 789 (9th Cir. 2020) (explaining the mechanics of a fraud-on-the-market theory of loss causation).

Plaintiffs argue that they have alleged two corrective disclosures in the instance case: (1) a

January 25, 2019 SIRF Report ("SIRF Report"); and (2) a January 31, 2019 Corcept Press Release ("January Press Release"). TAC at ¶¶ 450, 464. Defendants argue that Plaintiffs have failed to adequately allege loss causation because the SIRF Report and January Press Release are not adequate corrective disclosures. Mot. at 23–25. The Court addresses the two alleged corrective disclosures in turn.

a. SIRF Report

Plaintiffs allege that Defendants' misrepresentations and fraudulent conduct were first disclosed to the market by the January 25, 2019 SIRF Report, which alleged 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." TAC ¶ 450. Plaintiffs allege that 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." *Id.* The day the report was published Corcept's share price fell $1.52, or more than 11%. *Id.* at ¶ 463.

Defendants argue that the SIRF Report was not a "corrective disclosure" that resulted in market revelation of fraud for three reasons: (1) the SIRF Report relies entirely on publicly-available information and Plaintiffs have not plausibly alleged why that information was not reflected in the company's stock price; (2) Plaintiffs have not, and cannot, argue that other market participants had not done the same analysis found in the SIRF Report; and (3) the SIRF Report disclosed only a risk of fraud. Mot. at 23–25. Plaintiffs argue in opposition that the SIRF Report (1) "connected disparate non-public and public data not readily available to the market"; (2) "no other market analyst demonstrated knowledge of, or reliance on, the information underlying the SIRF Report's conclusions"; and (3) Corcept had not directed investors to the newly revealed information. Opp. at 21.

Defendants first argue that because Plaintiffs allege that Corcept's stock trades in an efficient market, allegedly fraudulent activity cannot be "revealed" to the market by a purportedly corrective disclosure if that disclosure is derived entirely from public filings. "[Corcept's] stock is

deemed to trade in an efficient market in which all publicly available information about the company, both positive and negative, is quickly incorporated into the stock price. . . . A corrective disclosure, though, must by definition reveal new information to the market that has not yet been incorporated into the price." *In re Bofl Holding*, 977 F.3d at 794.

The SIRF Report contains information derived from FDA Freedom of Information Act ("FOIA") requests, Open Payments data, Medicare Part D data, and Corcept's own publicly released growth data. TAC at ¶¶ 455–459. Each of these sources of information are publicly available. This makes Plaintiffs' task more difficult because Corcept's "stock price should already reflect whatever public information [the report] might be based upon." *In re Bofl Holding*, 977 F.3d at 794. However, this fact alone does not doom Plaintiffs' argument. Instead, "[t]o rely on a corrective disclosure that is based on publicly available information, a plaintiff must plead with particularly facts plausibly explaining why the information was not yet reflected in the company's stock price." *Id*. "For pleading purposes, [Plaintiffs] need[] to allege particular facts plausibly suggesting that other market participants had not done the same analysis." *Id.* (emphasis removed).

Plaintiffs have met that standard in the instant case. Plaintiffs allege that 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." TAC at ¶ 455. Plaintiffs allege that on the basis of this research, the SIRF Report "reveal[ed] 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." *Id.* at ¶ 450. Plaintiffs thus allege that "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." *Id.* at ¶ 461.

Defendants argue that the SIRF Report did not provide new information to the market because the underlying data on which the SIRF Report was based was "accessed and understood by analysts covering Corcept, including Bank of America's Peter Stapor, who asked a question on a 2017 earnings call about that data." Reply at 15. However, Peter Stapor's single question, which inquired about the "91 death cases associated with" Korlym that are referenced in the FAERS data, does not demonstrate that the market knew of and digested the information contained in the SIRF Report. *Id.* Specifically, Peter Stapor's question on the 2017 earnings call did not mention Corcept's off-label marketing scheme or any of Corcept's marketing or sales practices. The question concerned only the deaths associated with use of Korlym. *Id.* Thus, Defendants have not demonstrated that any analyst report or analyst question prior to the SIRF Report provided information regarding Corcept's off-label marketing scheme to the market.

Accordingly, based on Plaintiffs' allegations regarding the information concerning Defendants' off-label marketing scheme provided by the SIRF Report, the Court finds that "the alleged corrective disclosure provided new information to the market that was not yet reflected in the company's stock price." *In re Bofl*, 977 F.3d at 795. Thus, Plaintiffs' have adequately pled that the SIRF Report was a corrective disclosure. *Id.*

b. January Press Release

Plaintiffs also allege that Corcept's January 31, 2019 Press Release was a second corrective disclosure. Plaintiffs allege that in the Press Release, Defendants "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." TAC at ¶ 464. The day the Press Release was published, Corcept shares fell $1.15, or more than 10%. *Id.*

Defendants argue that the January Press Release was not a "corrective disclosure" that resulted in market revelation of fraud because the January Press Release did not call into question or render untrue any statements made by Defendants. Mot. at 25. Plaintiffs reply that the

corrective disclosure does not need to explicitly disclose the fraud at issue. Opp. at 25.

The Court agrees with Defendants. The January Press Release does not mention fraudulent conduct, off-label marketing, increased scrutiny from insurance companies, or the allegations of the SIRF Report. Instead, the January Press Release simply reports Corcept's 2018 preliminary selected financial results and 2019 revenue guidance. *See* TAC at ¶ 464.

Plaintiffs allege that the projected forecast in sales for Korlym in 2019 announced in the Press Release represents a "sharp slowdown in sales," which Plaintiffs argue was "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." *Id.* at ¶ 464.

However, as the Court noted in its November 20, 2020 Order granting Defendants' motion to dismiss, Plaintiffs have done little to substantiate these allegations in the TAC. *See* ECF No. 124, at 45. The Press Release itself offers no guidance as to the cause of the revenue forecast, and Plaintiffs' allegations are little more than conjecture. Moreover, there are no facts alleged in the TAC that support the allegation that the market understood the January Press Release to be a revelation of Corcept's allegedly fraudulent conduct. "[W]hile the court assumes that the facts in a complaint are true, it is not required to indulge unwarranted inferences." *Metzler*, 540 F.3d at 1064–65 (explaining that "[t]he TAC's allegation that the market understood the June 24 and August 2 disclosures as a revelation of Corinthian's systematic manipulation of student enrollment is not a 'fact.'"). Accordingly, the Court finds that Plaintiffs have failed to adequately plead that the January Press Release was a corrective disclosure.

Thus, the Court finds that only the SIRF Report was a corrective disclosure. *In re Bofl Holding*, 977 F.3d at 794 ("A corrective disclosure . . . must by definition reveal new information to the market that has not yet been incorporated into the price."). Because Plaintiffs have adequately pled that the SIRF Report was a corrective disclosure and Defendants do not otherwise challenge the sufficiency of Plaintiffs' allegations regarding loss causation, the Court finds that Plaintiffs have sufficiently pled loss causation for Statements 2, 3, 8, 9, 12, 13, 17, 18, 22, 23, 26,

28, and 29.

In sum, the Court finds that Plaintiffs have adequately plead actionable false and misleading statements, scienter, and loss causation as to Statements 2, 3, 8, 9, 12, 13, 17, 18, 22, 23, 26, 28, and 29. Accordingly, the Court DENIES Defendants' motion to dismiss Plaintiffs' claim against all Defendants for violation of § 10(b) of the Exchange Act and Rule 10b-5 as to Statements 2, 3, 8, 9, 12, 13, 17, 18, 22, 23, 26, 28, and 29.

B. Claim Two: Violation of § 20(a) of the Exchange Act

Congress has established liability in § 20(a) for "[e]very person who, directly or indirectly, controls any person liable" for violations of the securities laws. 15 U.S.C. § 78t(a). To prove a prima facie case under § 20(a), a plaintiff must prove: (1) "a primary violation of federal securities law;" and (2) "that the defendant exercised actual power or control over the primary violator." *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1065 (9th Cir. 2000).

Defendants argue that "[b]ecause Plaintiffs have failed" to adequately plead a primary violation of § 10(b), "the Section 20(a) claim should also be dismissed." Mot. at 25. However, Plaintiffs have adequately pled a primary violation of § 10(b). Accordingly, the Court DENIES Defendants' motion to dismiss Plaintiffs' § 20(a) claim as to all Defendants.

IV. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss Plaintiffs' TAC is GRANTED in part and DENIED in part. Specifically, Defendants' motion to dismiss Plaintiffs' § 10(b) and Rule 10b-5 claim against all Defendants is GRANTED with prejudice as to Statements 1, 4-7, 10, 11, 14-16, 19-21, 24, 25, and 27, and DENIED as to Statements 2, 3, 8, 9, 12, 13, 17, 18, 22, 23, 26, 28, and 29. Furthermore, Defendants' motion to dismiss Plaintiffs' § 20(a) claim against all Defendants is DENIED.

IT IS SO ORDERED.

Dated: August 24, 2021

Lucy H. Koh

LUCY H. KOH
United States District Judge