UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

IN RE INTUITIVE SURGICAL SECURITIES LITIGATION	Case No.: 5:13-CV-01920-EJD **ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS** **[Re: Docket No. 53]**

I. BACKGROUND

Presently before the court in this securities fraud litigation is corporate Defendant Intuitive Surgical Inc. ("Intuitive") and individual Defendants Gary S. Guthart ("Guthart"), Marshall L. Mohr ("Mohr"), and Lonnie M. Smith's ("Smith") (collectively, "Defendants") Motion to Dismiss lead Plaintiff Employees' Retirement System of the State of Hawaii's ("Plaintiff") Amended Class Action Complaint. Def. Mot. to Dismiss, Docket Item No. 53. The court previously determined that this motion was suitable for decision without oral argument and vacated the hearing pursuant to Civil Local rule 7-1(b). Having fully reviewed the parties' papers, and for the following reasons, the court will GRANT in part and DENY in part Defendants' motion.

a. Factual and Procedural History

Intuitive is a biomedical corporation that designs, manufactures, and sells da Vinci Surgical Systems ("da Vinci"), its sole product and primary source of revenue. Am. Class Action Compl. ("CAC") ¶¶ 29, 40, Docket Item No. 48. Intuitive common stock is publicly traded on NASDAQ under the ticker symbol "ISRG." Id. ¶ 29. Plaintiff purchased or otherwise acquired Intuitive stock during the period between February 6, 2012 and July 18, 2013, inclusive (the "Class Period"). Id. ¶ 25. Individual Defendants Guthart, Mohr and Smith were employed with Intuitive during the Class Period. Id. ¶¶ 30-32. Guthart has served as Intuitive's CEO since January 2010. Id. ¶ 30. Mohr has served as Intuitive's Senior Vice President and Chief Financial Officer since March 2006. Id. ¶ 31. Smith served as Intuitive's Chairman of the Board and as an executive officer during the Class Period. Id. ¶ 32.

The da Vinci Surgical System is a robotic surgical system that uses three-dimensional computer technology to allow surgeons to remotely operate a suite of tiny computer-assisted tools through a small tube inside a patient. Id. ¶ 41. Because da Vinci is the only robotic surgical system in the United States approved by the Food and Drug Administration ("FDA") for soft tissue procedures, Intuitive enjoyed rapid growth during the Class Period. Id. ¶¶ 38-39. Total revenue rose from $1.41 billion in 2010, to $1.76 billion in 2011, to $2.18 billion in 2012. Id. ¶ 39. By December 31, 2012, there were 2,585 da Vinci systems installed in 2,025 hospitals worldwide. Id. As a result of Intuitive's financial success, stock prices also began to rise, reaching all-time highs exceeding $500 per share during the Class Period. Id. ¶ 10.

One of da Vinci's most commonly used tools is the Hot Shears Monopolar Curved Scissors ("monopolar scissors"). Id. ¶ 43. The monopolar scissors are a convenient tool for physicians because they are used to both cut normally and to cauterize tissue through the application of monopolar electricity via an electrode. Id. To ensure that the electricity is only channeled through that electrode, the metal parts of the scissors are covered with insulating rubber sleeves ("tip covers"). Id. ¶ 44. According to Plaintiff, the tip covers were prone to tiny cracks or slits that prevented them from properly insulating the metal instruments, thus allowing electricity to escape

into the patient's body, damaging tissue and internal organs. Id. ¶¶ 44-46. Given this serious defect, Plaintiff alleges that these tip covers greatly jeopardized the safety of the monopolar scissors and the da Vinci system in general.

According to Plaintiff, Intuitive became aware of this defect via medical device reports ("MDRs"). Pursuant to FDA regulations, if an adverse event (death or serious injury) occurs at a hospital, and the hospital receives or otherwise becomes aware of information that reasonably suggests that a medical device may have caused or contributed to that event, the hospital must report that information to the manufacturer through an MDR. Id. ¶ 62; see also 21 U.S.C. §360i(b)(1)(B); 21 C.F.R. §§ 803.30, 803.50. If the hospital's report reasonably suggests that the device may have contributed to a serious injury or death, or malfunctioned in such a way that it could have caused serious injury or death, then the manufacturer must also report the MDR to the FDA. Id. ¶ 63; see also 21 C.F.R. § 803.50(a). Plaintiff alleges that, instead of reporting the MDRs to the FDA, Intuitive responded to them by issuing a "secret recall" in October 2011, wherein Intuitive issued a letter that corrected the instructions for proper use of the monopolar scissors in order to avoid damaging the tip covers. Id. ¶ 51. Intuitive later issued two other letters, which Plaintiff alleges also constituted secret recalls, addressing other issues: one clarified that da Vinci was not, at the time, cleared for thyroidectomies, and the other gave instructions for proper instrument inspection. Id. ¶¶ 52-54. Intuitive did not report to the FDA that it had sent these letters, which the FDA later determined to be a violation of 21 C.F.R. § 806.10 . Id. ¶¶ 53, 159.

Plaintiff further alleges that Defendants misclassified and/or failed to report the MDRs that it received. Id. ¶ 5. In September 2012, the FDA met with Intuitive to address its underreporting and miscategorization of the MDRs. Id. ¶ 6. As a result of this meeting and the increased scrutiny, Intuitive was left with "no choice," according to Plaintiff, but to change its reporting policies by (i) reporting MDRs not previously submitted to the FDA, and (ii) upcoding many MDRs previously labeled "other" to "serious injury." Id. ¶ 73. This change in reporting led to an increased number of "serious injury" MDRs reported by Intuitive after September 2012. Id. ¶ 209. Plaintiff alleges

that the 40% increase in total number of MDRs reported by Intuitive after this meeting demonstrates that Defendants had been previously suppressing MDRs from the FDA. Id. ¶ 73.

The change in MDR reporting practices set the wheels in motion for a number of events that would ultimately have an adverse effect on Intuitive's stock price. Due to the aforementioned increase in MDRs, the FDA began a safety probe of Intuitive in January 2013 by sending confidential surveys to da Vinci customers in order to determine "whether adverse event reports sent to the agency [were] 'a true reflection of problems' with the robots, or the result of other issues." Id. ¶ 84. When news of this probe became public, it had an immediate impact on the stock price. On February 28, 2013, Bloomberg broke the news of this FDA probe to the public. Id. ¶ 84. That day, Intuitive's stock price fell 11 percent by the close of the market, to $509.89. Id. On March 5, 2013, another Bloomberg article reported that MDRs sent to U.S. regulators linked da Vinci to at least 70 deaths since 2009. Id. ¶ 175. That day, Intuitive's share price dropped $22.78, approximately 3%, from a closing price of $541.32 on March 4, 2013 to a closing price of $525.72. Id. ¶ 175(b). Plaintiff alleges that the news of the investigation and possible safety concerns also had a detrimental effect on Intuitive's 2013 first quarter financial report and preliminary second quarter financial report, which caused Intuitive stock to continue to dip, falling to $484.75 after the announcement. Id. ¶¶ 176-177.

As a result of the precipitous drop in the stock price, two securities fraud class action lawsuits were brought in this district on behalf of persons who purchased or otherwise acquired publicly-traded Intuitive securities during the purported class period: Abrams v. Intuitive Surgical, Inc., et al., No. 13-CV-01920, filed April 26, 2013 and Adel v. Intuitive Surgical, Inc., et al., No. 13-CV-02365, filed May 24, 2013. Plaintiffs in both suits alleged that Defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act ("Exchange Act") and Securities and Exchange Commission Rule 10b-5 by making numerous materially false and misleading statements and omissions regarding the safety of the da Vinci system and Intuitive's compliance with FDA regulations. On June 25, 2013, Plaintiff and Darien Adel each filed a Motion for Consolidation of Related Actions, Appointment as Lead Plaintiff, and Approval of Selection of Lead Counsel in the instant action. Dkt. Nos. 14, 23. Adel subsequently

withdrew his motion and voluntarily dismissed his case without prejudice. Dkt. Nos. 33, 39. While those motions were pending, on July 19, 2013, Intuitive publicly released a Warning Letter issued by the FDA, citing Intuitive's failure to adequately report recalls and adverse events. Id. ¶ 178. That same day, Intuitive's stock price declined by $28.81 and closed at $392.67—the first time the stock had dropped below $400 since before the beginning of the Class Period. Id. On October 15, 2013, Plaintiff and a second named plaintiff, Greater Pennsylvania Carpenters' Pension Fund, filed the CAC, supplementing their allegations with the FDA Warning Letter. See Dkt No. 53. On November 18, 2013, the court granted Plaintiff's Motion for Appointment as Lead Plaintiff. See Docket Item No. 50. The CAC remains the operative complaint in this action, as Plaintiff did not file an amended complaint after its appointment as Lead Plaintiff.

In the CAC, Plaintiff alleges that during the Class Period, Defendants made numerous materially false and misleading statements and omissions regarding the safety of the da Vinci system and Intuitive's compliance with FDA regulations. CAC ¶¶ 182-269, Dkt. No. 48. These statements spanned fourteen months and arose within Intuitive's public filings with the SEC, press releases, and quarterly earnings call with investors. Id. Plaintiff alleges that these statements and omissions were false and misleading because they failed to disclose (i) Intuitive's alleged regulatory violations, including the failure to report MDRs, adverse reports, design defects, recalls, and failure to follow design protocols, (ii) da Vinci's defects and performance problems resulting in injury and death, and (iii) the material rise in da Vinci adverse events. Id. ¶ 181. Of these alleged false or misleading statements, many are financial statements made in Intuitive's quarterly or yearly financial reports, which provide a retrospective accounting on everything from total revenue, to numbers of da Vinci procedures, to da Vinci system sales. Id. ¶¶ 182-269. Other challenged statements from the SEC filings, press releases, and earnings calls include:

- Assertions that da Vinci represents a "new generation of surgery," combining the benefits of minimally invasive surgery ("MIS") for patients with the ease of use, precision, and dexterity of open surgery." Id. ¶ 182(a)(b).

- Warnings regarding potential "Risk Factors," specifically warnings that "[i]f defects are discovered in our products, we may incur additional unforeseen costs, hospitals may not purchase our products and our reputation may suffer. … Because our products are designed to be used to perform complex surgical procedures, we expect that our customers will have an increased sensitivity to such defects. In the past, we have voluntarily recalled certain products as a result of performance problems. We cannot assure that our products will not experience component aging, errors or performance problems in the future."[1] Id. ¶ 184.
- Statements acknowledging the FDA regulations that Intuitive was required to follow, including, but not limited to, quality assurance procedures, the MDR reporting procedures, and the "the reporting of Corrections and Removals, which requires that manufacturers report to the FDA recalls and field corrective actions taken to reduce a risk to health or to remedy a violation of the FDCA [Federal Food, Drug, and Cosmetic Act] that may pose a risk to health." Id. ¶ 186. Intuitive further acknowledged that it was subject to FDA surveillance to determine compliance, noting that if the FDA found Intuitive failed to comply "it can institute a wide variety of enforcement actions, ranging from a regulatory letter to a public Warning Letter to more severe civil and criminal sanctions." Id. ¶ 186(a).
- Statements that Intuitive may from time to time be involved in "a variety of claims, lawsuits, investigations and proceedings relating to securities laws, product liability, patent infringement, contract disputes" and other matters that may arise in the normal course of business. Id. ¶¶ 216(b), 225(b), 232(b), 238(a), 246(b).
- Warnings with regard to Intuitive's potential financial exposure from product liability lawsuits that may be brought against it, and the possibility of product recalls necessitated by a design or manufacturing defect. Id. ¶ 246(a). Intuitive acknowledged that such a claim or product recall could "harm our reputation or

[1] Intuitive continued to maintain thereafter that these "Risk Factors" remained unchanged. Id. ¶¶ 190-238

result in a decline in revenues" and admitted that "[n]egligence claims have been made against us in the past." Id.

- Statements in a March 13, 2013 press release addressing "general inquiries regarding a recent rise in [MDRs]" that the rise did not "reflect a change in product performance but rather a change in MDR reporting practices." Id. ¶ 206. Intuitive characterized the change in practice as an "administrative change" that "has not increased the total number of adverse event reports," and noted that the change would result "in an increase in events in the 'serious injury' subcategory and a corresponding decrease in the 'other' subcategory." Id.
- A statement that Intuitive was "in the midst of a concerted effort by critics of robotic surgery, to challenge the benefitted range of patients" but that "[Intuitive was] confident that those who invest their time in a serious review of the clinical evidence on da Vinci" would find ample evidence of the device's benefits. Id. ¶ 211.
- A statement that "during the first quarter of 2013, there have been articles published and papers written questioning patient safety and efficacy associated with da Vinci Surgery … we believe that da Vinci Surgery continues to be a safe and effective surgical method …" Id. ¶ 213(a).

II. LEGAL STANDARDS

Federal Rule of Civil Procedure 8(a)(2) requires that a complaint contain short and plain statements showing the pleader is entitled to relief. See Fed R. Civ. P. 8(a)(2). A motion brought under Rule 12(b)(6) "tests the legal sufficiency" of these allegations. Navarro v. Block, 250 F.3d 729, 732 (9th Cir. 2001); see Fed R. Civ. P. 12(b)(6). The court may dismiss a claim due to "the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." Balistreri v. Pacifica Police Dep't, 901 F.2d 696, 699 (9th Cir. 1988). The court accepts as true all of the plaintiff's allegations and construes them in the light most favorable to the plaintiff. In re Gilead Sciences Sec. Litig., 536 F.3d 1049, 1055 (9th Cir. 2008). However, the

court is not bound to accept as true "a legal conclusion couched as a factual allegation." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007).

To survive a motion to dismiss, a plaintiff does not need to plead detailed factual allegations, but must allege "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 570). A facially plausible allegation will allow the court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. "The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully." Id. (internal quotation marks omitted).

In addition to Rule 8's requirements, fraud cases are also governed by the heightened pleading standard of Rule 9(b). A plaintiff averring fraud or mistake must plead with particularity the circumstances constituting fraud, but malice, intent, knowledge and other conditions of the mind may be averred generally. See Fed. R. Civ. P. 9(b). Particularity under Rule 9(b) requires the plaintiff to plead the "who, what, when, where, and how" of the misconduct alleged. Kearns v. Ford Motor Co., 567 F.3d 1120 (9th Cir. 2009). In the context of a securities litigation case, Rule 9(b) requires the particular circumstances indicating falseness of the defendant's statements to be pled, specifically, "an explanation as to why the statement or omission complained of was false or misleading." In re GlenFed, Inc. Sec. Litig., 42 F.3d 1541, 1548 (9th Cir. 1994), superseded by statute on other grounds as stated in Marksman Partners, L.P. v. Chantal Pharm. Corp., 927 F. Supp. 1297 (C.D. Cal. May 21, 1996) .

The Rule 9(b) requirement "has long been applied to securities complaints." Zucco Partners LLC v. Digimarc Corp., 552 F.3d 981, 990 (9th Cir. 2009) (citing Semegen v. Weidner, 780 F.2d 727, 729, 734–35 (9th Cir. 1985)). In accordance with that rule, courts in the past required plaintiffs in securities fraud cases to plead falsity with particularity, while allowing scienter to be alleged generally. Id. However, in 1995 Congress enacted the Private Securities Litigation Reform Act (PSLRA), which "significantly altered pleading requirements in securities fraud cases." Id. (quoting Gompper v. VISX, Inc., 298 F.3d 893, 895 (9th Cir. 2002)). Under the

PSLRA, to survive a motion to dismiss, a plaintiff must now plead both falsity and scienter with particularity. In re Daou Sys., Inc., 411 F.3d 1006, 1014 (9th Cir. 2005).

III. DISCUSSION

1. "Puzzle Pleading" under Rule 8

Defendants first argue that Plaintiff's "puzzle-like complaint" violates the most basic of pleading standards: Rule 8's requirement of "short and plain statements." Def. Mot. to Dismiss 6, Dkt. No. 53. A "puzzle pleading" is a complaint that forces the defendants and/or court to sort out the alleged statements and match them with the corresponding adverse facts in order to "solve the puzzle of interpreting Plaintiff's claims." In re Splash Tech. Holdings, Inc. Sec. Litig., 160 F. Supp. 2d 1059, 1074-75 (N.D. Cal. 2001); see also In re GlenFed, 42 F.3d at 1553 (describing the plaintiffs' puzzle-like complaint as "rambl[ing] through long stretches of material quoted from defendants' public statements … unpunctuated by any specific reasons for falsity"). In Splash, the court noted that the puzzle-like structure of the complaint rendered it "exceedingly difficult to discern precisely which statements are alleged to be misleading." 160 F. Supp. 2d at 1073.

Plaintiff's CAC is indisputably cumbersome, surpassing one hundred pages in length. In thirty of those pages, Plaintiff recites boilerplate corporate statements made by Defendants and allege that the each statement was rendered false or misleading because Defendants failed to disclose a number of alleged material facts. However, the breadth of the CAC alone does not create the type of "puzzle-like" complaint that warrants dismissal. See In re Cornerstone Propane Partners, L.P., 355 F. Supp. 2d 1069, 1081 (N.D. Cal. 2005) (finding that puzzle-pleadings "abuse the principles of Rule 8 not because they are not short" but because they are not plain). Plaintiff here has precisely detailed each problematic statement, alleged that each statement is false and misleading, and alleged the reasons as to why each statement was false or misleading. Plaintiff generally avoids lengthy quotations in favor of highlighting problematic portions of statements. As evidenced by Exhibit A to their Motion to Dismiss, Defendants can parse out with relative ease the statements at issue and the reasons as to why they are alleged to be false and misleading. As such,

Plaintiff's CAC fulfills the purpose of Rule 8 by putting Defendants on notice of the true substance of the claims against them. See Splash, 160 F. Supp. 2d at 1074.

2. Sufficiency of the Allegations Under the PSLRA

In their motion to dismiss, Defendants argue that Plaintiff has failed to state any claim under Section 10(b) of the Securities and Exchange Act ("Exchange Act") or under SEC Rule 10b-5 that satisfies the PSLRA's heightened pleading standards. Section 10(b) of the Securities and Exchange Act ("Exchange Act") provides that it shall be unlawful for any person "to use or employ, in connection with the purchase or sale of any security … any manipulative or deceptive device or contrivance in contravention of such rules and regulations." 15 U.S.C. § 78(b). SEC Rule 10(b)(5) implements this provision by making it unlawful for any person "to make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading" in connection with the purchase or sale of a security. 17 C.F.R. §240.10b-5(b).

Plaintiff alleges that Defendants engaged in a scheme to defraud investors by representing that da Vinci was a safe and viable alternative to open surgery, when in fact Defendants knew that da Vinci had been experiencing defects that, when discovered, would seriously impair its marketability. To adequately state such a claim, Plaintiff must allege facts sufficient to establish: "(1) a material representation or omission by the defendant, (2) scienter, (3) a connection between the misrepresentation or omission and the purchase or sale of a security, (4) reliance upon the misrepresentation, (5) economic loss, and (6) loss causation." Matrixx Initiatives, Inc. v. Siracusano, 131 S. Ct. 1309, 1317 (2011) (quoting Stoneridge Inv. Partners LLC v. Scientific-Atlanta, Inc., 552 U.S. 148, 157 (2008)). Defendants have challenged the sufficiency of the allegations as to the elements of material misstatements and scienter. The court will first address the sufficiency of the material misstatements, taking each set of statements in turn. Then the court will address whether Plaintiff has sufficiently pled scienter as to any of the sufficiently pled material misstatements.

a. False or Misleading Statements

Defendants first contend that Plaintiff has failed to identify any statement in the CAC which is false or misleading under the PSLRA. To sufficiently allege a material misstatement for a Section 10(b) claim, the plaintiff must specify each statement alleged to have been misleading and the reason(s) why that statement is misleading; if those allegations are made on information and belief, the plaintiff must also allege all facts on which that belief is formed. Daou, 411 F.3d at 1014; see also 15 U.S.C. § 78u–4(b)(1). For an omission to be misleading, "it 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). A material omission is one that a reasonable investor would consider to significantly alter the total mix of information. Matrixx, 131 S. Ct. at 1317. "Silence, absent a duty to disclose is not misleading under Rule 10b-5." Basic v. Levinson, 485 U.S. 224, 238, 239 & n.17. A duty to disclose exists only "to … make statements in light of the circumstances under which they were made not misleading." 17 C.F.R. § 240.10b-5(b)

In the CAC, Plaintiff alleges that sixty-four separate statements made by Defendants were false and misleading because, in making them, Defendants failed to disclose various regulatory violations, da Vinci's defects regarding the monopolar scissors and faulty tip covers, and the material rise in da Vinci adverse events and products liability suits that resulted from these defects. The set of challenged statements can be categorized as follows: (i) statements made regarding da Vinci's safety and efficacy, (ii) financial accounting reports, (iii) warnings of potential risks the company may face, and (iv) statements regarding the FDA regulations the Company faced. The court will address each category of statements in turn.

i. Statements Regarding da Vinci's Safety and Efficacy

Defendants first assert that Plaintiff's claims as to statements made by Intuitive and the individual Defendants regarding da Vinci's safety and efficacy should be dismissed because, as alleged, these statements are not materially misleading. Plaintiff argues that the statements alleged satisfies its pleading burden under the PSLRA because it has plausibly and with particularity

identified statements made by Defendants regarding da Vinci's safety that, in light of the factual circumstances alleged, may have misled the reasonable investor as to da Vinci's market viability. Throughout the Class Period, Defendants made numerous statements via their SEC filings and press releases pronouncing da Vinci was a beneficial, safe and effective alternative to traditional surgery. These statements include (i) repeated assertions that it believes that da Vinci represents "a new generation of surgery" that "combines the benefits of minimally invasive surgery (MIS) for patients with the ease of use, precision, and dexterity of open surgery" (CAC ¶¶ 188, 133, 198, 213(a), Dkt. No. 48); (ii) a statement that despite questions posed by recent news articles, Intuitive believed "that da Vinci Surgery continues to be a safe and effective surgical method …" and that "da Vinci surgery has proven safety, efficacy, economic and ergonomic benefits when compared to the open surgical procedures it is replacing" (Id. ¶ 213(a)); and "[a] statement that Intuitive was in the midst of a concerted effort by critics of robotic surgery, to challenge the benefitted range of patients" but that "[Intuitive was] confident that those who invest their time in serious review of the clinical evidence on da Vinci" will find ample evidence of the device's benefits (Id. ¶ 211). Plaintiff alleges that Intuitive's failure to disclose (i) additional unreported adverse event reports and its failure to report those to the FDA, (ii) the number and nature of products liability claims brought against the company during the Class Period, and (iii) three "secret recalls" that took place in October, 2011 rendered these statements false or misleading. Briefly, the court finds that all of the above alleged statements and omissions are sufficient to state a claim under the PSLRA, and will address the classes of omissions in turn.

First, according to Plaintiff, Intuitive both misclassified numerous adverse event reports of serious injury under the "other" category instead of in the "serious injury" category and categorically suppressed thousands MDRs by failing to report them to the FDA database. CAC ¶ 65, Dkt. No. 48. In the CAC, Plaintiff points to the significant spike in both serious injury MDRs and overall MDRs that occurred shortly after the September 2012 meeting with the FDA.[2] Id. ¶¶ 73, 75. Meanwhile, at the same time Intuitive was allegedly receiving and suppressing these

[2] This meeting, according to Plaintiffs, took place at the behest of the FDA in order to bring Intuitive MDR reporting practices into compliance.

numerous MDRs, Defendants were making the aforementioned statements praising da Vinci's safety and efficacy. Because da Vinci is Intuitive's sole product, and the success of da Vinci relied in large part on the perceived safety benefits as a medical device, Plaintiff alleges that these omissions created a materially false impression of da Vinci's market power.

The baseline to determine whether an undisclosed adverse report is material "remains whether a reasonable investor would have viewed the non-disclosed information as having significantly altered the total mix of information made available." Matrixx, 131 S.Ct. at 1321 (emphasis in original). Defendants had a duty to disclose this material information if their statements created a state of affairs that differed in a material way from the one that actually existed. Brody, 280 F.3d at 1006. While the "total mix" standard "does not mean that … manufacturers must disclose all reports of adverse events," Plaintiff here has alleged with particularity that thousands of MDRs went unreported or misclassified. Matrixx, 131 S.Ct. at 1321. Taking Plaintiff's contentions as true, the court concludes that it is plausible that the reasonable investor would find the existence of these numerous unreported MDRs to significantly alter the total mix of information available and that Defendants' statements created an impression of da Vinci's safety that materially differed from reality. Therefore, the omission of the MDRs plausibly rendered Defendants' statements as to the safety and efficacy of da Vinci false or misleading.

Second, Plaintiff asserts that Defendants' statements were false or misleading because they did not disclose either the existence or the nature of the corrective letters sent out to da Vinci hospitals in October 2011. In the CAC, Plaintiff alleges with particularity the circumstances behind the corrective letters (the tip cover defect and serious injuries that resulted), and the circumstances stemming therefrom (namely, the FDA Warning Letter). Plaintiff has therefore plausibly alleged an omission that the reasonable shareholder may find to significantly alter the total mix of information available with regard to da Vinci's safety. Intuitive's alleged failure to disclose these recalls gives rise to a plausible inference that the statements regarding da Vinci safety created an impression that differed materially from the one that actually existed.

Third, Plaintiff asserts that Defendants' failure to disclose specific information about the number and nature of product liability suits it faced during the Class Period rendered Intuitive's statements false or misleading because the omission of this information gave a false impression of da Vinci's safety. See CAC ¶ 189, Dkt. No. 48. Defendants contend that they were under no duty to reveal this information because the "Risk Factors" section already stated that Intuitive may be subject to products liability suits from time to time. However, Plaintiff plausibly alleges that these statements were misleading because they lacked specificity as to these lawsuits, their growing number, and their severe nature. See id. ¶¶ 189, 194, 199, 204, 214. For similar reasons as with the previous two omissions, the court finds this omission, as alleged, sufficient to raise a plausible inference that Defendants' statements regarding Intuitive safety were misleading under the PLSRA.

Defendants' corporate puffery argument does not alter the court's conclusion. A statement of corporate puffery is "so exaggerated or vague that no reasonable investor would rely upon it when considering the total mix of information available." Splash, 160 F. Supp. 2d at 1076 (internal quotation marks omitted); see also No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp., 320 F.3d 920, 934-35 (9th Cir. 2003). Such statements are "not capable of objective verification" and "lack a standard against which a reasonable investor could expect them to be pegged." In re Impac Mortg. Holdings, Inc. Sec. Litig., 554 F. Supp. 2d 1083, 1096 (C.D. Cal. 2008) (internal quotation marks and citation omitted). Here, Intuitive's repeated statements regarding da Vinci's safety, ergonomic benefits, and efficacy could be objectively assessed through safety reports such as the MDRs or peer reviewed studies. It is plausible that a reasonable investor would reasonably rely on these assertions of safety coming from the company when considering the total mix of information available. Accordingly, as alleged, these statements plausibly exceed mere expressions of corporate optimism.[3] In sum, the statements made regarding da Vinci's safety and benefits are sufficient to state a claim under the PSLRA pleading requirements.

[3] Even if these statements amount only to corporate puffery, they may still be plausibly actionable. See In re Apple Computer Sec. Litig., 886 F.2d 1109, 1113 (9th Cir. 1989) (holding that "projections and general expressions of optimism may be actionable under the federal securities laws" if the speaker is aware of any underlying facts that seriously undermine the statement.)

ii. Financial Accounting Reports

The next set of statements Plaintiff challenges are Intuitive's annual and quarterly accounting reports on everything from total revenue to system sales. Defendants contend that these sets of statements are accurate historical data and Plaintiff has failed to explain why they are inaccurate or how they are actionable. Historical financial reports are actionable if plaintiffs can plead with particularity facts showing that, by failing to disclose other information, the reports "conveyed a false or misleading impression." In re Convergent Tech. Sec. Litig., 948 F.2d 507, 512 (9th Cir. 1991). "[T]he disclosure required by the securities laws is measured not by literal truth, but by the ability of the material to accurately inform rather than mislead prospective buyers." Id.; see also Brody, 280 F.3d at 1006 (noting that the plaintiffs had correctly asserted that "a statement that is literally true can be misleading and thus actionable under securities law"). Thus, Plaintiff's pleading burden with regard to these literally accurate historical statements is fundamentally the same as its burden on other categories of statements. Plaintiff must specify each financial statement alleged to have been misleading and the reason(s) why that financial statement was misleading.

Examples of the challenged statements of historical financial data include reports that "[a]pproximately 360,000 da Vinci procedures were performed during the year ended December 31, 2011, up approximately 29% from last year" and "[s]ystem revenue increased 18% to $777.8 million during the year ended December 31, 2011 from $660.3 million during the year ended December 31, 2010." Plaintiff does not dispute the accuracy of the numbers reported; instead it argues that these statements were misleading when made because Defendants failed to disclose information that may have warned investors that this financial performance was in jeopardy. See CAC ¶ 231, Dkt. No. 48. In essence Plaintiff argues that these historical statements are misleading because they do not account for or otherwise disclaim the potential forward-looking implications presented by the MDRs and product liability lawsuits. But because Defendants' statements are literally true backward-looking financial reports, the type of which are typically included in SEC filings, the court finds these statements, as alleged, would not plausibly mislead a reasonable

investor as to the future state of Intuitive's market success. Therefore, Plaintiff has failed to state a claim for securities fraud as to these statements under the PSLRA's pleading standard.

iii. Risk Factors Disclosures

Next, Plaintiff alleges that a number of the statements made in the "Risk Factors" portion of Defendants' SEC filings were rendered false or misleading because Defendants failed to disclose material information regarding da Vinci's defects, the MDRs, products liability suits, and recalls. Defendants contend that they were under no duty to disclose this information because the statements Plaintiff points to did not give a false or misleading impression of the risks Intuitive faced. Examples of these statements include: (i) declarations that Intuitive may from time to time be involved in "a variety of claims, lawsuits, investigations and proceedings relating to securities laws, product liability, patent infringement, contract disputes" and other matters that may arise in the normal course of business (CAC ¶¶ 216(b), 225(b), 232(b), 238(a), 246(b), Dkt. No. 28); (ii) warnings with regard to potential financial exposure from product liability lawsuits, and the possibility of product recalls necessitated by a design or manufacturing defect (Id. ¶ 246(a)); and (iii) warnings that "[i]f defects are discovered in our products, we may incur additional unforeseen costs, hospitals may not purchase our products and our reputation may suffer. … Because our products are designed to be used to perform complex surgical procedures, we expect that our customers will have an increased sensitivity to such defects" (Id. ¶ 184). Plaintiff argues that the ambiguous nature of these statements, such as the suggestion that da Vinci may "possibly" be subject to defects and that "from time to time" Intuitive may face products liability suits, render them misleading.

Plaintiff has specifically alleged that, far from the stated "from time to time," Intuitive faced a growing number of personal injury/products liability lawsuits and received an abundance of information in the form of MDRs showing that Intuitive was highly likely to face additional suits in the future. However, that the statements were not wholly complete does not necessarily render them misleading to the reasonable investor. For example, in Brody, the plaintiffs complained that the defendant company's general statements that it had received "expressions of interest" from

potential acquirers were false and misleading because the company did not specifically disclose that it had received actual proposals from three different parties. 280 F.3d at 1007. The Ninth Circuit disagreed with this characterization of the defendants' statements, noting that the information the company did provide was entirely consistent with the more detailed explanation of the merger process that the plaintiffs argued the press release should have included. Id. The court held that Rule 10b-5 does not contain a "freestanding completeness requirement" because "[n]o matter how detailed and accurate disclosure statements are, there are likely to be additional details that could have been disclosed but were not." Id. at 1006.

Here, while the disclosures may have been incomplete for failing to disclose the exact number of lawsuits, they were not plausibly misleading because Intuitive made it explicitly clear through them that products liability lawsuits can and will continue to be a risk to its future revenues. Defendants continually warned that they faced significant risk of product liability claims and that, in fact, products liability claims had been made against them in the past. Therefore, omitting specific details such as the number of products liability lawsuits made against them was not an omission that "affirmatively created 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. Because the omissions of the specific number of products liability lawsuits faced did not plausibly render any of Intuitive's risk factors disclosures misleading, these statements are not sufficient to state a claim for securities fraud.

iv. FDA Regulatory Procedures

Finally, Plaintiff challenges statements made by Defendants in their SEC filings that listed out their duties pursuant to FDA regulations, including quality assurance procedures, the MDR regulations, and the "reporting of Corrections and Removals." CAC ¶ 185(a), Dkt. No. 48. Intuitive further specified that it was subject to FDA authority to determine compliance, noting that if the FDA found Intuitive failed to comply "it can institute a wide variety of enforcement actions, ranging from a regulatory letter to a public Warning Letter to more severe civil and criminal sanctions." Id. In the CAC, Plaintiff contends that these statements were materially false and

misleading because they failed to disclose that Defendants had already systematically violated FDA regulations by issuing recalls without reporting them to the FDA, in violation of 21 C.F.R. § 806.10.

Because the statements of these regulations are literally accurate, Plaintiff must plead facts showing that Defendants' statements "conveyed a false or misleading impression." Convergent, 948 F.2d at 512. Even taking as true Plaintiff's allegations that Defendants violated FDA regulations, Plaintiff has failed to plead any facts showing how these violations render statements regarding the FDA requirements themselves false or misleading. Therefore, the court finds that Plaintiff has not adequately pled its security fraud claims to the extent those claims depend on these statements.

v. Determination

In sum, the court finds that statements made by Intuitive with respect to da Vinci's safety benefits are sufficient to state a claim for securities fraud under the PSLRA pleading standard. Plaintiff pled these statements with particularity and specified why they could be misleading to a reasonable investor. In contrast, Plaintiff has failed to plausibly allege how Defendants' financial accounting reports, risk factor disclosures, and FDA regulation statements are false or misleading to the satisfaction of the PSLRA.

b. Scienter

Defendants contend that even if Plaintiff has sufficiently alleged false or misleading statements, the CAC must nevertheless be dismissed because Plaintiff failed to properly plead facts giving rise to a strong inference of scienter. In addition to sufficiently alleging falsity, plaintiffs in securities fraud actions must state with particularity facts evidencing "the defendant's intention 'to deceive, manipulate, or defraud.'" Tellabs Inc. v. Makor, 551 U.S. 308, 313 (2007) (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 194 at n.12 (1976)). The facts alleged must give rise to a strong inference that the defendant acted with the requisite state of mind. 15 U.S.C. §§ 78u-4(b)(2). Plaintiff must "plead, in great detail, facts that constitute strong circumstantial evidence of

deliberately reckless or conscious misconduct." In re Silicon Graphics, Inc. Sec. Litig., 183 F.3d 970, 974 (9th Cir. 1999).

Because "[t]he strength of an inference cannot be decided in a vacuum," the court must engage in a comparative evaluation, considering all competing inferences. Tellabs, 551 U.S. at 313. The court must evaluate scienter in the context of the entirety of the complaint. Id. at 323. A strong inference of scienter will be "cogent and at least as compelling as any opposing inference of nonfraudulent intent." Id. at 314. Here, Plaintiff must allege facts showing that Defendants intended to deceive investors by touting the safety benefits of Intuitive while failing to disclose the product recalls, defects, and MDRs.

i. Individual Defendants' Knowledge of Potential Defects

Plaintiff alleges that the individual Defendants knew about da Vinci related injuries, FDA violations, and the concealment of serious defects and thus knew that their statements regarding the safety benefits of da Vinci were false or misleading. To support this allegation, Plaintiff first relies on statements from a confidential witness, Intuitive's former Financial Planning and Analysis Manager in Sales and Marketing ("FP&A Manager"). As the Ninth Circuit explained in Zucco, to satisfy the PSLRA's pleading requirements, a plaintiff relying on statements from confidential witnesses to establish scienter must describe the confidential witnesses "with sufficient particularity to establish their reliability and personal knowledge" and the witness's statements "must themselves be indicative of scienter." 552 F.3d at 995.

The FP&A Manager had access to adverse event reports but only created sales and marketing reports. Plaintiff alleges that he "frequently interacted" with the individual Defendants and knew that Intuitive tracked adverse events and categories of adverse events, and that he compiled that data. According to the FP&A Manager, Defendants Smith and Guthart closely monitored these reports and could even recite the numbers. Plaintiff here has sufficiently described the relationship and employment of the FP&A Manager to satisfy the first factor, and have pled statements that are indicative of scienter. Thus, taking as true the factual allegation that Defendants Smith and Guthart were acutely aware of the numerous adverse effects da Vinci was

imposing on patients while continuing to tout da Vinci's safety benefits and financial performance, while downplaying the risk factors, Plaintiff has sufficiently pled a strong inference of scienter. See Iqbal, 556 U.S. at 678 (finding that for purposes of a motion to dismiss, the court must take all factual allegations in the complaint as true, but disregard any asserted legal conclusions).

ii. Defendants' Stock Sales

Plaintiff also alleges that Defendants' stock sales were so unusual and suspicious that they too give rise to a strong inference of scienter. While "[p]ersonal financial gain may weigh heavily in favor of a scienter inference," such gain must still be weighed against all other inferences and remain "cogent" in light of those other inferences. Tellabs, 551 U.S. at 325. The Ninth Circuit has found that scienter can be adequately alleged from unusual or suspicious insider stock sales when "[f]or each defendant, Plaintiffs outlined the individual's holdings, his class period sales, when the sales occurred, the percentage of owned shares that were sold, and the total proceeds that were generated from the sale." America West, 320 F.3d at 938. Unusual or suspicious insider stock sales may support a finding of scienter if the sales are "dramatically out of line with prior trading practice at times calculated to maximize the personal benefit from undisclosed inside information." Id. In determining whether a trading pattern is suspicious, the "relevant factors to consider are: (1) the amount and percentage of shares sold by insiders; (2) the timing of the sales; and (3) whether the sales were consistent with the insider's prior trading history." Id.

Here, Plaintiff has alleged with particularity each individual Defendant's holdings, class period sales, timing, percentage of owned shares sold, and the proceeds generated. See CAC ¶ 131, Exs. C-E, Dkt. No. 48. Plaintiff also pleads facts sufficient to support a strong inference of scienter under the America West factors. First, Plaintiff alleges that the individual Defendants sold a combined 223,000 shares for proceeds in excess of $124 million during the Class Period. CAC ¶¶ 132-135; 140-145, Dkt. No. 48. Second, Plaintiff alleges that Defendants sold their shares at times after Intuitive learned of information that would adversely affect Intuitive stock, but before the public learned the information, such as after the September 2012 meeting with the FDA but before acknowledging their change in MDA reporting practices to the public in March 2013. Id. ¶¶

137, 208. Finally, Plaintiff alleges that these trading practices were inconsistent with past history, particularly, Defendant Guthart's massive stock sales during the Class Period compared with his complete inaction in the Control Period.[4] Id. ¶ 133. Defendants argue that there are other, innocuous inferences that can be made from these facts, for example, chalking up the timing of the trades as correlating with quarterly earnings calls. Even so, taking all of Plaintiff's allegations as true, the facts pled remain cogent and give rise to a strong inference of scienter.

iii. Holistic Review of Scienter Claims

Pursuant to Tellabs, the court must engage in a holistic approach to determine whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter." 551 U.S. at 323. Plaintiff has pled facts that, when taken as true, show that Defendants knew that their statements regarding da Vinci's safety benefits were false or misleading when said, and that Defendants had financial motivation to maintain a misleading impression of da Vinci's safety. Taken together, these facts support a strong inference of scienter which remains cogent even in light of competing inferences. Therefore, Plaintiff has pled scienter with sufficient particularity to support their Section 10(b) and Rule 10b-5 claims as to statements made regarding da Vinci safety benefits.

3. Section 20(a) Claim

To prevail on its claim under Section 20(a) of the Act, Plaintiff must demonstrate "a primary violation of federal securities law" and that "the defendant exercised actual power over the primary violator." Zucco, 552 F.3d at 990 (quoting America West, 320 F.3d at 945). Section 20(a) claims may be dismissed if a plaintiff "fails to adequately plead a primary violation of section 10(b)." Id. Defendants do not dispute the Section 20(a) claim on grounds other than its viability under Section 10(b). Having found that Plaintiff has adequately alleged a Section 10(b) claim, the court finds that Plaintiff has also adequately alleged their Section 20(a) claim.

[4] Plaintiffs analyzed the trading by the individual Defendants during the Class Period and during the equal-length period immediately preceding the Class Period beginning August 26, 2010 and ending February 5, 2012 (the "Control Period").

IV. CONCLUSION

For the reasons stated above, the court GRANTS in part and DENIES in part Defendants' Motion to Dismiss. Plaintiff's claims are DISMISSED with leave to amend to the extent they are premised on statements made by Defendants regarding financial data, risk factors disclosures, and FDA compliance procedures.

Any amended complaint must be filed within fifteen days of the date of this Order. Plaintiff is advised that it may not add new claims or parties without first obtaining Defendants' consent or leave of court pursuant to Federal Rule of Civil Procedure 15.

IT IS SO ORDERED

Dated: August 21, 2014

EDWARD J. DAVILA
United States District Judge