

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

BRADLEY COOPER, Individually and
on Behalf of all Others Similarly
Situated; TODD LABAK,

No. 14-CV-0360 CW
ORDER DISMISSING
SECOND AMENDED
COMPLAINT WITHOUT
LEAVE TO AMEND

Plaintiffs,

THORATEC CORPORATION; GERALD F. BURBACH; TAYLOR C. HARRIS; and DAVID SMITH.

Defendants.

Plaintiffs Bradley Cooper and Todd Labak bring this putative class action lawsuit, on behalf of themselves and all other persons who bought or otherwise acquired the common stock of Thoratec Corporation (the Class Members) between May 11, 2011 and August 6, 2014 (the Class Period). This action claims violations of the Securities Exchange Act of 1934 and the Rules promulgated thereunder, against Defendants Thoratec Corporation, Gerhard Burbach, Taylor Harris and David Smith.

Plaintiffs allege that, during the Class Period, Defendants induced Class Members to acquire Thoratec stock at artificially inflated prices, by making knowingly and intentionally misleading and false statements regarding the safety of HeartMate II (HMII), one of Thoratec's medical device products. On January 24, 2014, Plaintiffs filed a complaint and on June 20, 2014, they filed a first amended complaint (1AC). Defendants moved to dismiss and, on November 26, 2014, the Court granted that motion with leave to amend. On January 20, 2015, Plaintiffs filed a second amended

1 complaint (2AC) and Defendants now move to dismiss the 2AC in its
2 entirety. Plaintiffs oppose the motion. Having considered the
3 papers filed by the parties, the Court GRANTS the motion to
4 dismiss, without leave to amend.

5 BACKGROUND

6 I. Request for Judicial Notice

7 Defendants ask that the Court take judicial notice of several
8 documents. Defendants' Request for Judicial Notice (RFJN), Docket
9 No. 52, Exs. 1-30; Docket No. 66, Exs. 31-45. "[A] court may take
10 judicial notice of matters of public record." Sami v. Wells Fargo
11 Bank, 2012 WL 967051, at *4 (N.D. Cal.) (citation omitted).

12 As a general rule, we may not consider any material beyond
13 the pleadings in ruling on a Rule 12(b)(6) motion. We may,
14 however, consider materials that are submitted with and
attached to the Complaint. We may also consider unattached
evidence on which the complaint necessarily relies if:

15 (1) the complaint refers to the document; (2) the document is
central to the plaintiff's claim; and (3) no party questions
16 the authenticity of the document. Pursuant to Federal Rule
of Evidence 201, we may also take judicial notice of matters
17 of public record, but not of facts that may be subject to
reasonable dispute. More specifically, we may not, on the
basis of evidence outside of the Complaint, take judicial
18 notice of facts favorable to Defendants that could reasonably
be disputed.

19
20 United States v. Corinthian Colleges, 655 F.3d 984, 998-99 (9th
21 Cir. 2011).

22 Plaintiffs do not object to exhibits two through four, seven
23 through nine, eleven through thirteen, fifteen, and twenty through
24 thirty; however, they state that the exhibits should only be
25 considered "for the limited purpose of what they state and when
26 they are filed." Docket No. 61 at 2. Accordingly, the Court
27 takes judicial notice of the above exhibits for that purpose.

1 Plaintiffs object to exhibits five, six, ten, fourteen, and
2 thirty-one through forty-five in their entirety, because "they are
3 not referred to or relied upon in the [2AC] and are not the type
4 of documents that should be the subject of judicial notice." Id.

5 Exhibit five is a copy of the dictionary entry for "person-
6 years" from Stedman's Medical Dictionary (28th edition 2006). Id.
7 at 1467. Defendants offer the term as one component of
8 determining the rate of thrombosis. Because Plaintiffs refer
9 extensively to the rate of thrombosis, and refer to studies that
10 use the term, the Court will take judicial notice of this medical
11 term.

12 Exhibit six is the September 6, 2013 Interagency Registry for
13 Mechanically Assisted Circulatory Support (INTERMACS) "Initial
14 Analyses of Suspected Pump Thrombosis." Plaintiffs correctly
15 state that this study is not directly incorporated into the 2AC,
16 which instead refers to the INTERMACS "analysis of pump thrombosis
17 in the HeartMate II left ventricular assist device," which was
18 published online on November 27, 2013. RFJN, Ex. 9. However,
19 exhibit six presents the preliminary analysis of the same data
20 upon which exhibit nine relies, and exhibit nine refers to exhibit
21 six. Accordingly, the Court will take judicial notice of this
22 exhibit.

23 Exhibit ten consists of letters sent to the editors of the
24 New England Journal of Medicine (NEJM). These letters were sent
25 to the NEJM in response to a study published therein that reported
26 increasing rates of thrombosis associated with HMII. Plaintiffs
27 argue that the letters are Defendants' "attempt to prove that the
28 NEJM study was not reliable. The exhibit itself is an opinion of

1 an author -- not a fact, which will be highly contested throughout
2 the litigation, but also whose authentication may be disputed."
3 Docket No. 61 at 7. While Defendants counter that the letters are
4 not offered to dispute the reliability of the NEJM study, but
5 rather to show that "practitioners from other centers reported
6 varying levels of thrombus for their patients," the Court is
7 persuaded by Plaintiffs' argument. Accordingly, Defendants'
8 request for judicial notice of exhibit ten is denied.

9 Exhibit fourteen is a January 2014 article published in the
10 Journal of Heart and Lung Transplantation (JHLT). One of the
11 doctors who wrote this article also published a 2012 article on
12 the rate of thrombosis associated with a competitor's device,
13 HeartWare, and Plaintiffs refer to that article in the 2AC. See
14 2AC ¶¶ 55 and 167. The 2014 article, according to Defendants, is
15 the "completed analysis of an earlier 'update' of the study"
16 Plaintiffs refer to in the 2AC. Defendants offer the document to
17 show that the JHLT study reported a thrombus rate of 0.08 events
18 per patient-year for the HeartWare device. Defendants' argument
19 is unpersuasive; Defendants offer the document for the purpose of
20 establishing that the HeartWare device had a thrombosis rate
21 similar to that of the HMII. That is a disputed fact.
22 Accordingly, the Court denies Defendants' request for judicial
23 notice of this exhibit.

24 Exhibits thirty-one through forty-five are included in
25 Defendants' "Supplemental Request for Judicial Notice in Support
26 of their Reply." Docket No. 65. Defendants offer the exhibits to
27 respond to two arguments raised in Plaintiffs' opposition.
28 Plaintiffs move to strike this supplement, arguing that Defendants

1 did not seek leave from the Court to file a supplement to their
2 reply. Moreover, they argue that the supplement is Defendants'
3 attempt to introduce new evidence.

4 The Court does not rely on these documents in reaching its
5 conclusion; thus it denies the supplemental request for judicial
6 notice.

7 II. Facts

8 The following facts are taken from Plaintiffs' 1AC, 2AC and
9 documents of which the Court takes judicial notice. These facts
10 are taken as true for the purposes of this order.

11 Thoratec is a medical device corporation that researches,
12 develops, manufactures and markets devices for circulatory support
13 and vascular graft applications. 2AC ¶ 2. It develops and
14 manufactures the HMII, a heart pump used to support heart function
15 and blood flow in people who have heart failure. Id. ¶¶ 34, 35.
16 Defendants are high-level executives who were employed by Thoratec
17 during the Class Period.¹

18 Thoratec received Food and Drug Administration (FDA)
19 approvals for HMII in April 2008 and January 2010, after
20 approximately five to seven years of testing for safety and
21 effectiveness. Id. ¶¶ 41, 43. In its summary of safety and
22 effectiveness for the device, the FDA published data indicating
23 the HMII had a two percent rate of thrombus, also called

24
25 ¹ During the Class Period, Defendant Gerhard Burbach was the
26 President and Chief Executive Officer (CEO); Defendant Taylor C.
27 Harris became the Chief Financial Officer and Vice President on
28 October 11, 2012; and Defendant David V. Smith was the Executive
Vice President and Chief Financial Officer between December 2006
and July 2011.

1 thrombosis, a potential complication when blood clots in the
2 device. Id. ¶ 41.

3 Plaintiffs allege that, during the Class Period, the number
4 of HMII-related incidents of thrombosis increased "dramatically."
5 Id. ¶ 78. The FDA collects, for devices it regulates, data
6 related to Serious Adverse Effects (SAEs) as reported by
7 manufacturers and importers as well as health care professionals,
8 patients and consumers. Id. ¶ 80. It collects this data in a
9 public database, known as the Manufacturer and User Facility
10 Device Experience database (MAUDE). Id. Plaintiffs allege a
11 dramatic increase of SAEs involving thrombosis between 2010 and
12 2014. In 2010, there were fifty-six SAEs involving thrombosis;
13 200 in 2011; 487 in 2012; 473 in 2013; and 264 in the first half
14 of 2014. Id.

15 Plaintiffs also allege that the sales of the HMII were only
16 moderately increasing in contrast to the number of thrombosis-
17 related events. According to Plaintiffs, revenue from sales of
18 the HMII were \$333 million in 2010; \$366 million in 2011; \$434
19 million in 2012; \$444 million in 2013; and \$212 million in the
20 first half of 2014. Id. ¶ 82.

21 In addition to the MAUDE reports, a study discussing HMII's
22 increasing thrombosis rates published on November 27, 2013 in the
23 New England Journal of Medicine (NEJM) reported, "Starting in
24 approximately March 2011, the occurrence of confirmed pump
25 thrombosis at 3 months after implantation increased from 2.2%
26 . . . to 8.4% . . . by January 1, 2013." Id. ¶ 128. This report
27 covered three centers where HMIs were implanted. Id. The
28 finding was reported in the next day's issue of the New York

1 Times. Id. ¶ 194. Also on November 27, 2013, the Journal of
2 Heart and Lung Transplantation published a study titled
3 "Interagency Registry for Mechanically Assisted Circulatory
4 Support (INTERMACS) analysis of pump thrombosis in the HeartMate
5 II left ventricular device," which likewise reported an increase
6 in the rate of HMII-related thrombosis. Id. ¶ 130. The INTERMACS
7 study reported that "freedom from device exchange or death due to
8 thrombosis went from 99% at 6 months in 2009 to 94% in 2012." Id.
9 Plaintiffs allege that, on November 29, 2013, after the two
10 studies and the news article were published, Thoratec stock
11 decreased by six and one half percent. Id. ¶ 129.

12 Plaintiffs allege that, prior to the publication of the NEJM
13 article and INTERMAC results, Defendants were aware of the
14 thrombosis issues with HMII. Id. ¶ 134. They also allege that,
15 in spite of their knowledge to the contrary, Defendants continued
16 to market the device as having low thrombosis rates. According to
17 Plaintiffs, this deception gave HMII a competitive edge over the
18 HeartWare device, which entered the market a year after HMII did.
19 Id. ¶¶ 47-57.

20 In the complaint, Plaintiffs allege that twenty-five
21 statements made by Defendants were false or misleading regarding
22 the safety of HMII, leading to an inflated stock price during the
23 Class Period. Plaintiffs allege that, as a result of Defendants'
24 deception, Class Members were harmed when the stock price declined
25 following the publication of the NEJM article and INTERMACS
26 results. In addition, Plaintiffs allege that, during the Class
27 Period, Defendants engaged in insider trading. Id. ¶¶ 86-87.
28 They allege that, "as the class period went on, and Defendants

1 gained more knowledge of the increased thrombosis rate, they
2 continued to dump shares at alarming rates." Id.

3 Plaintiffs assert, on behalf of themselves and other
4 similarly situated individuals, two causes of action against all
5 Defendants: (1) violations of § 10(b) of the Securities Exchange
6 Act and Rule 10b-5 promulgated thereunder; and (2) violations of
7 § 20(a) of the Exchange Act.

LEGAL STANDARD

9 A complaint must contain a "short and plain statement of the
10 claim showing that the pleader is entitled to relief." Fed. R.
11 Civ. P. 8(a). The plaintiff must proffer "enough facts to state a
12 claim to relief that is plausible on its face." Ashcroft v.
13 Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v.
14 Twombly, 550 U.S. 544, 570 (2007)). A claim is facially plausible
15 "when the plaintiff pleads factual content that allows the court
16 to draw the reasonable inference that the defendant is liable for
17 the misconduct alleged." Id.

18 In considering whether the complaint is sufficient to state a
19 claim, the court will take all material allegations as true and
20 construe them in the light most favorable to the plaintiff.
21 Metzler Inv. GMBH v. Corinthian Colls., Inc., 540 F.3d 1049, 1061
22 (9th Cir. 2008). The court's review is limited to the face of the
23 complaint, materials incorporated into the complaint by reference,
24 and facts of which the court may take judicial notice. Id.
25 However, the court need not accept legal conclusions, including
26 "threadbare recitals of the elements of a cause of action,
27 supported by mere conclusory statements." Iqbal, 556 U.S. at 678
28 (citing Twombly, 550 U.S. at 555).

1 When granting a motion to dismiss, the court is generally
2 required to grant the plaintiff leave to amend, even if no request
3 to amend the pleading was made, unless amendment would be futile.
4 Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv. Inc., 911
5 F.2d 242, 246-47 (9th Cir. 1990). However, the court has
6 discretion to deny leave to amend, especially where a plaintiff
7 has previously amended the complaint. See Allen v. City of
8 Beverly Hills, 911 F.2d 367, 373-74 (9th Cir. 1990).

9 " In addition to the pleading requirements of Rule 8, there
10 are more demanding pleading requirements for certain causes of
11 action, especially securities fraud." In re Rigel Pharm., Inc.,
12 Sec. Litig., 697 F.3d 869, 876 (9th Cir. 2012). Rule 9(b)
13 provides, "In all averments of fraud or mistake, the circumstances
14 constituting fraud or mistake shall be stated with particularity."
15 Fed. R. Civ. P. 9(b). The allegations must be "specific enough to
16 give defendants notice of the particular misconduct which is
17 alleged to constitute the fraud charged so that they can defend
18 against the charge and not just deny that they have done anything
19 wrong." Semegen v. Weidner, 780 F.2d 727, 731 (9th Cir. 1985).
20 Statements of the time, place and nature of the alleged fraudulent
21 activities are sufficient, provided the plaintiff sets forth "what
22 is false or misleading about a statement, and why it is false."
23 In re GlenFed, Inc., Sec. Litig., 42 F.3d 1541, 1548 (9th Cir.
24 1994), superseded by statute on other grounds, Private Securities
25 Litigation Reform Act (PSLRA) of 1995, Pub. L. No. 104-67.

26 In 1995, Congress enacted the Private Securities Litigation
27 Reform Act of 1995 (PSLRA), Pub. L. No. 104-67, which amends the
28 Securities Exchange Act of 1934, 15 U.S.C. §§ 78a-78lll.

1 Although Rule 9(b) does not require that scienter be plead with
2 particularity, see Concha v. London, 62 F.3d 1493, 1503 (9th
3 Cir. 1995), the PSLRA does. See 15 U.S.C. § 78u-4(b)(2). The
4 PSLRA provides that "the complaint shall, with respect to each act
5 or omission alleged to violate this chapter, state with
6 particularity facts giving rise to a strong inference that the
7 defendant acted with the required state of mind." 15 U.S.C.
8 § 78u-4(b)(2). Because the instant action alleges violations of
9 § 10(b), the "required state of mind" is defined by that section.
10 See In re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970, 975
11 (9th Cir. 1999), abrogated on other grounds by S. Ferry LP, No. 2
12 v. Killinger, 542 F.3d 776 (9th Cir. 2008). "This means that a
13 plaintiff must provide, in great detail, all the relevant facts
14 forming the basis of her belief." Silicon Graphics, 183 F.3d at
15 985. Factual allegations that are not based on plaintiffs'
16 personal knowledge are allegations that are made on information
17 and belief. Thus, for example, if a plaintiff's sole basis for an
18 allegation is a statement from a non-plaintiff witness, that
19 allegation is made on information and belief, and the plaintiff
20 must plead all facts on which that belief is based. See id. at
21 985, 998 n.21. This does not mean, however, that a plaintiff
22 must, for each allegation plead on information and belief, state
23 every fact possessed that is in any way related to the allegation.
24 Id. at 999.

25 Section 10(b) of the Securities Exchange Act makes it
26 unlawful for any person to "use or employ, in connection with the
27 purchase or sale of any security . . . any manipulative or
28 deceptive device or contrivance in contravention of such rules and

1 regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b); see
2 also 17 C.F.R. § 240.10b-5 (Rule 10b-5). Rule 10b-5(b) clarifies
3 that it is "unlawful for any person, directly or indirectly, . . .
4 to make any untrue statement of material fact or to omit to state
5 a material fact necessary in order to make the statements made, in
6 the light of the circumstances under which they were made, not
7 misleading[.]" 17 C.F.R. § 240.10b-5(b). The PSLRA thus requires
8 that a plaintiff plead with particularity "facts giving rise to a
9 strong inference that the defendant acted with," at a minimum,
10 deliberate recklessness. See 15 U.S.C. § 78u-4(b) (2); Silicon
11 Graphics, 183 F.3d at 977. Facts that establish a motive and
12 opportunity, or circumstantial evidence of "simple recklessness,"
13 are not sufficient to create a strong inference of deliberate
14 recklessness. See id. at 979. In order to satisfy the heightened
15 pleading requirement of the PSLRA for scienter, a plaintiff "must
16 state specific facts indicating no less than a degree of
17 recklessness that strongly suggests actual intent." Id.

DISCUSSION

I. Order Granting the Motion to Dismiss 1AC

20 In the November 26, 2014 Order granting Defendants' motion to
21 dismiss the 1AC, the Court discussed several reasons why the 1AC
22 was deficient. First, it found that the 1AC failed to allege
23 facts sufficient to support the allegations that any statement
24 with regard to the rate of thrombosis made by Defendants was
25 false. Plaintiffs had alleged that the number of thrombosis
26 events had increased during the Class Period, but did not state
27 facts sufficient to support the allegation that the rate of
28 thrombosis had increased.

1 Second, the Court stated that the IAC's allegations with
2 regards to statements in financial disclosures, statements of
3 corporate optimism, opinions, forward-looking statements, and the
4 statements of third parties were non-actionable. The Court also
5 found that statements which referred to the results of specific
6 studies were non-actionable because Plaintiffs did not allege that
7 Defendants mischaracterized the results of those studies.

8 Third, the Court found that allegations that relied solely on
9 the MAUDE data, data that the FDA specifically warned was not to
10 be used to establish the rates of events, was unavailing.
11 Plaintiffs did not state facts sufficient to support their
12 allegation that Defendants were aware of any internal data that
13 showed an increase in the rate of thrombosis. Likewise,
14 Plaintiffs failed to allege facts sufficient to show that, even if
15 the rate of thrombosis was increasing, Defendants' statements
16 about thrombosis were false or misleading when made.

17 The Court also found that Plaintiffs failed to plead adequate
18 facts to support scienter and loss causation. Plaintiffs did not
19 state facts as to the content or timing of the alleged internal
20 reports that were needed to support a strong inference of
21 deliberate recklessness. Furthermore, Plaintiffs' reliance on the
22 statements of Confidential Witnesses was unavailing because they
23 failed to allege facts to support that these witnesses were in a
24 position to have personal knowledge that Defendants knew about
25 actual increases in the rate of thrombosis.

26 Plaintiffs also alleged a violation of § 20(a) of the
27 Exchange Act, but that cause of action failed because they failed
28 to allege a § 10(b) cause of action. Plaintiffs were given leave

1 to amend the complaint if they could do so without contradicting
2 prior pleadings.

3 II. Changes in the 2AC

4 At the hearing on the motion to dismiss the 1AC, the Court
5 instructed that if Plaintiffs filed an amended complaint, they
6 must also submit a redlined copy of the 1AC with their 2AC.
7 However, to the extent that Plaintiffs moved paragraphs around,
8 the Court permitted them submit a notice of the changes made in
9 the 2AC, which Plaintiffs have done. Docket No. 50.

10 In the notice, they state the following aspects of the
11 complaint have changed: (1) the Class Period has shifted from
12 April 29, 2010 through November 27, 2013 to May 11, 2011 through
13 August 6, 2014; (2) Defendant Roxanne Oulman has been dropped as a
14 party; (3) Plaintiff Todd Labak has been added as a named
15 Plaintiff because Plaintiff Bradley Cooper did not purchase any
16 Thoratec stock during the amended Class Period; (4) the 2AC
17 focuses on statements made by Defendants that the thrombosis rates
18 were maintained at two to three percent, or that thrombosis rates
19 were consistently maintained at clinical trial rates;
20 (5) statements made by Defendants comparing HMII and the HeartWare
21 product support scienter instead of stand-alone actionable
22 statements; and (6) allegations based on SEC filings have been
23 removed.

24 Like the 1AC, Plaintiffs' 2AC alleges that, during the Class
25 Period: (1) the rate of thrombosis caused by HMII increased;
26 (2) Defendants knew of this increase; (3) they failed to disclose
27 the increase; and (4) they knowingly made misleading and/or false
28 statements to investors. Plaintiffs allege that, as a result, the

1 Class Members incurred losses when the deception was revealed to
2 the market. The Court now turns to the causes of action.

3
4 III. First Cause of Action: Violation of § 10(b) of the Securities
5 Exchange Act

6 To state a claim under § 10(b) and Rule 10b-5(b), Plaintiffs
7 must allege: "(1) a misrepresentation or omission of material
8 fact, (2) scienter, (3) a connection with the purchase or sale of
9 a security, (4) transaction and loss causation, and (5) economic
10 loss." In re Gilead Sciences Sec. Litig., 536 F.3d 1049, 1055
11 (9th Cir. 2008). For each statement that Plaintiffs allege to be
12 false or misleading, the PSLRA requires that the complaint state
13 "the reason or reasons why the statement is misleading." 15
14 U.S.C. § 78u-4(b) (1).

15 Plaintiffs identify twenty-five statements that they allege
16 are actionable under § 10(b). The Court will discuss these
17 statements in two groups: (1) statements made prior to November
18 27, 2013, which is when Plaintiffs allege that the "truth" was
19 revealed about the increased rate of thrombosis; and
20 (2) statements made after November 27, 2013.

21 A. Pre-November 27, 2013 statements

22 Plaintiffs identify fifteen statements made by Defendants
23 prior to November 27, 2013 that were allegedly false and
24 misleading. They argue Defendants knew, based on internal data,
25 that the rate of thrombosis was significantly higher than the two
26 to three percent rate that was established during the clinical
27 trials.

28 //

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1 1. Statements that refer to rates of thrombosis
2 Plaintiffs allege that, near the beginning of the Class
3 Period, Defendant Smith stated, "And you can see that we have very
4 low rates [of thrombosis associated with the HMII] here, between
5 0.02 and 0.03, with the Bridge and the DT trials." 2AC ¶ 90.
6 Plaintiffs allege similar statements made by Defendant Burbach
7 between September 13, 2011 and July 31, 2013, as well as by
8 Defendant Harris between September 22, 2011 and September 19,
9 2012. See id. ¶¶ 93, 96, 100, 103, 106, 109, 112, 115, 118, 119,
10 122, 123, 126 and 127. Plaintiffs allege that these statements
11 were false and misleading when made because Defendants knew that
12 "the thrombosis rate at the time of the statement had risen well
13 above that level" and that Defendants, according to the statements
14 of Confidential Witnesses, "would have been made aware of the
15 increase in events based on the Company's record keeping of SAEs."
16 Id. ¶¶ 91-92; see id. ¶¶ 94-95, 97-98, 101-102, 104-105, 107-108,
17 110-111, 113-114, 116-117, 118-121, 122, 123 and 127. Plaintiffs
18 refer to the MAUDE data to establish that Defendants were aware of
19 the increasing rate of thrombosis. In the Order dismissing the
20 1AC, the Court stated,

21 Plaintiff's allegations based on MAUDE data are unavailing.
22 The MAUDE front page includes the following disclaimer:
23 "Although MDRs [medical device reports] are a valuable source
24 of information, the passive surveillance system has its
25 limitations, including the submission of incomplete,
26 inaccurate, untimely, unverified or biased data." RFJN, Ex.
27 1. Furthermore, it states, "MDR data alone cannot be used to
28 establish the rates of events, evaluate a change in event
rates over time or compare rates between devices." Id. An
increase in the number of events does not translate into an
increased rate if the number of devices used has increased
also. Despite this warning, Plaintiff relies on this data as
evidence that the actual rates of thrombosis were increasing,
and that the Defendants knew the rates were increasing
because they were aware of the MAUDE data. Plaintiff does

1 not allege that any internal data on the actual rates of
2 thrombosis demonstrated an increase.

2 November 26, 2014 Order at 23.

3 The 2AC suffers from the same deficiency. In the 2AC,
4 Plaintiffs state, "The FDA's [MAUDE] database demonstrates that
5 during the Class Period, SAE's involving thrombosis were
6 increasing and being reported to Defendants at a much greater rate
7 than HeartMate II devices were being implanted." Id. ¶ 80. They
8 go on to assert, based on the MAUDE data, "The amount of adverse
9 events involving thrombosis that were reported to Defendants
10 during the Class Period" was increasing. Id.

11 As discussed in the previous order, the MAUDE data cannot be
12 used to establish the rates of SAEs, including thrombosis. Yet,
13 Plaintiffs continue to rely on the MAUDE data to indicate that the
14 number and rates of thrombosis were actually increasing. While
15 Plaintiffs also provide what they purport to be only a modest
16 increase or no change at all in the sales revenues of HMII, see
17 id. ¶¶ 82-84, as discussed below, sales revenues do not
18 sufficiently correlate with the number of devices in use or the
19 length of time that the devices have been implanted.²

20 As Defendants point out, the rates of thrombosis -- including
21 the clinical trial rate, which Plaintiffs use as their baseline
22 rate of two to three percent, see id. ¶ 100 -- are expressed in
23

24 ² In their opposition, Plaintiffs admit that they "were
25 unable to calculate unit volume vs. sales consistently throughout
26 the Class Period because Defendants only disclosed the unit volume
27 number on three occasions during the Class Period, but clearly
28 this information was known to Defendants. If the data would have
supported their position in their motion to dismiss, they would
have submitted it here." Docket No. 60 at 17 n.12.

1 terms of patient-years, which accounts not just for the number of
2 devices that have been implanted, but the number of years the
3 devices have been in place. See RFJN, Ex. 5. Plaintiffs downplay
4 this issue, stating that "a reasonable investor would believe that
5 the rates were maintained at 2% -- regardless of how Defendants
6 calculate them." Pls.' Opp., Docket No. 60 at 13. But Plaintiffs
7 fail to account for the fact that a reasonable investor would
8 calculate a change in rates using the same formula as that used to
9 calculate the baseline rate.

10 Thus, the alleged false and misleading statements that refer
11 to an actual change in thrombosis rates based on the MAUDE data
12 and sales revenue cannot support a claim for violation of § 10(b).
13 Accordingly, the Court shall disregard these statements (2AC
14 ¶¶ 90, 93, 96, 100, 103, 106, 109, 112, 115, 118, 119, 122, 123,
15 126 and 127) when considering the sufficiency of the 2AC.

16 2. Statements that refer to published studies

17 Furthermore, several statements made by Defendants that
18 Plaintiffs allege were false or misleading when made refer to
19 rates of thrombosis as published or as a result of clinical trials
20 or other studies. See id. ¶ 90 ("with the Bridge and the DT
21 trials"), ¶ 96 ("very low thrombus rate in the clinical trial
22 environment . . . [t]hat's been well documented and published");
23 ¶ 100 ("low rates . . . from an array of published articles");
24 ¶ 103 ("consistently low adverse event rates as published and
25 presented in a variety of peer-reviewed publications"); ¶ 106
26 ("lowest published rates of adverse events"); ¶ 109 ("[t]here's
27 obviously been a lot of literature . . . showing HeartMate II
28 thrombus rates in the low single-digits"); ¶ 112 ("when we look at

1 national level data spanning the full spectrum of centers, the
2 rates of thrombus . . . are very consistent with the clinical
3 trial"); and ¶ 119 ("lowest rates of some critical adverse events
4 that have been published in peer-reviewed literature"). In the
5 order dismissing the LAC, the Court held that statements which
6 referred to specific studies were non-actionable unless Plaintiffs
7 alleged that Defendants mischaracterized the results of those
8 studies. See November 26, 2014 Order at 21. Plaintiffs do not so
9 allege. Thus, these statements (2AC ¶¶ 90, 96, 100, 103, 109, 112
10 and 119) are non-actionable for this reason also.

11 3. Statements unrelated to thrombosis

12 In addition, several statements Plaintiffs allege were
13 misleading did not refer to thrombosis rates at all. Plaintiffs
14 allege that, prior to November 27, 2013, Defendants made five
15 statements about the number of units sold while failing to
16 disclose that thrombosis rates were increasing. See id. ¶¶ 118,
17 122, 123, 126 and 127. For example, Plaintiffs allege that, on
18 May 1, 2012, Defendant Burbach, in a press release about
19 Thoratec's 2012 first quarter financial results, touted HMII's
20 "broad-based . . . unit growth of 32% in both the U.S. and
21 international markets." Id. ¶ 118. Plaintiffs allege that
22 "Burbach failed to disclose the fact that there was a 220%
23 increase in the amount of thrombosis related events reported to
24 the Company for this same quarter[.]" Id. As discussed above,
25 Plaintiffs do not allege facts sufficient to support the
26 allegation that there was an actual increase in rates or that the
27 Company was aware of those rates. Thus, these statements (2AC ¶¶

1 118, 122, 123, 126 and 127) are non-actionable for this reason as
2 well.

3 B. Post-November 27, 2013 statements

4 Plaintiffs allege that, after November 27, 2013, Defendants
5 made ten statements that were false or misleading when made. See
6 id. ¶¶ 138, 140, 143, 146, 149, 151, 154, 156, 159 and 162.
7 Plaintiffs allege that, in these statements, Defendants downplayed
8 the seriousness of the thrombosis problem related to HMII.

9 1. Statements that refer to the rate of thrombosis

10 Plaintiffs allege that, on March 3, 2014, Defendant Harris
11 stated, "Our internal data also mirrors the broad INTERMACS'
12 database which showed an overall lower rate of complications than
13 what were shown in the New England Journal of Medicine article."
14 Id. ¶ 154. Plaintiffs concede that the INTERMACS database
15 actually demonstrated a lower rate of thrombosis than was reported
16 in the NEJM article, but claim the statement was false or
17 misleading because the INTERMACS database "still demonstrated a
18 rate that was dramatically more than the pre-approval clinical
19 rate that Defendants reported prior to the NEJM study." Id.
20 ¶ 155. It is not clear what is false or misleading about
21 Defendant Harris's statement. A statement of "lower" rate could
22 be proven false, but Plaintiffs never allege that Thoratec's
23 internal data was inconsistent with the INTERMACS database or that
24 Defendants mischaracterized the INTERMACS database.

25 This flaw can be found in several of Plaintiffs' allegations.
26 See id. ¶ 138 ("our internal data is consistent with the data
27 that's in the . . . INTERMACS Registry that's published in the
28 Journal of Heart and Lung Transplant"); ¶ 140 ("we've seen

1 stabilization in that rate [referring to the INTERMACS database
2 rates]"); ¶ 143 ("[O]ur internal data is very consistent with the
3 INTERMACS registry"); ¶ 146 ("moreover our more recent data shows
4 stabilization in thrombosis rates . . . in contrast to the still
5 increasing rates suggested by [NEJM article]"); ¶ 149 ("we expect
6 additional clinical data . . . will be released . . . including
7 results from centers experiencing lower levels of thrombosis");
8 ¶ 151 ("there are centers that have very low rates . . . and there
9 are centers who have higher rates of thrombosis"); and ¶ 156 ("as
10 we've looked at our internal data . . . we saw a stabilization
11 over a year ago . . . if that trend holds then that will start to
12 filter through the larger public data sources like the INTERMACS
13 registry"). Plaintiffs have not alleged that any of these
14 statements misrepresent the INTERMACS data or Thoratec's internal
15 data.

16 Plaintiffs also allege that, on May 13, 2014, Defendant
17 Burbach made the following statement: "The full universe of
18 adverse events, stroke is down, bleeding is down, infection is
19 down as you look at the HeartMate II in this time period where you
20 saw thrombus up." Id. ¶ 162. Plaintiffs allege that this
21 statement was false or misleading because "adverse events due to
22 thrombosis were not down." Id. ¶ 163. Yet, Defendant Burbach
23 clearly refers to the perception that the rate of thrombosis may
24 have gone up. Plaintiffs do not allege any facts to support the
25 inference that this statement was false.

26 Thus, the Court shall disregard these statements (2AC ¶¶ 138,
27 140, 143, 146, 149, 151, 154, 156 and 162) in considering the
28 sufficiency of Plaintiffs' 2AC.

1 2. Revenue guidance

2 Plaintiffs allege that Defendants presented revenue guidance
3 that was "unachievable when made" given the alleged rise in the
4 rate of thrombosis. Id. ¶ 160.5 For a forward-looking statement such as . . . public guidance
6 to constitute a material misrepresentation giving rise to
7 Section 10(b) or Rule 10b-5 liability, a plaintiff must prove
8 either "(1) the statement is not actually believed [by the
speaker], (2) there is no reasonable basis for the belief, or
9 (3) the speaker is aware of undisclosed facts tending
seriously to undermine the statement's accuracy."10 In re Oracle Corp. Sec. Litig., 627 F.3d 376, 388 (9th Cir. 2010)
11 (citing Provenz v. Miller, 102 F.3d 1478, 1487 (9th Cir. 1996)).12 Plaintiffs allege that, on May 6, 2014, Defendants Burbach
13 and Harris "reiterated guidance of \$520 million to \$535 million in
14 expected revenue in 2014" while downplaying the "seriousness of
15 the rising thrombosis rates." Id. ¶ 159. Defendant Burbach
16 allegedly stated, "The issue of thrombus remains a multifaceted
17 adverse event with many contributing factors, and we believe that
18 our internal initiatives combined with more recently released
19 clinical data present a balanced view of the issue that will
20 continue to advance the therapy." Id. Plaintiffs state that
21 Defendant Burbach was misleading the investment community as to
22 the extent of the "growing concern in the clinician community over
the thrombosis rate." Id. ¶¶ 159-160.23 Plaintiffs do not allege any facts to support the inference
24 that Defendant Burbach's statement was a material
25 misrepresentation. Even though Thoratec revised downward its
26 revenue guidance in August 2014, Plaintiffs do not allege facts
27 sufficient to support the inference that Defendant Burbach's May
28 2014 statement had no reasonable basis. Indeed, Plaintiffs allege

1 that, in August 2014, Defendant Burbach provided the following
2 reason to explain why revenue for the company was less than
3 expected:

4 Beginning with adverse events, we believe perceptions about
5 pump thrombosis since the late 2013 New England Journal of
6 Medicine article along with greater scrutiny of clinical
7 outcomes overall continues to be the largest factor impacting
8 our business on a worldwide basis. While we expect that this
would be a headwind during the first half of the year is now
clearly the impact is persisting longer than expected.
Specifically, we believe some implanting clinicians have
become more selective in their patient evaluation criteria.

9 Id. ¶ 166.

10 This statement is far from Plaintiffs' characterization that,
11 in August 2014, Defendants finally admitted "the truth." Indeed,
12 this statement supports an inference that Defendants believed that
13 the decrease in sales of HMII was due to clinicians choosing
14 patients more carefully, not that they believed there was
15 something inherently wrong with the device.

16 Furthermore, by the time this statement was made, Plaintiffs
17 allege, the market had already learned the truth. Accordingly,
18 they cannot allege that the information with regard to thrombosis
19 was undisclosed. Thus, the Court shall disregard the May 6, 2014
20 statement (2AC ¶ 159) in considering the sufficiency of
21 Plaintiffs' 2AC.

22 B. Scienter

23 Defendants argue that even if Plaintiffs' § 10(b) cause of
24 action does not fail for the reasons discussed above, it fails
25 because Plaintiffs fail to plead scienter adequately.

26 To plead scienter adequately under the PSLRA, the complaint
27 must "state with particularity facts giving rise to a strong
28 inference that the defendant acted with the required state of

1 mind." 15 U.S.C. § 78u-4(b)(2)(A). A sufficient inference of
2 scienter is "a strong inference that the defendant acted with an
3 intent to deceive, manipulate, or defraud." Metzler, 540 F.3d at
4 1061. "The Supreme Court has emphasized that courts 'must review
5 all the allegations holistically' when determining whether
6 scienter has been sufficiently pled. The relevant inquiry is
7 'whether all of the facts alleged, taken collectively, give rise
8 to a strong inference of scienter, not whether any individual
9 allegation, scrutinized in isolation, meets that standard.'" Reese v. Malone, 747 F.3d 557, 569 (9th Cir. 2014) (citing Tellabs Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 323 (2007));
10 see also N.M. State Inv. Council v. Ernst & Young LLP, 641 F.3d
11 1089, 1095 (9th Cir. 2011).

12 Plaintiffs argue that Defendants acted knowingly or, at the
13 very least, with reckless disregard for the truth when they made
14 the statements discussed above. Based on information they
15 received from Confidential Witnesses and their interpretation of
16 the MAUDE database, Plaintiffs allege that Defendants were aware
17 of internal reports that demonstrated a rise in thrombosis rates.
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1. Deliberate recklessness

2 "Deliberate recklessness means that the reckless conduct
3 'reflects some degree of intentional or conscious misconduct.'"
4 Reese, 747 F.3d at 569 (quoting S. Ferry LP, 542 F.3d at 782).
5 "'[A]n actor is [deliberately] reckless if he had reasonable
6 grounds to believe material facts existed that were misstated or
7 omitted, but nonetheless failed to obtain and disclose such facts
8 although he could have done so without extraordinary effort.'"
9 Id. (quoting In re Oracle, 627 F.3d at 390).

10 In the order dismissing the 1AC, the Court found that, even
11 assuming Plaintiffs' 1AC allegations were true, Defendants'
12 statements did not give rise to a "strong inference" of deliberate
13 recklessness. It stated,

14 The 1AC's allegations about internal reports of an increasing
15 rate of thrombosis fail to support an inference that the
16 reports contained information that contradicted Defendants'
17 statements when they were made. Further, absent allegations
18 about the contents and timing of specific reports,
19 Plaintiff's allegations based on MAUDE data, FDA recalls and
20 adverse internal reports at best raise an inference of
21 negligence, rather than a strong inference of deliberate
22 recklessness. . . . Defendants contend that Plaintiff's only
23 allegation of knowing misconduct is his vague and legally
24 inadequate assertion that Defendants knew of unidentified
25 negative internal reports. "[M]ere boilerplate pleadings
26 [about unidentified negative internal reports] will rarely,
27 if ever, raise a strong inference of deliberate
28 recklessness." See Silicon Graphics, 183 F.3d at 984.

22 November 26, 2014 Order at 26-27.

23 The 2AC suffers from this same flaw. Plaintiffs rely on the
24 fact that the MAUDE data was publicly available to show that an
25 increase in the rate of thrombosis was "reported to" the Company.
26 See, e.g., 2AC ¶ 92. As discussed above, however, Plaintiffs do
27 not state facts sufficient to support the assertion that internal
28 reports corresponded with the MAUDE data and, thus, contradicted

1 Defendants' public statements. Thus, these allegations cannot
2 support a strong inference of deliberate recklessness.

3 2. Confidential Witnesses

4 Plaintiffs also rely on the statements of six Confidential
5 Witnesses to support scienter.

6 [C]onfidential witness statements may only be relied upon
7 where the confidential witnesses are described with
8 sufficient particularity to support the probability that a
9 person in the position occupied by the source would possess
10 the information alleged. Accordingly, the complaint must
11 provide an adequate basis for determining that the witnesses
12 in question have personal knowledge of the events they
13 report. To determine whether the complaint has done so, we
14 look to the level of detail provided by the confidential
15 sources, the corroborative nature of the other facts alleged
16 (including from other sources), the coherence and
17 plausibility of the allegations, the number of sources, the
18 reliability of the sources, and similar indicia.

19 Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981, 995 (9th Cir.
20 2009).

21 Plaintiffs rely on the same Confidential Witness statements
22 alleged in the 1AC to support their 2AC allegation of scienter.
23 The Court's previous order stated, "Plaintiff fails to allege
24 facts sufficient to support that the confidential witnesses were
25 in a position to have personal knowledge that Defendants knew of
actual increases in the thrombosis rate." November 26, 2014 Order
at 27. Accordingly, the Court found that the statements made by
the Confidential Witnesses were insufficient to support scienter.
The same is true here. Thus, the statements of the Confidential
Witnesses cannot support a strong inference of scienter.

26 3. Motive

27 In addition, Defendants argue that Plaintiffs' motive
28 allegations are insufficient to support a strong inference of
scienter. "Facts showing mere recklessness or a motive to commit

1 fraud and opportunity to do so provide some reasonable inference
2 of intent, but are not independently sufficient." Reese, 747 F.3d
3 at 569. The Ninth Circuit has noted that where "Plaintiffs'
4 allegation is essentially that these defendants possessed inside
5 information on [the company's] imminent collapse . . . one would
6 expect that they would have sold a good proportion of their
7 holdings." In re Worlds of Wonder Sec. Litig., 35 F.3d 1407, 1427
8 (9th Cir. 1994) (citing and affirming the district court's ruling
9 on this issue); see also Wenger, 2 F. Supp. 2d at 1251 ("stock
10 sales alone cannot create a strong inference of scienter").

11 In the 2AC, Plaintiffs allege, "Defendants [Burbach and
12 Harris] were motivated to disseminate materially false or
13 misleading statements, as well as omit to disclose material
14 information about the Device, including, but not limited to, the
15 increase in the rate of thrombosis during the Class Period, in
16 order to, *inter alia*, counter the rising competition from
17 HeartWare . . . and personally profit from sales of stock in their
18 portfolios during the Class Period." 2AC ¶ 186.

19 In the previous order, the Court found that these same
20 allegations of motive were insufficient to support a strong
21 inference of scienter because Plaintiffs did not allege "that the
22 shares sold by Defendants during the Class Period were 'a good
23 proportion' of their shares. Instead, Plaintiff only alleges that
24 Defendants sold more shares during the Class Period than they had
25 prior to the Class Period." November 26, 2014 Order at 30. The
26 same is true here. It is true that, "along with other evidence of
27 recklessness, information that compares stock sales before and
28 after the Class Period may be indicative of scienter." Id. at 30-

1 31. However, as discussed throughout this Order, Plaintiffs fail
2 to allege other evidence of recklessness.

3 Moreover, as Defendants point out, there is no evidence of a
4 discrepancy between Defendant Harris's stock sales before and
5 after the Class Period because Defendant Harris did not join the
6 company as an officer until October 2012, well into the Class
7 Period. See Mot. to Dismiss at 23. As to Defendant Burbach,
8 Plaintiffs still fail to allege that he sold a "good proportion"
9 of his shares. Instead, they allege only that during the Class
10 Period Defendant Burbach sold "three times the amount of shares he
11 sold prior to the Class Period." 2AC ¶ 87. While they state that
12 he sold 196,702 shares prior to the Class Period, and 582,656
13 shares during the Class Period, Plaintiffs do not state what
14 proportion of Defendant Burbach's total stock amount those shares
15 comprised.³

16 Given these pleading defects, Plaintiffs have not alleged
17 facts sufficient to support a strong inference of scienter.
18 Accordingly, the cause of action for violating § 10(b) is
19 dismissed in its entirety for this reason also.

20 C. Loss Causation

21 Finally, Defendants argue that Plaintiffs' § 10(b) cause of
22 action fails because it does not plead loss causation.

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³ Plaintiffs allege that Defendant Burbach sold twenty-eight
25 percent of his shares during the Class Period. However, they also
26 allege that he owned 183,374 shares in May 2011 and 132,104 in
27 November 2011. See Docket No. 60 at 21 n.16. As Defendants point
28 out those calculations are inconsistent with Plaintiffs'
allegation that Defendant Burbach sold over 500,000 shares during
the Class Period. See Docket No. 63 at 10 n.11.

1 Pleading loss causation "requires a plaintiff to show that a
2 misrepresentation that affected the integrity of the market price
3 also caused a subsequent economic loss." Erica P. John Fund, Inc.
4 v. Halliburton Co., 131 S. Ct. 2179, 2186 (2011).

5 [T]he fact that a stock's price on the date of purchase was
6 inflated because of [a] misrepresentation does not
7 necessarily mean that the misstatement is the cause of a
8 later decline in value. . . . [T]he drop could instead be the
9 result of other intervening causes, such as changed economic
10 circumstances, changed investor expectations, new industry
11 specific or firm-specific facts, conditions, or other events.
12 If one of those factors were responsible for the loss or part
13 of it, a plaintiff would not be able to prove loss causation
14 to that extent. This is true even if the investor purchased
15 the stock at a distorted price, and thereby presumptively
16 relied on the misrepresentation reflected in that price.

17 Id.

18 In its previous order, the Court stated that only if
19 Plaintiff "properly alleged that Defendants made false statements
20 about the rate of thrombosis, [could he] then . . . allege loss
21 causation due to the NEJM's correction and the subsequent drop in
22 the stock price." November 26, 2014 Order at 32-33. As discussed
23 above, Plaintiffs have not made the requisite showing in the 2AC
24 and, thus, cannot plead adequate loss causation. The 2AC's cause
25 of action for a violation of § 10(b) is dismissed in its entirety
26 for this reason as well.

27 For all the reasons discussed above, the 2AC fails to state a
28 claim for violating § 10(b). Accordingly, the Court GRANTS
Defendants' motion to dismiss this cause of action. Because
Plaintiffs have previously been afforded leave to amend their
complaint, the Court grants the motion to dismiss without leave to
amend. See Allen, 911 F.2d at 373-74.

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1 IV. Second Cause of Action: Violations of § 20(a)

2 "[T]o prevail on their claims for violations of § 20(a),
3 plaintiffs must first allege a violation of § 10(b) or Rule 10b-
4 5." In re LDK Solar Sec. Litig., 584 F. Supp. 2d 1230, 1251-52
5 (N.D. Cal. 2008) (citing Lipton v. Pathogenesis Corp., 284 F.3d
6 1027, 1035 n.15 (9th Cir. 2002)).

7 As discussed above, Plaintiffs have failed to plead
8 adequately a primary violation under § 10(b) and, hence, the Court
9 must dismiss the § 20(a) cause of action. In addition, in the
10 order dismissing the 1AC, the Court found that Plaintiffs failed
11 adequately to impute "controlling persons" liability under
12 § 20(a) because they did not allege adequately that Thoratec is
13 liable for a § 10(b) violation. Accordingly, Plaintiffs could not
14 allege that any of the individual Defendants are liable as
15 "controlling persons." Plaintiffs did not cure this deficiency in
16 the 2AC. Thus, the 2AC's cause of action for violating § 20(a)
17 fails for this reason also.

18 For all the reasons stated above, Plaintiffs fail to state a
19 claim for a violation of § 20(a); they have not plead sufficient
20 facts to support their § 10(b) cause of action and they have not
21 adequately plead that Thoratec is liable for a § 10(b) violation.
22 Accordingly, the Court GRANTS Defendants' motion to dismiss this
23 cause of action. Because Plaintiffs have previously been afforded
24 leave to amend their complaint, the Court grants the motion
25 without leave to amend. See Allen, 911 F.2d at 373-74.

26 CONCLUSION

27 For the reasons set forth above, the Court GRANTS Defendants'
28 motion to dismiss the 2AC (Docket No. 51) in its entirety without

1 leave to amend. The Clerk of the Court shall enter judgment and
2 close the file. The parties shall bear their own costs.

3 IT IS SO ORDERED.

4 Dated: November 10, 2015



5 CLAUDIA WILKEN
6 United States District Judge