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**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA**

ERVIN DERR and PETER  
SHOEMAKER, individually and on  
behalf of others similarly situated,  
  
Plaintiffs,  
  
vs.  
  
RA MEDICAL SYSTEMS, INC., et  
al.  
  
Defendants.

CASE NO. 19cv1079-LAB-AHG

**ORDER:**

- 1) GRANTING IN PART REQUESTS FOR JUDICIAL NOTICE;**
- 2) GRANTING IN PART MOTIONS TO DISMISS [Dkt. 29; Dkt. 30]; and**
- 3) GRANTING MOTION FOR LEAVE TO FILE SUR-REPLY [Dkt. 40].**

Plaintiffs Ervin Derr and Peter Shoemaker brought this action against Defendants Ra Medical Systems, Inc. (“Ra”), Andrew Jackson, Richard Heymann, Maurice Buchbinder, Martin Colombatto, Richard Mejia, Jr. (collectively, the “Ra Defendants”), Dean Irwin, Melissa Burstein, and Martin Burstein (collectively with the Ra Defendants, “Defendants”), alleging violations of the securities laws. Ra is a medical device manufacturer that sells the DABRA laser system and catheter, which is designed to dissolve plaque

1 in vascular blockages. Plaintiffs allege, generally, that Defendants made a  
2 series of false or misleading statements, beginning with the Registration  
3 Statement issued in connection with Ra's IPO, that tended to gloss over  
4 known problems with the DABRA system, Ra's internal financial reporting, and  
5 Ra's sales training programs. When the allegedly omitted problems came to  
6 light, the value of Ra's stock collapsed, harming shareholders who had  
7 purchased shares in Ra without knowing of the challenges the company faced.  
8 Based on these allegations, Plaintiffs seek to recover for violations of Section  
9 11 of the Securities Exchange Act of 1933, 15 U.S.C. § 77k, and Sections  
10 10(b), 15, and 20a(a) of the Securities Exchange Act of 1934. 15 U.S.C. §§ 78j,  
11 78o, 78t.

12 Irwin, Melissa Burstein, and Martin Burstein filed a motion to dismiss the  
13 Amended Complaint, and the Ra Defendants followed suit with a motion of  
14 their own. Plaintiffs, they argue, lack standing under Sections 11 and 15  
15 because they can't trace their shares to the IPO and fail to allege any false or  
16 misleading statements as necessary to state claims under Sections 10(b) and  
17 20(a). Plaintiffs sought leave to file a sur-reply.

18 The Court finds a valid reason for additional briefing, and so it **GRANTS**  
19 Plaintiffs leave to file the sur-reply. (Dkt. 40.) Because the Court finds that  
20 Plaintiffs haven't alleged facts to support standing under Sections 11 and 15,  
21 it **GRANTS IN PART** both motions to dismiss. (Dkt. 29; Dkt. 30.) The  
22 Amended Complaint alleges viable claims against Ra, Irwin, and Jackson  
23 under Section 10(b) and against Irwin and Jackson under Section 20, though,  
24 so the motions are **DENIED IN PART** as to those claims.

## 25 **BACKGROUND**

26 The Court summarizes the Amended Complaint's allegations as follows.  
27 Ra's sole business is manufacturing and selling the DABRA system, which the  
28 FDA approved for use in ablating a channel in occlusive peripheral vascular

1 disease, a form of peripheral artery disease. That sort of procedure is  
2 commonly known as an atherectomy, but the FDA considers “atherectomy” to  
3 encompass a wider range of procedures. Accordingly, the DABRA system’s  
4 approval for channel ablation in occlusive peripheral vascular disease not not  
5 translate to approval for use in atherectomies. (See *id.* ¶ 99.) Irwin, Ra’s co-  
6 founder, served as its CEO, Chief Technology Officer, Co-President, and  
7 Board Chairman until August 12, 2019. Melissa Burstein, Irwin’s wife, is Ra’s  
8 other co-founder and served as an Executive Vice President and director until  
9 March 2019, then solely as Vice President from April 2019 through November  
10 1, 2019. Martin Burstein, Jackson, Heymann, Buchbinder, Colombatto, Mejia,  
11 Saad, and Enquist are each directors of Ra.

12 Ra initiated a device recall in February 2018. It explained to the FDA,  
13 “Lasers/Catheters did not calibrate during set-up prior to use.” (Dkt. 29-23  
14 at 1.) Ra stated that it addressed the issue by sending service technicians to  
15 customer facilities to service affected lasers beginning on February 15, 2018.

16 Five months later, on July 16, 2018, Ra filed an S-1 Registration  
17 Statement with the SEC in preparation for its initial public offering. It made its  
18 final amendment to that Statement on September 24, 2018. Ra then went  
19 public on September 27, 2018, at a price of \$17.00 per share. Derr purchased  
20 500 shares of Ra stock at \$7.30 on February 6, 2019. Beginning on  
21 February 8, 2019, Shoemaker purchased 615 shares of Ra stock in February  
22 2019, paying between \$6.93 and \$7.28 per share.<sup>1</sup>

23 In August 2019, Ra made a series of announcements that had a  
24 deleterious effect on its stock price. It announced that it had terminated Irwin  
25 and that its Audit Committee was investigating allegations made in an  
26 anonymous complaint. (Dkt. 21 ¶ 133.) It announced, too, that “[i]n the fourth

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27 <sup>1</sup> Shoemaker purchased another 150 shares in November 2019, after joining  
28 this lawsuit, at \$1.53 per share.

1 quarter of 2018 and first quarter of 2019, [it] experienced inconsistencies in its  
2 DABRA catheter manufacturing process.” (*Id.* ¶ 133.) Following equipment  
3 upgrades and process modifications, it stated that it believed the problem had  
4 been solved, but “[t]he percentage of catheters that fail to calibrate at customer  
5 sites . . . began to increase after decreasing during April and May 2019.” (*Id.*)

6 Ra reported in September 2019 that it had initiated a voluntary recall of  
7 the catheters in the DABRA system “due to a change in product labeling.” (*Id.*  
8 ¶ 141.) The catheters, which had been labeled with expiration dates twelve  
9 months after manufacturing, were now being labeled with a two-month  
10 expiration period. (*Id.*)

11 A month after that, on October 31, 2019, the Audit Committee issued a  
12 report. It found that: (1) the DABRA system frequently failed to calibrate and  
13 occasionally overheated; (2) Ra’s explanations regarding fourth quarter 2018  
14 and first quarter 2019 sales “created a risk of confusion” because they didn’t  
15 explicitly disclose these issues; (3) Ra had failed to make timely Medical  
16 Device Reports concerning issues with the DABRA system to the FDA; (4) Ra  
17 had “engaged in systematic efforts to replace product held by customers,” but  
18 failed to document these efforts as a recall; (5) Ra had failed to properly  
19 document “certain payments to physicians,” including \$300,000 paid to three  
20 individuals; and (6) Ra had instructed its salespeople to “characterize DABRA  
21 as performing atherectomy and to encourage doctors to seek reimbursement  
22 using atherectomy codes.” (*Id.* ¶ 144.) That failure to document payments to  
23 physicians was subsequently revealed to arise from a series of deficiencies in  
24 its internal controls aggregating to a material weakness. (*Id.* ¶ 151.)

### 25 **STANDARD OF REVIEW**

26 A Rule 12(b)(6) motion to dismiss is a preliminary evaluation of a party’s  
27 pleading, intended to “test[] the legal sufficiency of [the] claim.” *Navarro v.*  
28 *Block*, 250 F.3d 729, 732 (9th Cir. 2001). Parties don’t need to prove their

1 claims at such an early stage, only state them sufficiently. *See, e.g., Bell*  
2 *Atlantic Corp. v. Twombly*, 550 U.S. 544, 563 n. 8 (complaint “may not be  
3 dismissed based on . . . assessment that the plaintiff will fail to . . . prove his  
4 claim”).

5 A Rule 12(b)(6) motion to dismiss calls for a preliminary evaluation of a  
6 party’s pleading and tests only whether the pleading provides “a short and  
7 plain statement of the claim showing that the pleader is entitled to relief, in  
8 order to give the defendant fair notice of what the claim is and the grounds  
9 upon which it rests.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)  
10 (internal marks and citation omitted). The required short and plain statement  
11 “does not need detailed factual allegations,” only “factual allegations . . .  
12 enough to raise a right to relief above the speculative level . . . on the  
13 assumption that all the allegations in the complaint are true.” *Id.* (internal  
14 marks and citations omitted). The Court must make all reasonable inferences  
15 that can be made in the plaintiff’s favor. *Dahlia v. Rodriguez*, 735 F.3d 1060,  
16 1066 (9th Cir. 2013). Reasonable inferences are those with “plausible  
17 grounds”—the complaint’s factual allegations must “raise a reasonable  
18 expectation that discovery will reveal evidence” supporting that inference.  
19 *Twombly*, 550 U.S. at 556.

20 On the other hand, if the necessary facts are merely *possible* on the  
21 facts alleged, rather than plausible, the complaint fails to state a claim.  
22 *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009) (plausibility standard “asks for  
23 more than a sheer possibility that a defendant has acted unlawfully”).  
24 Competing inferences consistent with the alleged facts can undermine a  
25 claim’s plausibility. But a movant has to offer more than just another version  
26 of events to carry its burden on a motion to dismiss. The proposed alternative  
27 must be “so convincing that plaintiff’s explanation is *implausible*.” *Starr v.*  
28 *Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011) (emphasis in original); *see also*

1 *Iqbal*, 556 U.S. at 681 (allegations don't support inference of unlawful behavior  
2 "given more likely explanations" of facts alleged); *cf. In re Century Aluminum*  
3 *Co. Securities Litig.*, 729 F.3d 1104, 1108 (9th Cir. 2013) (upholding dismissal  
4 where inferential steps to claim were "merely *possible* rather than plausible").  
5 Allegations that "tend to exclude the possibility" of a explanation are enough  
6 to avoid dismissal, even if those allegations can't foreclose such explanations  
7 conclusively. *Id.* Ultimately, a court must "draw on its judicial experience and  
8 common sense" to evaluate whether the inference supporting a claim is  
9 plausible despite the availability of other inferences. *Iqbal*, 556 U.S. at 679;  
10 *see also Starr*, 652 F.3d at 1216.

11 In the securities context, however, plaintiffs must also satisfy the  
12 heightened pleading requirements of the Private Securities Litigation Reform  
13 Act ("PSLRA"). Under the PSLRA, a claim for securities fraud must raise a  
14 "strong inference" of scienter. 15 U.S.C. § 78u-4(b)(2). "[W]hen determining  
15 whether plaintiffs have shown a strong inference of scienter, the court must  
16 consider all reasonable inferences to be drawn from the allegations, including  
17 inferences unfavorable to the plaintiffs." *Gompper v. VISX, Inc.*, 298 F.3d 893,  
18 897 (9th Cir. 2002).

19 The PSLRA also requires that a claim "specify each statement alleged  
20 to have been misleading, the reason or reasons why the statement is  
21 misleading, and, if an allegation regarding the statement or omission is made  
22 on information and belief, the complaint shall state with particularity all facts  
23 on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). "By requiring  
24 specificity, § 78u-4(b)(1) prevents a plaintiff from skirting dismissal by filing a  
25 complaint laden with vague allegations of deception unaccompanied by a  
26 particularized explanation stating why the defendant's alleged statements or  
27 omissions are deceitful." *Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540  
28 F.3d 1049, 1061 (9th Cir. 2008).

## DISCUSSION

### I. Judicial Notice and Incorporation by Reference

Because Rule 12(b)(6) focuses on whether the challenged pleading fails to state a claim, courts generally can't consider materials outside the pleadings. See *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (2018). This is less restrictive than it sounds—the pleading's contents incorporate materials not explicitly quoted or attached by reference, so long as the materials' authenticity is not contested and the pleading "necessarily relies" on them. *Parrino v. FHP, Inc.*, 146 F.3d 699, 706 (9th Cir. 1998), *superseded by statute on other grounds as stated in Abrego Abrego v. Dow Chemical Co.*, 443 F.3d 676, 681 (9th Cir. 2006). Courts may consider, too, matters susceptible to judicial notice. *Khoja*, 899 F.3d at 998.

The Ninth Circuit has cautioned, though, that "[t]he overuse and improper application of judicial notice and the incorporation-by-reference doctrine . . . can lead to unintended and harmful results," particularly in the securities fraud context, "where there is already a heightened pleading standard, and the defendants possess materials to which the plaintiffs do not yet have access." *Id.* 998. The Court thus must take care to avoid taking notice of disputed facts contained in public records, even if the existence and contents of those records aren't subject to reasonable dispute. *Id.* at 999.

Between the two motions to dismiss, Defendants ask the Court to take judicial notice of 25 documents. Irwin, Melissa Burstein, and Martin Burstein, who propound 22 of these, refer to only 11 of them in their brief. Because the remaining 11 aren't used to support any briefed argument, the Court **DENIES** the request to take judicial notice of those documents.

Of the 11 that Irwin and the Bursteins reference, Plaintiffs oppose judicial notice of eight: Exhibits I, J, K, L, Q, R, S, and T. Exhibits I, J, K, L, and Q are Statements of Changes in Beneficial Ownership filed with the SEC. These

1 documents run afoul of *Khoja*'s warning against taking notice of disputed facts  
2 contained in judicially noticeable documents. While the Court could take  
3 judicial notice that, by these documents, Irwin represented to the SEC that his  
4 stock sales were "mandated by [his] award agreement," the fact of that  
5 representation isn't relevant to the motion to dismiss. (See, e.g., Dkt. 29-12 at  
6 2.) The Court can't accept as uncontroverted fact the contents of Irwin's  
7 representations, see *Khoja*, 899 F.3d at 999, so the Request for Judicial  
8 Notice as to these documents is **DENIED**.

9 Exhibits R and S provide definitions of "atherectomy," but these  
10 definitions aren't relevant. The Amended Complaint alleges that the FDA has  
11 approved DABRA for "ablating a channel in occlusive peripheral vascular  
12 disease," but not for "atherectomy," and that the FDA has insisted on enforcing  
13 the distinction between the two indications. (See, e.g., Dkt. 21 ¶¶ 4, 11, 73,  
14 169-70.) It alleges, too, that "the FDA definition of atherectomy [is] narrower  
15 than the colloquial one." These exhibits provide only that colloquial definition,  
16 and to the extent that the Individual Defendants argue that the FDA is drawing  
17 a distinction without a difference, that argument is irrelevant to claims that the  
18 Defendants violated the FDA's regulations using the FDA's definitions. The  
19 Request for Judicial Notice as to Exhibits R and S is **DENIED**.

20 Exhibit T purports to be a recall notice available through an FDA website,  
21 <https://www.accessdata.fda.gov>. Plaintiffs contend that, because it isn't an  
22 SEC filing, Defendants haven't shown that it's a public record that is "generally  
23 known" or "can be accurately and readily determined from [a] source[] whose  
24 accuracy cannot reasonably be questioned." (Dkt. 36, quoting Fed. R. Evid.  
25 201.) But there are many sources whose accuracy can't reasonably be  
26 questioned, and if the SEC is one (it is), then the FDA is, too. Accordingly, the  
27 Request for Judicial Notice as to Exhibit T is **GRANTED IN PART**—the Court  
28 takes judicial notice of its existence and contents, but not the truth of the



1 assertions therein.

2 The Ra Defendants seek judicial notice of their Exhibits 1, 4, and 5.  
3 Plaintiffs oppose as to Exhibits 4 and 5, which are Statements of Changes in  
4 Beneficial Ownership filed with the SEC. The Ra Defendants ask the Court to  
5 accept the representations in those documents as true, but as discussed with  
6 respect to Exhibits I, J, K, L, and Q, the Court can't do that. (Dkt. 30 at 32.)  
7 The Ra Defendants' Request for Judicial Notice is **DENIED** as to Exhibits 4  
8 and 5.

9 The Requests for Judicial Notice as to the remaining documents—  
10 Individual Defendants' Exhibits A, U, and V and Ra Defendants' Exhibit 1—  
11 are **GRANTED**.

12 **II. Plaintiffs Allege False or Misleading Statements under Sections**  
13 **10(b) and 20(a).**

14 The basic elements of a Section 10(b) claim are: (1) a material  
15 misrepresentation or omission; (2) made with scienter; (3) in connection with  
16 the purchase or sale of a security; (4) inducing reliance by plaintiffs; (5)  
17 plaintiffs' economic loss; and (6) a causal nexus between the  
18 misrepresentation or omission and the loss. *Dura Pharms. v. Broudo*, 544 U.S.  
19 336, 341-42 (2005). "Section 20(a) extends liability for violations of other  
20 provisions of the 1934 Act, including § 10(b), to certain so-called 'controlling  
21 persons,'" *Desai v. Deutsche Bank Sec. Ltd.*, 573 F.3d 931, 938 (9th Cir.  
22 2009). In other words, without liability under Section 10(b), there can be no  
23 liability under Sections 20(a).

24 Plaintiffs assert the Section 10(b) and 20(a) claims against Ra, Irwin,  
25 and Jackson only. Those Defendants challenge the existence of an actionable  
26 false or misleading statement, but they don't contest materiality, reliance, or  
27 economic loss.

28 The SEC has promulgated Rule 10b-5 to implement Section 10(b)—that

1 rule makes it “unlawful to . . . make any untrue statement of a material fact or  
2 to omit to state a material fact necessary in order to make the statements  
3 made, in light of the circumstances under which they were made, not  
4 misleading.” *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37 (2011).  
5 “Silence, absent a duty to disclose, is not misleading under Rule 10b-5.” *Basic*  
6 *Inc. v. Levinson*, 485 U.S. 224, 239 n.17 (1988). And, as discussed above, a  
7 plaintiff must identify with specificity each false or misleading statement and  
8 explain why it is false or misleading—it’s not enough to “fil[e] a complaint laden  
9 with vague allegations of deception unaccompanied by a particularized  
10 explanation stating why the defendant’s alleged statements or omissions are  
11 deceitful.” *Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049,  
12 1061 (9th Cir. 2008); 15 U.S.C. § 78u-4(b)(1).

13 “Rule 10b-5 prohibits only misleading and untrue statements, not  
14 statements that are incomplete. Often, a statement will not mislead even if it  
15 is incomplete or does not include all relevant facts.” *In re Cutera Securities*  
16 *Litig.*, 610 F.3d 1103, 1109 (9th Cir. 2010). Statements are misleading only if  
17 they “would give a reasonable investor the impression of a state of affairs that  
18 differs in a material way from the one that actually exists.” *Id.*, quoting *Berson*  
19 *v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985 (9th Cir. 2010).

20 Plaintiffs here allege a plethora of information that they contend Ra,  
21 Irwin, and Jackson should have disclosed. They don’t identify any statement  
22 that was actually false, though, and they plausibly allege that only one  
23 category of statements was rendered misleading by the missing information.

#### 24 A. Risk Factors Are Actionable under Section 10(b)

25 Plaintiffs seek to establish Section 10(b) liability first by pointing to Ra’s  
26 identification of risk factors in connection with its Registration Statement.  
27 Hoping to take these bases for liability out in one fell swoop, Ra, Irwin, and  
28 Jackson argue that a reasonable investor couldn’t read a disclosure of a risk

1 as an assurance that the risk hasn't already materialized. But the Ninth Circuit  
2 has held Section 10(b) liability can be premised on a risk disclosure that fails  
3 to "alert[] the reader that some of [the disclosed] risks may already have come  
4 to fruition." *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1181 (2009),  
5 *aff'd*, 563 U.S. 27 (2011); *cf. also In re Apple Computer Sec. Litig.*, 886 F.2d  
6 1109, 1115 (9th Cir. 1989) (investors put on notice of generic risks of doing  
7 business aren't put on notice, too, of risks that have matured into problems).

8 *B. The Amended Complaint Sufficiently Alleges False or Misleading*  
9 *Statements*

10 Plaintiffs first contend that Ra, Irwin, and Jackson should have disclosed  
11 the DABRA system's calibration issues. In its Registration Statement, Ra  
12 disclosed risks of "*unforeseen* situations in the manufacturing and assembly  
13 of [Ra's] products" and "a voluntary product recall by [Ra] that *could occur*  
14 because of, for example, component failures, device malfunctions . . . or  
15 quality-related issues such as manufacturing errors or design or labeling  
16 defects." (Dkt. 21 ¶¶ 242, 244 (emphasis added).) It also stated in March 2019  
17 that "production limitations in [Ra's] manufacturing process" negatively  
18 impacted its fourth quarter 2018 revenue "as [Ra] scaled up catheter  
19 production." (Dkt. 21 ¶ 120.) Both sets of statements may have been  
20 technically true, but both would mislead a reasonable investor.

21 As to the Registration Statement risk disclosures, Ra allegedly knew of  
22 the DABRA system's calibration issues and conducted a recall from February  
23 2018 through August 2019, a period encompassing the issuance of the  
24 Registration Statement and the IPO. Disclosing "unforeseen" manufacturing  
25 issues and the risk that a recall "could occur" is misleading when failing to  
26 mention that manufacturing issues had arisen and a recall was already  
27 underway. *Siracusano*, 585 F.3d at 1181.

28 The March 2019 statements suggest to a reasonable investor that Ra

1 simply couldn't keep up with demand "as [it] scaled up catheter production."  
2 (Dkt. 21 ¶ 120.) In fact, the "production limitations" weren't just limiting the  
3 number of catheters Ra could produce—the catheters Ra did produce were  
4 defective, too. And the defect in question wasn't a temporary setback,  
5 affecting only a single quarter's results, that could be remedied by increasing  
6 capacity—the catheters' failure to calibrate had persisted for over a year. (*Id.*  
7 ¶ 125 (Ra stated in March 2019 in connection with "production limitations" that  
8 "[it had] only recently begun manufacturing at scale").)

9 Ra, Irwin, and Jackson argue that the statements regarding the  
10 calibration problems merely reflect an evolving understanding of the issue.  
11 (Dkt. 29 at 20; Dkt. 30 at 26.) But Plaintiffs plausibly allege that Ra was aware  
12 of the calibration issue in February 2018 and understood the issue to be the  
13 same one that caused problems through March 2019, while Ra's statements  
14 to investors in March 2019 suggested that the problem dated only to the fourth  
15 quarter of 2018 and was a question of production capacity, rather than a  
16 product flaw that Ra had been trying but failing to solve for over a year. (See  
17 Dkt. 23-3 (recall began in February 2018); Dkt. 21 ¶ 144 (March 2019  
18 statements "created a risk of confusion" because they failed to reference  
19 "DABRA catheter['s] frequent[] fail[ure] to calibrate").) Whether Ra, Irwin, and  
20 Jackson learned more about the issue over time, they failed to disclose it as it  
21 turned into a persistent one, obscuring it instead behind vague risk warnings  
22 and insinuations that "production issues" were merely a question of insufficient  
23 capacity to meet demand. These statements would mislead a reasonable  
24 investor as to the nature and severity of the DABRA system's problems and  
25 Ra's overall business outlook.

26 The remaining theories, though, don't manage to identify any misleading  
27 statements. Plaintiffs contend that Ra's statements that its strategy "include[d]  
28 continuing to hire experienced medical device sales personnel," (*Id.* ¶ 224),

1 and that some representatives “[were] hitting the ground right away,” (*id.* ¶  
2 226), were misleading because Ra failed to mention that its sales training  
3 program was inadequate. But Plaintiffs don’t explain how a reasonable  
4 investor would infer from these strategy statements that Ra’s sales training  
5 programs were of any particular quality. Nor would a reasonable investor have  
6 relied on such an inference—even an explicit statement that Ra believed it  
7 had adequate training programs would have been a non-actionable statement  
8 of optimism. See *Cutera*, 610 F.3d at 1111.

9 Ra’s omission that it was marketing DABRA systems for the non-  
10 indicated use of atherectomy didn’t render any statement misleading, either.  
11 To the contrary, a reasonable investor would infer from Ra’s statements that  
12 it believed it could legally encourage physicians to use the DABRA system for  
13 atherectomy without marketing DABRA for that purpose. In Ra’s November  
14 2018 10-Q, it stated “the FDA or other regulatory agencies . . . could . . .  
15 conclude that we have engaged in off-label promotion . . . [but] we believe that  
16 we can promote the device [for atherectomy] using the truthful and not  
17 misleading information.” (Dkt. 21 ¶ 240.) And in its 2018 10-K, filed in March  
18 2019, Ra stated that it “received correspondence from a competitor claiming  
19 [its] promotion for DABRA as an atherectomy tool . . . is off-label promotion,”  
20 but it “disagree[d] . . . and believe[d] FDA’s regulations and judicial case law  
21 allow companies to engage in certain forms of truthful, non-misleading and  
22 non-promotional speech concerning the of-label use of products, and we  
23 believe that we comply with these restrictions.” (*Id.* ¶ 290.) A reasonable  
24 investor would have understood from this statement that Ra was encouraging  
25 physicians to use DABRA for atherectomy and risking regulatory scrutiny as a  
26 result.

27 Lastly, Plaintiffs contend that Irwin and Jackson’s Sarbanes-Oxley  
28 (“SOX”) Certifications were misleading for failure to disclose deficiencies in

1 internal controls. But those certifications attest, in relevant part, only that the  
2 certifier has evaluated Ra’s disclosure controls and procedures and presented  
3 his conclusions. (*Id.* ¶¶ 252, 254.) Notably absent is an unqualified certification  
4 that the controls and procedures are effective. Just as notable is the absence  
5 from the Amended Complaint of any allegation that Irwin and Jackson were  
6 aware of a material weakness in Ra’s controls and procedures at the time of  
7 the SOX certifications. Under these circumstances, the SOX Certifications  
8 can’t form a basis for Section 10(b) liability. See *Wanca v. Super Micro*  
9 *Computer, Inc.*, No. 5:15-cv-4049-EJD, 2018 WL 3145649 (N.D. Cal. Jun. 27,  
10 2018) (no 10(b) liability for SOX certification where plaintiff failed to allege why  
11 certification “[b]ased on [declarant’s] knowledge” was false).

### 12 C. *Scienter*

13 Under the PSLRA, a claim for securities fraud must raise a “strong  
14 inference” of scienter. 15 U.S.C. § 78u-4(b)(2). Scienter is the “mental state  
15 embracing intent to deceive, manipulate, or defraud.” *Tellabs, Inc. v. Makor*  
16 *Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007). “The inference that the  
17 defendant acted with scienter need not be irrefutable, . . . or even the most  
18 plausible of competing inferences.” *Id.* To avoid dismissal, the plaintiff must  
19 allege enough facts that “a reasonable person would deem the inference of  
20 scienter cogent and at least as compelling as any opposing inference one  
21 could draw from the facts alleged.” *Id.* The requirement to allege specific facts  
22 is stringent—courts require, for example, that allegations based on witness  
23 statements that an executive referenced or had access to a report also “detail  
24 the actual contents of [those] reports.” *Police Retirement System of St. Louis*  
25 *v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1063 (9th Cir. 2014). Nevertheless,  
26 in “rare circumstances where the nature of the relevant fact is of such  
27 prominence that it would be ‘absurd’ to suggest that management was without  
28 knowledge of the matter,” a plaintiff may rely on inference rather than

1 particularized allegations. *South Ferry LP, No. 2 v. Killinger*, 542 F.3d 776,  
2 786 (9th Cir. 2008).

3 The Amended Complaint establishes such circumstances as to Ra and  
4 Irwin. Irwin was, among other roles, CEO, Chairman of the Board of Directors,  
5 and (most critically) Chief Technology Officer of Ra, a 118-employee company  
6 that sold two products. (Dkt. 21 ¶¶ 34, 63, 359.) Jackson was the company's  
7 Chief Financial Officer. (*Id.* ¶ 35.) One of Ra's two products, the DABRA  
8 system, began experiencing calibration issues necessitating initiation of a  
9 voluntary recall shortly before the company's IPO, and Ra submitted a recall  
10 notice to the FDA identifying Irwin as the contact person for information on the  
11 recall. (Dkt. 21 ¶¶ 91, 183; Dkt. 29-23.) It's unclear whether these issues would  
12 be of greater interest to Ra's CFO, CEO, and Board Chairman or to its Chief  
13 Technology Officer and point person for recall inquiries, but it would be absurd  
14 to suggest that any of those officers was ignorant of the situation. Between  
15 them, Irwin and Jackson held all five roles, and so the Amended Complaint's  
16 allegations establish a strong inference that they possessed the required  
17 mental state for a Section 10(b) violation.<sup>2</sup>

18 Ra, Irwin, and Jackson argue that the Court shouldn't infer scienter  
19 because Ra and its Board investigated and disclosed the issues, behavior  
20 "inconsistent with an intent to deceive." (Dkt. 29-1 at 23, quoting *In re PETCO*  
21 *Corp. Sec. Litig.*, No. 05-CV-0823 H(RBB), 2008 WL 8876554, at \*6 (S.D. Cal.  
22 Apr. 29, 2008); Dkt. 30 at 30 (same)). But the court in *PETCO* used this

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23  
24 <sup>2</sup> Defendants contend that the Court can't rely on stock sales by Irwin, Melissa  
25 Burstein, and Jackson nor on Plaintiffs' confidential witnesses to establish  
26 scienter. Because the Court doesn't rely on any of these, it need not reach  
27 these questions, but it notes that nothing properly considered on a motion to  
28 dismiss establishes that the stock sales were non-voluntary. See *infra*,  
Section I (improper to take judicial notice of Irwin and Jackson's statements to  
the SEC regarding the nature of their sales).

1 rationale not to wash the company's hands of all its officers' scienter, but to  
2 separate culpable officers from innocent ones on a motion for summary  
3 judgment. See *PETCO*, 2008 WL 8876554, at \*6. The court then followed  
4 Ninth Circuit precedent concluding that the company would be assigned the  
5 scienter of any corporate officer who "made or substantially contributed to the  
6 drafting of a false statement." *Id.*

7 Irwin wasn't part of the investigation, having been terminated as the  
8 investigation was beginning, and Plaintiffs don't allege any particular role for  
9 Jackson in the Audit Committee's investigation. Absent such allegations, the  
10 Court can't find that the investigation is inconsistent with either one's alleged  
11 intent to deceive. And since the Amended Complaint alleges that Ra's  
12 misleading statements were made or substantially contributed to by both Irwin  
13 and Jackson, their scienter can be ascribed to Ra. (See, e.g., Dkt. 21 ¶ 234  
14 (3Q18 10-Q containing misleading statements was signed by Irwin and  
15 Jackson); *id.* ¶ 120 (Irwin made statements regarding "production limitations .  
16 . . as we scaled up catheter production" in press release issued on Ra's  
17 behalf).)

#### 18 *D. Section 20(a)*

19 Irwin and Jackson argue only that "control person" liability is  
20 inappropriate because Plaintiffs fail to allege any primary violation of  
21 Section 15(b). (Dkt. 29-1 at 25; Dkt. 30 at 14.) Plaintiffs do allege a primary  
22 violation of Section 15(b), though, so their Section 20(a) claim survives, too.

### 23 **III. Plaintiffs Fail to Allege Standing Under Sections 11 and 15.**

24 Section 11 "provides a cause of action to any person who buys a security  
25 issued under a materially false or misleading registration statement." *In re*  
26 *Century Aluminum Co. Securities Litigation*, 729 F.3d 1104, 1106 (9th Cir.  
27 2013). And unlike Section 10(b), a claim under Section 11 doesn't require  
28 either a false statement or a statement rendered misleading by the omission



1 of material information. See *Steckman v. Hart Brewing Co.*, 143 F.3d 1293,  
2 1296 (9th Cir. 1998). The “false or misleading statement” prong element can  
3 be met by the omission of a material fact required to be stated in the  
4 registration statement. *Id.* But plaintiffs face a different hurdle: a plaintiff  
5 pleading a claim under Section 11 must allege “that the shares they purchased  
6 came from the pool of shares issued” in connection with the registration  
7 statement at issue.

8 In some instances, clearing this bar is simple: where the only shares in  
9 the market are those issued in connection with the registration statement,  
10 plaintiffs can satisfy their burden of pleading standing by alleging that fact.  
11 *Century Aluminum*, 729 F.3d at 1106. “[I]n such a situation, “by definition *all*  
12 of the company’s shares will be directly traceable to the offering in question.”  
13 *Id.* at 1107. But this won’t suffice if there are shares in the market that weren’t  
14 issued in connection with the registration statement. *Id.* In that situation,  
15 plaintiffs must trace the chain of title for their shares to the challenged offering.

16 In their briefing, Plaintiffs contend that “all of [Ra]’s publicly traded  
17 shares were issued in the IPO.” (Dkt. 35 at 10.) Defendants disagree, but  
18 make the more salient point, too: Plaintiffs don’t *allege* that all of Ra’s shares  
19 were issued under the Registration Statement, they simply assert it in their  
20 briefing. And they allege no other facts in support of the conclusory allegations  
21 that Derr and Shoemaker purchased their shares “pursuant and/or traceable  
22 to the Registration Statement in connection with the Company’s IPO.” (Dkt. 21  
23 ¶¶ 31-32.)

24 Plaintiffs protest that Defendants don’t show that other shares were  
25 actually sold. But whether Defendants offer something persuasive in place of  
26 missing allegations is beside the point. Plaintiffs bear the burden of pleading  
27 facts supporting the inference of standing, and they haven’t carried that  
28 burden. See *Century Aluminum*, 729 F.3d at 1107. Without factual allegations

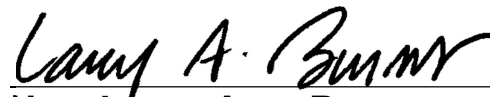
1 to support an inference that their shares can be traced to the IPO, Plaintiffs  
2 can't maintain a claim under Section 11. And without an adequately alleged  
3 Section 11 claim, they can't state a claim under Section 15, either. *See Rigel*  
4 *Pharmaceuticals, Inc. Securities Litig.*, 697 F.3d 869, 886 (2012); 15 U.S.C.  
5 § 78t(a).

6 **CONCLUSION**

7 Defendants Motions to Dismiss are **GRANTED IN PART**. Plaintiffs'  
8 claims under Sections 11 and 15 of the Exchange Act are **DISMISSED**  
9 **WITHOUT PREJUDICE**. The Motions are **DENIED IN PART** as to Plaintiffs'  
10 claims under Exchange Act Sections 10(b) and 20(a).

11 **IT IS SO ORDERED.**

12 Dated: March 24, 2021



13 **HON. LARRY ALAN BURNS**  
14 United States District Judge