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 WITH LEAVE TO AMEND DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' SECOND 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')." Second Amended Complaint, at 5, ECF No. 100–1 ("SAC").

Before the Court is Defendants' Motion to Dismiss. ECF No. 105 ("Mot."). Having considered the submissions of the parties, the relevant law, and the record in this case, the Court GRANTS Defendants' motion to dismiss with leave to amend.

I. BACKGROUND

A. Factual Background

Defendant Corcept Therapeutics Incorporated ("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." SAC ¶ 36. Defendant Joseph K. Belanoff is a co-founder of Corcept, and has served as Chief Executive Officer and Director of Corcept since 1999, and President of Corcept since 2014. *Id.* ¶ 37. Defendant Charles Robb has been Corcept's Chief Financial Officer since 2011. *Id.* ¶ 38. Defendant Sean Maduck was Corcept's Vice President of Sales and Marketing from 2012 to 2016 and Corcept's Senior Vice President of Commercial since 2016. *Id.* ¶ 39.

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.* ¶ 53. In April of 2011, Corcept submitted a New Drug Application ("NDA") for Korlym to the FDA. *Id.* ¶ 68. 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.* ¶ 69. Korlym is approved only to treat endogenous Cushing Syndrome and currently generates 100% of Corcept's revenue. *Id.* ¶ 57. There are two types of Cushing Syndrome, exogenous and endogenous. Endogenous Cushing Syndrome is far more rare, and treatment requires surgery, radiation, or medications. *Id.* ¶ 55. 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.* ¶ 61.

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.* ¶ 106 (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.* ¶ 109. Per the terms of the service agreement, Dohmen distributed Korlym to patients and recorded inventory levels. *Id.* ¶ 113. Dohmen was also responsible for providing Corcept with a monthly itemized invoice for services provided and six financial reports each day. *Id.* ¶ 114.

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.* ¶ 122. 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.* ¶ 119. 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.* ¶¶ 122–123.

Plaintiffs allege that in reaction to this looming loss of market exclusivity, Defendants began to aggressively market Korlym to endocrinologists. When that proved insufficient, Defendants began to market Korlym to "non-Specialist Endocrinologists and Primary Care Physicians." *Id.* ¶ 130. 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.* ¶ 132. Optime's co-founders and CFO are all former Dohmen employees. *Id.* ¶ 133. Plaintiffs allege that the service agreement between Corcept and Optime was structured in such a way as to allow

Corcept to "exert control of Optime, treating Optime as its ministerial arm while providing strict-day-to-day oversight on any project it sees fit." *Id.* ¶ 141.

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 at least 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 Id.* ¶ 241. 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.* ¶ 248. 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.* ¶ 242. When Plaintiffs refer to "payments to physicians," it is usually not clear which of these three kinds of payments they mean. At certain points in the SAC Plaintiffs specify the form of payment, but often Plaintiffs do not.

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.* ¶¶ 169–170. In 2013, for example, of the 298 physicians that Corcept made payments to, 203 were endocrinologists. *Id.* ¶ 167. In 2018, by contrast, 2438 physicians received payments from Corcept, of which only 1072 were endocrinologists. *Id.* ¶ 168. Plaintiffs point to a series of other changes in the composition and distribution of physician payments that they allege support this general trend. *Id.* ¶¶ 167–176. Plaintiffs allege that this increase illustrates Defendants' campaign to target non-specialist endocrinologists and primary care physicians. *Id.* ¶ 168. 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.* ¶ 178.

3. Corcept's Alleged Off-Label Marketing Scheme

Plaintiffs allege that the growth of Korlym's sales was also driven in large part by an illegal off-label marketing scheme. *Id.* ¶ 11. 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") and Plaintiffs' Expert ("PE"), Plaintiffs allege that Corcept began to aggressively market Korlym for off-label use, both as a treatment for "those with possible endogenous Cushing's Syndrome (but without a confirmed diagnoses)" and for "patients with a general Cushingoid appearance, Subclinical Cushing's Syndrome, purported 'Pre-Cushing's,' poorly controlled diabetes, obesity, and to 'pre-treat' patients with adrenal masses with Korlym prior to surgery." *Id.* ¶ 179. Marketing Korlym in this manner constitutes an off-label promotion, Plaintiffs argue, because it markets Korlym "as a first-line treatment option for each of these non-approved ailments and for use as a diagnostic tool for Cushing's Syndrome." *Id.* ¶ 180.

Plaintiffs allege that "Corcept's sales representatives [] employ[ed] a uniform, off-label

marketing pitch in every Corcept sales region across the country instructing physicians to use Korlym as a 'diagnostic tool' to diagnose patients, with no further testing to confirm the endogenous Cushing Syndrome Diagnosis." *Id.* ¶ 181. Plaintiffs further allege that Corcept sales representatives instructed 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.* ¶¶ 12–14.

Plaintiffs provide examples of this alleged off-label marketing scheme for each of their ten CWs. *Id.* ¶¶ 183–223. These physician CWs statements are described in turn:

- CW1 describes a Corcept sales representative who visited CW1's office frequently between 2017 and 2019, and who 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.* ¶ 183. 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.* ¶ 184. The SAC does not allege any further details about CW1's identity or professional status.
- CW2, "a family medicine physician from Oklahoma," recalls a Corcept sales representative coming into CW2's office beginning in 2018. CW2 recalls the sales representative 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 sales representative told CW2 that if "the DST was positive, then CW2 should immediately start the patients on Korlym." *Id.* ¶ 185. CW2 also recalls being instructed by the sales representative to "'close [CW2's] eyes' and not just look for physical symptoms of Cushing's Syndrome because 'anyone could have it.'" *Id.* ¶ 186. "CW2 recalls prescribing Korlym to two patients based on the Corcept rep's off-label marketing message." *Id.* ¶ 188.
- CW3, "an Endocrinologist practicing in Nebraska for over 15 years," recalls a Corcept sales representative 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.* ¶ 191. CW3 recalls that in late 2018 or early 2019, the sales representative began "recommending CW3 use Korlym 'proactively' to 'pre-treat' patients with adrenal masses, prior to surgery." *Id.* ¶ 193.
- CW4, "an Endocrinologist practicing in Pennsylvania for over 15 years," recalls being visited by a Corcept sales representative 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.* ¶ 196. The sales representative further pushed this marketing of Korlym at other events CW4 attended in February of 2020. *Id.* ¶ 200.

- CW5, "an Endocrinologist from New York practicing for over 10 years," had similar experiences with the same sales representative between 2017 and 2018. CW5 recalls that the sales representative "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.* ¶ 202.
- CW6, "an Endocrinologist practicing in West Virginia with over 20 years experience," described a Corcept sales representative telling CW6 "to use Korlym as a diagnostic tool to confirm a Cushing's diagnosis after a single mildly abnormal DST." *Id.* ¶ 204. 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.* ¶ 204.
- CW7, "an Endocrinologist from New York, practicing for over 6 years," was visited by a Corcept sales representative for several years. The sales representative told CW7 to "use DST as a diagnostic tool" and to use "Korlym as a 'bridge' for those awaiting surgery." *Id.* ¶ 206. The sales representative also provided CW7 with DST samples and offered to fill out insurance paperwork to get Korlym approved. *Id.* ¶ 207.
- CW8, "an Endocrinologist from Texas practicing for over nine years," recalls that beginning in 2016 or early 2017, a Corcept sales representative 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.* ¶ 210. CW8 recalls the sales representative also "inserting case studies into promotional materials that also promoted Korlym for off-label use." *Id.* ¶ 214.
- CW9, "an Endocrinologist from Ohio practicing for over twenty years," recalls a sales representative 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.* ¶ 215. The sales representative also suggested using Korlym "as a bridge to surgery." *Id.* ¶ 217.
- CW10, "a family medicine physician from California practicing for over 20 years," recalls that a Corcept sales representative visited CW10's office between March 2017 and October 2017. *Id.* ¶ 219. The sales representative "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.* ¶ 220. CW10 also recalls the sales representative "giving CW10 a tear sheet that promoted Korlym as a front line therapy for diabetic patients." *Id.*

Plaintiffs allege that this off-label marketing scheme, targeted at non-specialist endocrinologists, materially contributed to Corcept's revenue. For example, Plaintiffs allege that revenue from "non-Specialists Endocrinologists, i.e. community based endocrinologists, internists, family medicine physicians etc., increased 1,396.88% from 2014 to 2017." *Id.* ¶ 234.

However, Plaintiffs also allege that insurance providers suspected that there were a growing number of off-label prescriptions of Korlym, and so insurers tightened their requirements for approving Korlym, beginning in 2018. 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; and the Oklahoma Health Care Authority. *Id.* ¶¶ 264–272. 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%." *Id.* ¶ 273.

4. Defendants' Alleged Materially False and Misleading Statements

Plaintiffs allege that throughout the Class Period, Defendants made 37 false or misleading statements. *Id.* ¶ 274; Exhibit A: Statements Alleged to Have Been False and Misleading, ECF No. 100-1 ("Ex. A"). Plaintiffs argue that Defendants' false and misleading statements fall into seven 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; (5) Corcept's relationship to Optime, its specialty pharmacy; (6) the status of insurance reimbursements for Korlym; and (7) the percentage of patients who were prescribed Korlym for on-label use. *Id.* ¶ 275. These false or misleading statements were allegedly made in Defendants' company press releases, SEC filings, and earning conference calls and presentations. *Id.* ¶ 275. Because Plaintiffs do not identify which statements fall into which categories, the Court has organized Defendants' 37 statements from their false and misleading statement chart by category below, modifying slightly the categories and titles in order to try and group statements appropriately by topic. The Court cannot identify any statements directly related to Corcept's relationship to Optime, its specialty pharmacy, so the Court omits that category entirely.

a. Speaker and Education Programs (Statements # 1, 9, 16, 22, 28, 33, 35)

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.

Id. Ex. A at 1. Plaintiffs allege that Defendants made this statement, or a nearly identical statement, on six subsequent occasions. *Id.* at 20, 36, 51, 66, 77, 83.

b. Marketing and Promotional Materials (# 2, 10, 17, 23, 29, 36)

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 3. Plaintiffs allege that Defendants made this statement, or a nearly identical statement, on five subsequent occasions. *Id.* at 22, 38, 53, 68, 85.

c. Compliance with FDA-Regulations (# 3, 11, 18, 24, 30, 37)

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 6. Plaintiffs allege that Defendants made this statement, or a nearly identical statement, on five subsequent occasions. *Id.* at 25, 41, 56, 71, 88.

d. Screening and Increase in Diagnosis Rates (# 4, 7, 12, 14, 15, 21, 25, 32)

Plaintiffs allege that Defendants made the following statement in Corcept's Company Press Release on November 2, 2017: "More and more physicians recognize that Cushing's Syndrome sometimes goes undiagnosed and are screening more aggressively for the disease. There is also growing awareness that, for many patients, cortisol modulation with Korlym is the

best medical treatment." *Id.* at 8. Plaintiffs also allege that Defendants made this statement, or a similar statement, on seven subsequent occasions. *Id.* at 15, 27, 31, 34, 48, 58, 75.

e. Korlym Revenue and Sales Growth (# 5, 6, 8, 13, 19, 20, 26, 27, 31)

Plaintiffs allege that Defendant Belanoff 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 10 (second and third alterations in original). Plaintiffs allege that Defendants made a similar statement regarding the basis for Korlym's growth on eight occasions. Ex. A at 12, 18, 29, 43, 46, 60, 63, 73.

f. Insurance Reimbursement and On-Label Use of Korlym (# 34)

Plaintiffs allege that Defendant Maduck made the following statement in 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 80.

In sum, Plaintiffs allege 37 false and misleading statements by Defendants 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. SAC ¶ 29. Plaintiffs further allege that Defendants' statements were false and misleading because this off-label marketing scheme was the true basis for Corcept's revenue growth, and the marketing scheme failed to comply with FDA regulations on 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." *Id.*

¶ 276. 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.* ¶¶ 276–280. 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.* ¶ 281.

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. 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.* ¶ 282. On February 2, 2019, Corcept's share price declined by $1.15 and closed the day at $10.08. *Id.*

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 ("Mot."). On June 25, 2020, Plaintiffs filed an opposition. ECF No. 108 ("Opp'n"). On July 27, 2020, Defendants filed a reply. ECF No. 109 ("Reply").

C. Request for Judicial Notice

In connection with their motion to dismiss, Defendants request judicial notice of 11 documents, which include (1) *Clinical Guidelines: The Diagnosis of Cushing's Syndrome* ("Exhibit A"); (2) CMS Medicare Part D Data ("Exhibit B"); (3) SIRF Report ("Exhibit C"); (4) Corcept Form 8-K and 99.1 ("Exhibit D"); (5) CMS Open Payments Data ("Exhibit E"); (6) *Diagnosis and Differential Diagnosis of Cushing's Syndrome* ("Exhibit F"); (7) CMS National Provider Identifier Database: Joseph Matthews ("Exhibit G"); (8) CMS National Provider Identifier Database: Matthew Draelos ("Exhibit H"); (9) CMS National Provider Identifier Database: Mitchell Silverman ("Exhibit I"); (10) Corcept Form 8-K and Ex. 99.1 ("Exhibit J"); and (11) Corcept 10-K ("Exhibit K"). ECF No. 107 ("RJN").

"Although generally the scope of review on a motion to dismiss for failure to state a claim is limited to the Complaint, a court may consider evidence on which the complaint necessarily relies if: (1) the complaint refers to the document; (2) the document is central to the plaintiffs' claim; and (3) no party questions the authenticity of the copy attached to the 12(b)(6) motion." *Daniels–Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998 (9th Cir. 2010) (internal quotation marks and citations omitted). The Court may "treat such a document as 'part of the complaint, and thus may assume that its contents are true for purposes of a motion to dismiss under Rule 12(b)(6).'" *Marder v. Lopez*, 450 F.3d 445, 448 (9th Cir. 2006) (quoting *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003)).

Defendants contend that Exhibits A–F are referenced in Plaintiffs' SAC, and thus may be considered under the incorporation by reference doctrine. RJN at 2. Defendants argue that Exhibits G–K are proper subjects of judicial notice because they are SEC filings and documents drawn from public government databases. RJN at 3. Plaintiffs do not object to judicial notice being taken of these documents, but they contest what facts or inferences the Court may draw from the documents. *See* Opp'n at 3 n.2. The Court finds that Exhibits A–F are the proper subject of judicial notice because they are referenced throughout Plaintiffs' SAC. *See Ritchie*, 342 F.3d at 908 ("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."). The Court also finds that Exhibits G–K are the proper subject of judicial notice because they are SEC 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."). 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 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). As such, the Court GRANTS Defendants' request for judicial notice of Exhibits A–K in support of the motion to dismiss.

In connection with their reply in support of their motion to dismiss, Defendants request judicial notice of three documents, which include (1) FDA-Approved Label for Korlym ("Exhibit A"); (2) FDA-Approved Label for Herceptin ("Exhibit B"); FDA-Approved Label for Keytruda ("Exhibit C"). ECF No. 110. On August 10, 2020, Plaintiffs filed an opposition to Defendants request for judicial notice. ECF No. 111. On August 17, 2020, Defendants filed a reply in support of their request for judicial notice. ECF No. 113. Plaintiffs object to Exhibit B and Exhibit C, and argue that these exhibits are inappropriate for judicial notice because they are not referenced in the SAC and are unrelated to the facts and claims of this case. Because the Court does not rely on either of these exhibits, the Court DENIES Defendants' request for judicial notice of Exhibit B and Exhibit C, and GRANTS Defendants' unopposed request for judicial notice of Exhibit A.

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. SAC ¶¶ 382–401. 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. Below, the Court first discusses Defendants' alleged misrepresentations and finds that Plaintiffs have failed to adequately allege actionable misrepresentations. Second, the Court discusses Defendants' challenge to Plaintiffs' pleadings of scienter and finds that Plaintiffs have failed to adequately allege scienter. Finally, the Court discusses Plaintiffs' alleged loss causation and finds that Plaintiffs have failed to adequately allege loss causation.

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. SAC ¶¶ 274–275; Ex. A at 2–88, ECF No. 100-1. 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. The Court first addresses Defendants' challenge to the adequacy of Plaintiff's pleading of an off-label marketing scheme. The Court then addresses Plaintiffs' challenge to Defendants' statements and finds that none of the alleged misrepresentations or omissions are actionable.

a. Failure to Adequately Allege an 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." SAC ¶ 29. Defendants argue that Plaintiffs' allegations are insufficient to show that Corcept engaged in an off-label marketing scheme, and therefore, Plaintiffs have failed to plead material misrepresentations or omissions. Mot. at 7. 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 physician CWs; (2) Corcept's

physician education programs; (3) diagnosis rates of Cushing's Syndrome; and (4) insurance reimbursement practices for Korlym. The Court addresses each in turn.

i. Statements of Physician CWs

Plaintiffs first argue that the statements of their ten CWs and PE establish that Defendants were engaged in an off-label marketing scheme. Plaintiffs contend that these CWs statements confirm that "Corcept representatives aggressively marketed Korlym for off-label use," and that sales representatives marketed "Korlym as a first-line treatment." SAC ¶¶ 179–180. Taken together, Plaintiffs allege, "Corcept's sales representatives are employing a uniform, off-label marketing pitch in every Corcept sales region across the country instructing physicians to use Korlym as a 'diagnostic tool' to diagnose patients." *Id.* ¶ 181. Defendants argue that the CW statements are insufficient to plead a plausible off-label marketing scheme because: (1) instructing physicians to use a single DST as a diagnostic tool is not an indication of off-label promotion; (2) Plaintiffs fail to credibly allege that Corcept sales representatives received instruction from Defendants; and (3) there are no allegations that instructions were given to sales representatives to engage in off-label marketing. Mot. at 9–11.

The Court agrees with Defendants' third argument and finds it dispositive. However, the Court notes that Defendants' first argument involves a factual dispute and is therefore 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). The Court also notes that Defendants' second argument concerns scienter, not the adequacy of Plaintiffs' pleading of an off-label marketing scheme.

Defendants' third argument states that Plaintiffs have failed to adequately allege an off-label marketing scheme because Plaintiffs have failed to allege that sales representatives were instructed to engage in off-label marketing. Plaintiffs allege that CW1-10 and PE received instructions from Corcept's sales representatives to use a single DST as a diagnostic tool to screen for Cushing's Syndrome. If the patient was positive, or borderline positive, the sales

representative instructed the physician to start the patient on Korlym. Plaintiffs also allege that CW3, CW7, CW9, and PE all were instructed to use Korlym as a "bridge to surgery" or "pre-surgery" for patients, in conflict with the FDA-approved label for Korlym. *See* SAC ¶¶ 193, 206, 217, 301. Finally, Plaintiffs note that CW8, CW10, and PE all recount that tear sheets or case studies promoting off-label use of Korlym were given to them by sales representatives, although these documents are not described in any detail or quoted. *See Id.* ¶¶ 190, 214, 220.

Even accepting these allegations as true, the Court finds that Plaintiffs' CW statements are insufficient to plausibly allege an off-label marketing scheme. Critically, Plaintiffs have 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.

In cases from this circuit where courts have determined that an off-label marketing scheme was plausibly alleged, plaintiffs pled particularized facts illustrating that sales representatives were instructed by leadership within the company 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 (N.D. Cal. Jan. 26, 2005). Plaintiffs in that case alleged that their confidential witnesses attended three meetings where defendants were present and sales and marketing staff were instructed to market off-label. *Id*. Plaintiffs also alleged that their CWs "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.* Furthermore, the FDA subsequently sent Defendant Gilead a letter advising Gilead that its promotional activities violated the Federal Food, Drug, and Cosmetic Act. *Id.* at 3.

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).

Plaintiffs in the instant case, by contrast, have failed to allege that sales representatives were instructed by regional or district managers to engage in off-label marketing to physicians or that there was any coordinated effort to engage in a company-wide off-label marketing scheme. Rather, Plaintiffs have alleged that in five of Corcept's six sales regions, one, or at most two, sales representatives engaged in off-label marketing.

Furthermore, unlike other cases in this circuit that Plaintiffs cite, Plaintiffs' CWs are not former employees or insiders at Corcept, but rather physicians who have interacted with Corcept sales representatives. This makes it all the more difficult for Plaintiffs to adequately allege a company-wide off-label marketing campaign, given that Plaintiffs' CWs' statements provide no insight into instructions that Corcept sales representatives were given or Corcept's internal policy with respect to marketing Korlym off-label. This contrasts with, for example, *In re Gilead*, where "Plaintiffs' confidential witnesses (CW1 and CW2) attended various meetings at which Gilead's sales and marketing team received specific instructions to market Viread off-label." 2005 WL 181885 at *8. Similarly, in *In re Amgen*, "[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.'" 554 F. Supp. 2d at 1033 (internal citations removed).

Moreover, Plaintiffs' allegations in the instant case are weaker even than those in *Huang v. Higgins*, where the court found that plaintiffs failed to plausibly allege a company-wide off-label marketing scheme. 2019 WL 1245136, at *6–8 (N.D. Cal. Mar. 18, 2019). 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. Although Plaintiffs in the instant case alleged some details of meetings between sales representatives and CWs, the CWs themselves, unlike those in *Higgins*, are not current or former employees of Corcept. Thus, the physician CWs here fall short of even the insufficient allegations pled in *Higgins*, because the physician CWs do not have insight into what sales and marketing staff were instructed to say or do by Defendants.

Therefore, because Plaintiffs have failed to pled particularized allegations that Corcept sales representatives were instructed to market Korlym off-label, Plaintiffs have failed to sufficiently allege a company-wide off-label marketing scheme on the basis of their CW statements.

ii. Corcept's Physician Education Programs

Plaintiffs next allege that Defendants were engaged in an off-label marketing scheme as evidenced by their increased spending through a marketing strategy that targeted non-specialist endocrinologists and primary care physicians. Plaintiffs allege that in 2013, out of the 298 physicians who received payments from Defendants, 203 were endocrinologists. SAC ¶ 168. By 2018, out of the 2438 physicians who received payments from Defendants, only 1072 were endocrinologists. *Id.* Plaintiffs allege that the total number of payments made, the total number of physicians paid, and the total amount of payments to physicians all increased between 2013 and 2018. 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.* ¶ 168. Plaintiffs explain that Defendants targeted non-specialist endocrinologists because non-specialist endocrinologists are "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.* ¶ 178.

However, Plaintiffs fail to sufficiently connect any of these payment trends with increased

physician prescriptions of Korlym off-label. In *In re Amgen*, by contrast, "CW#4, a former oncology representative at Amgen . . . explained that Amgen would sponsor speakers programs for doctors, clinic managers and pharmaceutical directors *in order to advance off-label uses*." 544 F. Supp. 2d at 1033 (emphasis added). In the instant case, by contrast, Plaintiffs have failed to allege any statements by Defendants or Corcept employees that would indicate that the purpose or intent of Corcept's physician education programs were to advance or promote off-label use of Korlym.

Plaintiffs do allege that non-specialist endocrinologists and primary care physicians are more susceptible to off-label marketing, but that solitary allegation on its own is insufficient to adequately allege that increased spending by Defendants on marketing to non-specialist endocrinologists and primary care physicians demonstrates that Defendants were engaged in 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 Matthews in Sommerville, South Carolina—exemplify Defendants' off-label marketing scheme. SAC ¶¶ 18–21.

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.* ¶ 18. 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 was honoraria payments). *Id.* Plaintiffs therefore allege that "it is reasonable to infer that Dr. Back, at the direction of Corcept representatives, 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.* ¶ 237.

However, as Defendants argue, Plaintiffs have pled only the most circumstantial evidence

to substantiate this inference about Dr. Back's relationship to Defendants. 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. Furthermore, Plaintiffs suggest from this that the Court can infer that Defendants are engaged in an off-label marketing scheme. These allegations are not adequate to support these claims as currently pled. The Court accepts as true Plaintiffs' factual allegations, but it is not required to accept a chain of inferences that are unmoored from particularized allegations that demonstrate their basis. "[W]hile the court assumes that the facts in a complaint are true, it is not required to indulge unwarranted inferences in order to save a complaint from dismissal." *Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1064–65 (9th Cir. 2008).

Plaintiffs draw a similar inference from the practice of Dr. Matthews,[1] an endocrinologist from South Carolina. Dr. Matthews received $73,777 from Corcept in 2017 and made 85 Medicare Part D claims for Korlym in 2017, second only to Dr. Back. SAC ¶ 237.

As Defendants point out, Plaintiffs do not dispute that physicians are permitted to prescribe Korlym to their patients for off-label use. Mot. at 7 n.5; *see also Higgins*, 2019 WL 1245136, at *1 ("Once [a] product is approved, however, health care practitioners may also prescribe the product for 'off-label' uses, meaning uses not approved by the FDA."). Therefore, Plaintiffs' allegations with respect to Dr. Back and Dr. Matthews are only sufficient to show an off-label marketing scheme if these allegations are linked to evidence that Defendants marketed Korlym to Dr. Back and Dr. Matthews for off-label use. Plaintiffs have failed to provide any factual allegations that support that inference.

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,

[1] Plaintiffs sometimes refer to "Joseph Matthews," and at other times to "Joseph Mathews." *See* SAC ¶ 19 and 239. The Court has adopted the former spelling.

Plaintiffs allege that three healthcare insurers and one state health authority—Blue Cross/Blue Shield of South Carolina; Independence Blue Cross in Philadelphia, PA; Highmark Blue Cross/Blue Shield in Pittsburg, PA; and the Drug Utilization Review Board of Oklahoma—all modified their policies with respect to reimbursing claims for Korlym prescriptions between May of 2018 and January of 2019. SAC ¶¶ 264–272. 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 quartet previously, but declined in Q3 of 2018 to just 50.7%. *Id.* at ¶ 273. In Q1 of 2019 it fell to just 12.4%. *Id.* However, as Defendants argue, Plaintiffs have done little more than allege this connection between these insurance providers tightening their policies and Defendants' declining growth. Moreover, even if the Court were to assume that there was a connection between these events, that allegation does not adequately demonstrate that Defendants were engaged in an off-label marketing scheme.

Taken as a whole, Plaintiffs' various allegations with respect to Defendants' conduct do not plausibly allege an off-label marketing scheme. At most, even accepting Plaintiffs' allegations as true, Plaintiffs have plausibly alleged only (1) that a handful of Corcept sales representatives promoted Korlym off-label to Plaintiffs' confidential witnesses, and (2) that two doctors who received legal payments from Defendants prescribed Korlym to a high number of patients. These factual allegations are insufficient to establish that Defendants were engaged in a company-wide off-label marketing scheme.

b. Adequacy of Allegations of Falsity

Having found that Plaintiffs have failed to sufficiently allege 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, *inter alia*, 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*, 540 F.3d at 1070.

To satisfy these "exacting requirements," Plaintiffs must plead "specific facts indicating why" the statements at issue were false. *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 categories of statements that Plaintiffs allege are actionable. Specifically, the Court addresses statements related to: (1) speaker and education programs for physicians; (2) marketing and promotional materials; (3) compliance with FDA-regulations for off-label marketing; (4) screening and diagnosis rate for Cushing's Syndrome; (5) Korlym revenue and sales growth; (6) insurance reimbursement and on-label use of Korlym. The Court addresses each of these categories of statements in turn.

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 1, 20, 36, 51, 66, 77, 83. 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 1. 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 were instead "designed to dupe physicians into relying on a single screening test (the DST)" and to encourage physicians to "us[e] Korlym inappropriately as a 'bridge' to surgery." *Id.* at 1. Plaintiffs further argue that Defendants' statements were false

because multiple CWs recount experiences with a Corcept sales representative 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 2.

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. The most relevant section of Defendants' challenged statements reads: "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 1. The Court does not find anything in these statements that is rendered false or misleading by Plaintiffs' allegations. The Court has already found that Plaintiffs have failed to adequately allege a company-wide off-label marketing scheme, which largely dooms Plaintiffs' claim of falsity for the challenged statements. The Court has also found that Plaintiffs have failed to sufficiently allege that Defendants' payments to physicians in the form of honoraria or reimbursement for dinners were intended to facilitate off-label promotion or marketing of Korlym.

Even accepting as true the individual statements of Plaintiffs' CWs and PE, nothing in Defendants' challenged statements are rendered false by the CWs and PE statements. Absent an adequate pleading of a company-wide off-label marketing scheme, Plaintiffs have not alleged sufficient facts to demonstrate that Defendants were engaged in anything other than appropriate marketing of Korlym to the overwhelming majority of physicians. As such, Plaintiffs have failed to allege sufficient facts to render this category of statements false or misleading.

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 3, 22, 38, 53, 68, 85. 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 3. 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, Defendants "were instructing Corcept sales reps to primarily market Korlym for off-label use in patients without endogenous Cushing's." *Id.* Defendants' statements, Plaintiffs contend, "give[] the false impression that Corcept only marketed Korlym on-label." *Id.*

The Court agrees with Defendants that Plaintiffs have failed to adequately allege an off-label marketing scheme or that Defendants "were instructing Corcept sales reps to primarily market Korlym for off-label use." *Id.* Plaintiffs have failed to allege a single fact that supports the claim that Defendants instructed Corcept sales representatives to engage in off-label sales. Instead, Plaintiffs require that the Court infer from a handful of CW statements involving off-label marketing by Corcept sales representatives that sales representatives were being instructed by Defendants to market Korlym in this way. The Court finds no basis to make this inference, and therefore declines to do so. *Metzler*, 540 F.3d at 1064–65 (the court is "not required to indulge unwarranted inferences" in order to save a complaint from a motion to dismiss).

Plaintiffs cite *In re Amgen* in support of their argument that Defendants' statements were misleading because "[a] reasonable investor would have understood Defendants' statements to mean Corcept was promoting Korlym *exclusively* for on-label uses." Opp'n at 17–18 (emphasis in original). In *In re Amgen*, however, the court found that plaintiffs' CW statements from former Amgen district sales managers and sales representatives presented sufficient evidence to show that defendants *were* engaged in a widespread off-label marketing scheme and that it "emanated from [Amgen's] national office." 554 Supp. 2d at 1033–34. The court in *In re Amgen* therefore had a sufficient basis to determine that defendants' statements regarding their marketing practices were false and misleading when made. In the instant case, by contrast, Plaintiffs have failed to adequately allege that Defendants were engaged in an off-label marketing scheme or that

Defendants instructed Corcept sales representatives to market Korlym off-label.

The Court does acknowledge that Plaintiffs have alleged that ten CWs and PE recount experiences with Corcept sales representatives in which Korlym was marketed off-label. However, even if the Court were to construe Plaintiffs' argument as one of omission, rather than falsity, Defendants had no obligation to disclose a small number of off-label promotions.[2] This is because "§ 10(b) and Rule 10b–5(b) do not create an affirmative duty to disclose any and all material information." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44–45 (2011) (citing 17 C.F.R. § 240.10b–5(b)). Rather, "[t]o be actionable under the securities laws, an omission must . . . affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." *Brody v. Transitional Hosp. Corp.,* 280 F.3d 997, 1006 (9th Cir. 2002).

Here, Plaintiffs' failure to plead a widespread off-label marketing scheme dooms their omission claim. Instead, Plaintiffs have adequately pled only that ten CWs and PE experienced off-label marketing of Korlym. Defendants' omission of this small number of off-label promotions does not render their statements that Corcept markets Korlym for on-label use misleading. This is because such a small omission did not create an impression of a state of affairs that differed in a material way from the one that actually existed. *Brody*, 280 F.3d at 1006 ("To be actionable under the securities laws, an omission must . . . affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists."). As such, Defendants' challenged statements are not 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,

[2] Defendants argue that while Plaintiffs advance an omissions theory in their Opposition brief, their SAC and attached False and Misleading Statement Chart fail to pled omissions. However, the Court addresses omissions where Plaintiffs' argument suggests an omission theory was implied.

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 6, 25, 41, 56, 71, 88. Plaintiffs allege these statements were materially false and misleading because "Corcept did not market Korlym for on-label use" and Defendants "were instructing Corcept sales reps to primarily market Korlym for off-label use." *Id.* Plaintiffs also contend that "Defendants' statement[s] also give[] the false impression that Corcept only marketed Korlym on-label." *Id.* at 6.

The Court agrees with Defendants that these statements are not actionable. Because these statements were expressions of opinion, the 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 "while 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 7. Plaintiffs' failure to plead a company-wide off-label marketing scheme undermines their argument that Defendants' expression of opinion lacks any reasonable basis. The small number of off-label promotions of Korlym that Plaintiffs have adequately pled is insufficient to render Defendants' statements "objectively incorrect." *City of Dearborn Heights*, 856 F.3d at 615. The Court therefore finds that these statements not actionable.

iv. Screening and Increase in Diagnosis Rates of Cushing's Syndrome

Plaintiffs next argue that Defendants made false and misleading statements regarding screening for Cushing Syndrome and the increase in diagnosis rates. Specifically, Plaintiffs

challenge Defendants' statements that "[m]ore and more physicians recognize that Cushing's Syndrome sometimes goes undiagnosed and are screening more aggressively for the disease. There is also growing awareness that, for many patients, cortisol modulation with Korlym is the best medical treatment." Ex. A at 8, 27. Plaintiffs also allege that Defendant made a similar statement on five other occasions. *Id.* at 15, 31, 34, 48, 58, 75. Plaintiffs allege that these statements were materially false and misleading because "physicians were significantly increasing their screening and prescriptions of Korlym not because of increased awareness but, rather, because Corcept sales representatives were giving them misleading marketing information that instructed physicians to use a single DST screen . . . as a diagnostic tool." *Id.* at 8.

Plaintiffs' argument that these statements were materially false and misleading are again undermined by Plaintiffs' failure to plead a widespread off-label marketing scheme. Moreover, even if Plaintiffs had adequately pled a widespread off-label marketing scheme, Defendants' statements focus on the beliefs and motivations of physicians and their reasons for providing screening and treatment of Cushing's Syndrome. Thus, even if Plaintiffs had adequately pled a widespread off-label marketing scheme, that in and of itself would not render Defendants' statements materially false and misleading because it would not demonstrate that physicians had acted on the advice or instruction of Corcept sales representatives, rather than on their own medical judgment.

Instead, Plaintiffs have alleged only that two physicians—CW2 and CW10—acted on instructions from Corcept sales representatives and prescribed Korlym based on a DST test alone. Opp'n at 14 n.16. These two CW statements, which describe the CWs as prescribing Korlym on account of instructions from Corcept sales representatives, are not sufficient to render Defendants' statements materially misleading even if they are framed as a material omission. "To be actionable under the securities laws, an omission must . . . affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." *Brody*, 280 F.3d at 1006. Defendants' omission of the fact that two physicians prescribed Korlym off-label at the

instruction of Corcept's sales representatives is consistent with Defendants' challenged statements that physicians are screening more aggressively for Cushing Syndrome and are increasingly aware that Korlym is the best medical treatment for patients. The Court therefore finds that even accepting these two CW statements are true, Defendants' statements regarding screening for Cushing Syndrome and the increase in diagnosis rates were not misleading. As such, Defendants' statements are not actionable.

v. 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 10 (second and third alterations in original). Plaintiffs allege that Defendant made a similar statement regarding the basis for Korlym's growth on eight occasions. *Id.* at 12, 18, 29, 43, 46, 60, 63, 73. 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 10 (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).

Because Plaintiffs have failed to adequately allege a widespread off-label marketing campaign, the Court finds that Plaintiffs' first argument lacks merit. Absent adequate allegations of this kind, Plaintiffs have failed to plead that Corcept's revenue growth was the direct result of off-label promotion. Plaintiffs' second argument challenges Defendants' statements as misleading on the basis that Corcept's revenue growth was allegedly not due to its "focus[] on the endocrinologists who treat most patients with hypercortisolism," but rather due to Defendants'

promotion of Korlym to non-specialist endocrinologists and primary care physicians. *Id.* at 10. Plaintiffs argue that "Defendants' statement gave the false impression that Corcept was only targeting Specialist Endocrinologists." *Id.* at 11. Because Plaintiffs appear to argue that the failure to disclose the promotion of Korlym to non-specialist endocrinologists and primary care physicians was a material omission, Plaintiffs must adequately plead why the challenged omission "affirmatively create[d] an impression of a state of affairs that differs in a material way from the one that actually exists." *Brody*, 280 F.3d at 1006. Plaintiffs instead only point to Defendants' increased spending on payments and education programs for internists and family medicine physicians in 2017. Ex. A at 11. Absent sufficient allegations as to why Defendants' omission was materially misleading, Plaintiffs' vague assertions are insufficient. *See Brody*, 280 F.3d at 1006 ("[T]he plaintiffs' complaint must specify the reason or reasons why the statements made by THC were misleading or untrue, not simply why the statements were incomplete."). The Court therefore finds that these statements are not actionable.

vi. Insurance Reimbursement and On-Label Use of Korlym

Plaintiffs next argue that Defendants made a false and misleading statement regarding insurance reimbursement and 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 80. Plaintiffs argue that this statement was materially false and misleading because "it was unmoored from reality: the Company's off-label marketing push had resulted in non-endocrinologists prescribing Korlym to a myriad of patients without confirmed endogenous Cushing's diagnoses." *Id.* Plaintiffs further argue that this statement was materially false and misleading because Defendants "increased [their] honoraria payments by 322% in 2017 over the prior year, largely comprised of payments to high-prescribing physicians to host informal session or roundtable discussions." *Id.* at 81.

Plaintiffs' first argument is doomed by their failure to adequately plead an off-label marketing scheme. Instead, Plaintiffs have adequately pled only that two physicians prescribed

Korlym off-label as a result of instructions from Corcept sales representatives. This tiny number of off-label prescriptions is insufficient to render Defendants' statement materially false and misleading. Second, Plaintiffs' allegations as to Defendants' increase in honoraria spending does not render Defendants' statement materially false and misleading. Plaintiffs have failed to draw a sufficient logical connection between the increase in honoraria spending and the challenged statement. Under the heightened pleading standards of the PSLRA, Plaintiffs must "allege facts to bridge this logical gap," which they have failed to do here. *In re Gilead*, 2005 WL 181885, at *9. The Court thus determines that Defendants' statements regarding insurance practices and on-label use of Korlym are not actionable.

In summary, the Court finds that none of the allegedly false or misleading statements in Plaintiffs' complaint survive the instant motion to dismiss. Accordingly, the Court GRANTS Defendants' Motion to Dismiss Plaintiffs' § 10(b) and Rule 10b-5 cause of action. The Court provides leave to amend because Plaintiffs' may be able to adequately allege that Defendants made actionable false or misleading statements.

Although the Court grants Defendants' motion to dismiss because none of the allegedly false or misleading statements are actionable, in anticipation of an amended complaint, the Court addresses two additional topics raised in the instant motion: (1) scienter and (2) loss causation.

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, "the 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, the Court must 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 should "then consider 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) particularized facts demonstrating scienter in Individual Defendants, (2) various CW statements and other evidence when viewed holistically, and (3) the "core operations" theory. 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' individual allegations of scienter. The Court then engages in a holistic evaluation of the allegations. Lastly, the Court addresses the core operations theory.

a. Direct Evidence of Scienter for the Individual Defendants

Plaintiffs first contend that the SAC adequately pleads scienter because the SAC contains particularized facts demonstrating scienter for the Individual Defendants. Plaintiffs offer a series of factual allegations, each of which they argue support a strong inference of scienter for the Individual Defendants. The Court addresses each of these individual allegations to determine if they are sufficient to create a strong inference of scienter.

i. CW Allegations of an Off-Label Marketing Scheme

Plaintiffs first argue that a strong inference of scienter is supported by the statements of Plaintiffs' ten CWs and PE. SAC ¶ 299. Plaintiffs repeat their allegations that Corcept sales representatives marketed Korlym for off-label use. However, these allegations are insufficient to create a strong inference of scienter. First, none of the CWs allege that the Individual Defendants knew about the alleged off-label marketing scheme. Absent allegations by the CWs that Individual Defendants directed or were aware of the off-label marketing scheme when the allegedly false statements were made, the CW statements do not support a strong inference of scienter on their own. *See In re Solarcity Corp. Sec. Litig.*, 274 F. Supp. 3d 972, 1010 (N.D. Cal. 2017) ("Even when read together, these [CW statements] do not provide any information about the Individual Defendants' knowledge of the falsity of their statements when those statements were made."). The Ninth Circuit has made clear that confidential witness statements cannot create a strong inference of scienter unless the confidential witness "has reliable personal knowledge of the defendants' mental state." *Zucco*, 552 F.3d at 998; *Shenwick v. Twitter, Inc.*, 282 F. Supp. 3d 1115, 1149 (N.D. Cal. 2017) (CW allegations were insufficient because "[c]ritically, none of the CWs report communicating directly with" the individual defendants). Plaintiffs have failed to allege that any of the CWs had personal knowledge of the Individual Defendants' state of mind or

that they communicated with Individual Defendants. As such, the CWs statements are insufficient to create a strong inference of scienter.

ii. Knowledge of Prescription Information

Plaintiffs next argue that Defendants' statements regarding Corcept's knowledge of Korlym's distribution and prescription information create a strong inference of scienter. SAC ¶ 303. Plaintiffs allege a number of statements by Individual Defendants to support the allegation that Corcept knew where the overwhelming majority of its Korlym prescriptions were filled. *Id.* ¶¶ 344–353. However, even accepting these allegations as true, Plaintiffs have failed to demonstrate a strong inference of scienter because they have failed to allege that Individual Defendants themselves tracked prescription trends or had personal knowledge of where prescriptions for Korlym were sent.

In the Ninth Circuit, "corporate management's general awareness of the day-to-day workings of the company's business does not establish scienter—at least absent some additional allegation of specific information conveyed to management and related to the fraud." *Metzler*, 540 F.3d at 1068. Here, Plaintiffs have failed to plead any specific allegations that demonstrate that the relevant information was conveyed to the Individual Defendants or that they accessed that information. Instead, Plaintiffs have pled only Individual Defendants' general awareness of the day-to-day workings of Corcept's business. This is insufficient to create a strong inference of scienter.

iii. Corcept's Revenue Growth

Plaintiffs next argue that the rapid growth in Corcept's revenue supports a strong inference of scienter for the Individual Defendants. SAC ¶ 314. However, Plaintiffs fail to state with particularity any allegations as to how this rapid growth supports a finding that Defendants had knowledge that their statements were false and misleading when made. Instead, Plaintiffs rely on the vague assertion that Defendants must have been aware that absent off-label prescriptions, growth of the kind Corcept experienced could not be achieved. Vague assertions of this kind are

insufficient to support a strong inference of scienter under the heightened pleading standards of the PSLRA. *See Ronconi*, 253 F.3d at 432 (holding that under the PSLRA, "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.").

iv. Corcept's Senior Vice President of Commercial

Plaintiffs next argue that a strong inference of scienter is demonstrated by the conduct of Defendant Sean Maduck, Corcept's Senior Vice President of Commercial. Plaintiffs allege that Maduck "was directly responsible for overseeing the sales staff and the Company's education and training programs." SAC ¶ 320. Plaintiffs further point out that during a Corcept earnings call on February 22, 2018, Defendant Belanoff stated: "I would like to introduce you to a person who runs our Cushing's syndrome franchise, Sean Maduck, who's really done a fabulous job in really educating really about [sic] the people, about the disease throughout the county." *Id.* From these allegations, Plaintiffs argue that "it is reasonable to infer that Defendant Maduck, as the head of sales and marketing for Corcept responsible for overseeing such activities . . . was aware of Corcept's off-label marketing practices." *Id.* ¶ 321.

The Court agrees with Defendants that these allegations are insufficient under the PSLRA's heightened pleading standard for scienter. Plaintiffs have not alleged any document or statement that would demonstrate that Maduck was aware of the alleged off-label marketing scheme. The vague allegation that Maduck oversaw sales and marketing does not provide the "who, what, where, when, and how regarding [Maduck's] access to the relevant information that belies fraudulent intent." *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 2012 WL 1868874, at *19 (N.D. Cal. May 22, 2012). Absent particularized allegations of this kind, Plaintiffs' allegations fail to create a strong inference of scienter for Maduck.

v. Corcept's Revenue Source

Plaintiffs next point out that Korlym is Corcept's sole FDA-approved drug, and therefore that Corcept was central to its "core operations." SAC ¶ 323. However, Plaintiffs do not connect

this fact to their argument in support of scienter for the Individual Defendants, and the Court will not manufacture arguments on behalf of Plaintiffs.

vi. Corcept's Alleged Failure to Follow Industry Guidelines

Plaintiffs next argue that Corcept sales representatives' instructions to Plaintiffs' CWs regarding the proper diagnostic test for Cushing's Syndrome demonstrates a strong inference of scienter because the instructions were in violation of the proper industry guidance on diagnostic procedures. *Id.* ¶ 314. However, as the Court has already noted, this argument fails to support scienter because Plaintiffs have failed to sufficiently allege that Individual Defendants instructed Corcept sales representatives to give these instructions, or even that the Individual Defendants were aware that these instructions were being given to physicians. As such, these allegations do not create a strong inference of scienter.

vii. Payments to Physicians

Plaintiffs next argue that Corcept's increase in honoraria payments to physicians from 2016 to 2017 create a strong inference of scienter. Plaintiffs allege that honoraria payments were directed to physicians who had the most Korlym prescriptions, and that "this massive increase in Corcept's spending to physicians who prescribe the most Korlym supports an influence of Defendants' knowledge and/or recklessness with respect to the off-label marketing." *Id.* ¶ 332. Plaintiffs, however, fail to allege any specific facts that show why this allegation supports a strong inference of scienter for the Individual Defendants. This vague assertion lacks merit without specific allegations as to why a "massive increase" in spending by Defendants on honoraria payments supports scienter. Importantly, Plaintiffs have failed to allege any specific facts that demonstrate that the purpose or intent of honoraria payments was to facilitate or promote off-label prescriptions of Korlym. As such, Plaintiffs' allegations are insufficient to create a strong inference of scienter.

viii. Corcept's Limited Number of Sales Regions and Sales Representatives

Plaintiffs next argue that Plaintiffs' limited number of sales representatives and sales

regions support a strong inference of scienter. *Id.* ¶ 333. Plaintiffs explain that this small size "lends to an inference that the Individual Defendants knew or were reckless in not knowing of the off-label marketing scheme." *Id.* ¶ 335. The Court finds that this allegation on its own is insufficient to create a strong inference of scienter for the Individual Defendants. Importantly, Plaintiffs have not alleged that Individual Defendants actually accessed any sales or performance data.

ix. Awards to Sales Representatives

Plaintiffs next argue that Corcept's award of accolades to top performing sales representatives shows that Defendants monitored the performance of sales staff, and that this knowledge demonstrates that Defendants had knowledge of the alleged off-label marketing scheme. *Id.* ¶ 337. However, Plaintiffs do not allege that the Individual Defendants themselves had any knowledge of the performance of individual sales staff, or that Individual Defendants personally awarded or approved sales awards. As such, this allegation is insufficient to create a strong inference of scienter.

x. The Resignation of Corcept's Chief Medical Officer

Finally, Plaintiffs allege that the resignation of Corcept's Chief Medical Officer, Dr. Robert S. Fishman, supports a strong inference of scienter. *Id.* ¶ 341. Fishman tendered his resignation on November 13, 2018, effective January 31, 2019. Plaintiffs allege that this timing creates a strong inference of scienter for the Individual Defendants because Fishman's resignation followed shortly after Maduck made his allegedly false statement that "99% of [Corcept's] Korlym patients are on label." *Id.* ¶ 339. Plaintiffs argue that this timing is suspicious and supports an inference of scienter. As Defendants point out, however, Plaintiffs have failed to allege that Fishman had any knowledge of Maduck's statement on the earnings call, or that Fishman's departure was connected to off-label marketing or irregularities of any kind. Moreover, "[t]he complaint does not indicate whether [Fishman] was nearing retirement age, whether he left to pursue other opportunities, or even the length of his tenure. Thus the bare fact of [Fishman's]

retirement cannot support [Plaintiffs'] allegations of scienter." *Zucco*, 552 F.3d at 1002. As such, Plaintiffs' allegation regarding Fishman's retirement is insufficient on its own to create a strong inference of scienter.

The Court therefore finds that Plaintiffs' allegations, standing alone, are insufficient to create a strong inference of scienter.

b. Holistic Evaluation of the Evidence

Having determined that Plaintiffs' allegations, standing alone, are insufficient to create a strong inference of scienter, the Court now considers the "allegations holistically to determine whether they create a strong inference of scienter taken together." *In re NVIDIA*, 768 F.3d at 1056. Plaintiffs argue that their CW statements and other evidence, when evaluated together, create a strong inference of scienter for Individual Defendants.

"When conducting this holistic review . . . [the Court] must also take into account plausible opposing inferences that could weigh against a finding of scienter. Even if a set of allegations may create an inference of scienter greater than the sum of its parts, it must still be at least as compelling as an alternative innocent explanation." *Zucco*, 552 F.3d at 1006. Here, Defendants point specifically to two allegations that they argue create a plausible opposing inference that weighs against finding a strong inference of scienter.

First, Defendants argue that Plaintiffs fail to allege any personal financial motive to defraud on the part of the Individual Defendants. Mot. at 25. While a lack of motive is not dispositive of a finding of scienter, the United States Supreme Court has noted that it is a relevant consideration. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 325 (2007) (acknowledging that "motive can be a relevant consideration, and personal financial gain may weigh heavily in favor of a scienter inference"). Defendants argue specifically that Plaintiffs have failed to allege that the Individual Defendants' compensation was tied to meeting Corcept's revenue targets. However, although Plaintiffs have not alleged a personal financial motivation for Defendants' allegedly fraudulent conduct, Plaintiffs have alleged that Individual Defendants were

motivated to carry out an off-label marketing scheme by a general desire to keep Corcept profitable while the company had market exclusivity for Korlym, and to fund the ongoing costs of the company. SAC ¶¶ 344–353. Moreover, Defendants' argument, even if true, does not itself undermine Plaintiffs' argument for scienter because the Supreme Court has made clear that "absence of a motive allegation is not fatal." *Tellabs*, 551 U.S. at 325.

Second, Defendants argue that the SAC fails to allege any insider stock sales on the part of the Individual Defendants. Mot. at 26. Although lack of any stock sales by Individual Defendants during the Class Period does not conclusively establish a lack of scienter, it does support an opposing inference. *In re Rigel*, 697 F.3d at 884 ("[B]ecause none of the defendants sold stock during the period between the allegedly fraudulent statements and the subsequent public disclosure . . . the value of the stock and stock options does not support an inference of scienter . . . . In fact, it supports the opposite inference."). However, the Court does not have before it any evidence that Defendants did not sell stock during the Class Period. Instead, Plaintiffs have merely failed to allege that Defendants sold stock during the Class Period. Defendants' argument is therefore merely another factor for the Court to weigh.

Looking holistically at the allegations that Plaintiffs have pled, and weighing plausible opposing inferences, the Court finds that Plaintiffs have failed to adequately allege scienter for the Individual Defendants. "Although the allegations in this case are legion, even together they are not as cogent or compelling as a plausible alternative inference," namely, that while individual Corcept sales representatives may have engaged in off-label marketing to Plaintiffs' CWs, Defendants were not engaged in a secret, company-wide off-label marketing scheme. *Zucco*, 552 F.3d at 1007. Plaintiffs' allegations remain no more than an unconnected series of vague allegations as to what Individual Defendants might have done and known. Absent an adequate pleading that Defendants were engaged in an off-label marketing scheme, these allegations are less plausible than the competing inference that Individual Defendants were unaware of any off-label marketing in which their sales representatives were engaged, and Corcept's official marketing

practices were no different than ordinary business practices for a company of this kind. Accordingly, the Court finds that even when viewed holistically, Plaintiffs' allegations do not create a strong inference of scienter.

c. Core Operations Theory

Lastly, Plaintiffs argue that they have adequately pled 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*, 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 admittedly had access to the off-label prescription and patient data and, given that Corcept employed a uniform off-label marketing message Company-wide for a drug that comprised 100% of its revenue, it would be absurd to suggest Defendants were unaware of Corcept's off-label marketing scheme." Opp'n at 24. The Court agrees with Plaintiffs that this could be one of the "rare circumstances" where "such allegations may be sufficient, without accompanying particularized allegations," 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. Such a determination could be merited here because 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 the matter." *Id.* However, the Court has

already found that Plaintiffs have failed to adequately allege a company-wide off-label marketing scheme for Korlym. As such, Plaintiffs' argument for scienter under a core operations theory necessarily fails.

Accordingly, whether looked at individually, holistically, or under the core operations theory, Plaintiffs fail to adequately allege scienter.

3. Loss Causation

Finally, in anticipation of an amended complaint, 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, 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." SAC ¶ 364. Plaintiffs therefore 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).[3] Defendants argue that Plaintiffs have failed to adequately allege loss causation here because the SIRF Report and January Press Release are not adequate corrective disclosures. Mot. at 28–30. 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 paid physicians to prescribe Korlym for off-label uses and that Corcept's revenue growth was largely driven by off-label prescriptions." SAC ¶ 365. The day the report was published Corcept's share price fell $1.52, or more than 11%. *Id.* Defendants argue that the SIRF Report was not a

[3] On October 9, 2020, Defendants filed a Statement of Recent Decision, ECF No. 116. Defendants bring to the Court's attention *In re Bofl Holding, Inc. Sec. Litig.*, 977 F.3d 781 (9th Cir. 2020), a relevant Ninth Circuit decision issued after briefing on the instant motion was completed. On October 12, 2020, Plaintiffs filed a Motion for Leave to File Response to Defendants' Statement of Recent Decision, ECF No. 117. Plaintiffs' motion argues the merits and application of *In re Bofl Holdings*. Although "counsel may bring to the Court's attention a relevant judicial opinion published after the date the opposition . . . was filed," counsel must do so "without argument." Civil L.R. 7-3(d)(2). Defendants already brought the relevant judicial opinion to the Court's attention and the purpose of Plaintiffs' motion was merely to argue the application of the decision. The Court therefore DENIES Plaintiffs' Motion.

"corrective disclosure" that resulted in market revelation of fraud for three reasons: (1) Plaintiffs claim Corcept's stock traded in an efficient market and therefore Plaintiffs cannot rely on a purported corrective disclosure derived entirely from public filings; (2) the SIRF Report disclosed only a risk or potential for widespread fraud, and there was no subsequent revelation of the fraud itself; and (3) Plaintiffs cannot rely on the price decline after the SIRF Report to demonstrate that it was a correct disclosure. Mot. at 28–29.

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. Plaintiffs argue in reply that whether the SIRF Report contained only publicly available material is a question of fact not suitable for a motion to dismiss, and furthermore that the SIRF Report contained non-public information. Opp'n at 28.

The SIRF Report contains information derived from FDA FOIA requests, Open Payments data, Medicare Part D data, and Corcept's own publicly released growth data. Opp'n at 28; Exhibit C, ECF No. 3, at 1–8. 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).

Although Plaintiffs have described in sufficient detail the nature of the facts disclosed by the SIRF Report and its analysis, Plaintiffs have failed to sufficiently plead that this analysis had not yet been done by other market participants. *See* SAC ¶ 366. In order to adequately plead loss causation based on the SIRF Report under *In re Bofl Holding*, Plaintiffs must "allege particular facts plausibly suggesting that other market participants had not done the same analysis." 977 F.3d at 974. Because Plaintiffs have not yet done so, they have failed to plead loss causation with respect to the SIRF Report.

b. January Press Release

Plaintiffs allege that Corcept's January 31, 2019 Press Release was a second corrective disclosure. Plaintiffs allege that in the Press Release, Defendants "forecast a sharp slowdown in sales of Korlym in 2019 presumably 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.* ¶ 366. 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 30. Plaintiffs reply that the corrective disclosure does not need to explicitly disclose the fraud at issue. Opp'n at 30. Plaintiffs point to *Nuveen Mun. High Income Opportunity Fund v. City v. Alameda*, in which the Ninth Circuit stated that "[d]isclosure of the fraud is not a sine qua non of loss causation, which may be shown even where the alleged fraud is not necessarily revealed prior to the economic loss." 730 F.3d 1111, 1120 (9th Cir. 2013).

The January Press Release does not mention fraudulent conduct, off-label marketing, increased scrutiny from insurance companies, or the allegations of the SIRF Report. Rather, it simply reports 2018 preliminary selected financial results and 2019 revenue guidance. ECF No. 106-4 at 5. Plaintiffs allege that the projected forecast in sales for Korlym in 2019 announced in

the Press Release represents a "sharp slowdown in sales," which was "presumably 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." SAC ¶ 366.

However, Plaintiffs have done little to substantiate this allegation in their SAC. The Press Release itself offers no guidance as to the cause of the forecast, and Plaintiffs' allegations are little more than conjecture. There are certainly no facts alleged in the SAC that support the allegation that the market understood the January Press Release as 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 in order to save a complaint from dismissal." *Metzler*, 540 F.3d at 1064–65 ("The 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 loss causation.

In sum, the Court finds that because Plaintiffs have failed to adequately plead actionable false and misleading statements, failed to adequately plead scienter, and failed to adequately plead loss causation, Plaintiffs have therefore failed to state a claim for violation of § 10(b) of the Exchange Act and Rule 10b-5.

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 section 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). Because Plaintiffs have failed to plead a primary securities law violation, Plaintiffs have also failed to plead a violation of section 20(a). *See In re Cutera Sec. Litig.*, 610 F.3d 1103, 1113 n.6 (9th Cir. 2010). Accordingly, Defendants' motion to dismiss Plaintiffs' section 20(a) claim is GRANTED.

IV. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss Plaintiffs' amended complaint in its entirety is GRANTED. Because granting Plaintiffs an additional opportunity to amend the complaint would not be futile, cause undue delay, or unduly prejudice Defendants, and Plaintiffs have not acted in bad faith, the Court grants leave to amend. *See Leadsinger*, 512 F.3d at 532.

Should Plaintiffs choose to file an amended complaint, they must do so within 30 days of this Order. Failure to do so, or failure to cure the deficiencies identified in this Order and in Defendants' motion to dismiss, will result in dismissal of Plaintiffs' deficient claims with prejudice. Plaintiffs may not add new claims or parties without a stipulation or leave of the Court. If Plaintiffs choose to file an amended complaint, they must attach a redlined copy comparing the Third Amended Complaint with the Second Amended Complaint. Finally, any amended complaint must comply with this Court's Securities Class Action Standing Order, effective September 23, 2019.

IT IS SO ORDERED.

Dated: November 20, 2020

Lucy H. Koh

LUCY H. KOH
United States District Judge