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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

IN RE ATOSSA GENETICS, INC.)
SECURITIES LITIGATION) CASE NO. C13-1836 RSM
) ORDER GRANTING DEFENDANTS'
) MOTIONS TO DISMISS
_____)

I. INTRODUCTION

This matter comes before the Court on the Atossa and Individual Defendants' (collectively "Atossa Defendants") Motion to Dismiss under Federal Rule of Civil Procedure 12(b)(6), and the Underwriter Defendants' Motion to Dismiss also under Rule 12(b)(6). (Dkts. #38 and #41).¹ In their motions, Defendants argue that Plaintiffs' Amended Complaint should be dismissed because it fails to adequately allege facts against any of the Defendants sufficient to support the alleged causes of action, and that Plaintiffs lack standing to bring certain of their claims. They further argue that Plaintiffs fail to plead facts sufficient to meet the heightened pleading standards for fraud actions. Plaintiffs oppose the motions, setting forth alleged facts that they believe are sufficient to support their claims (Dkt. #49). Plaintiffs also argue that the standing question is premature and requires further discovery before this Court should address

¹ The Court also considers Defendants' requests for Judicial Notice of certain documents, and the Underwriter Defendants' Motion to Strike, as well as Plaintiffs' untimely Request for Judicial Notice. Dkts. #40, #41 at 7-11, #57 and #60.

1 it. For the reasons set forth below, the Court GRANTS Defendants’ motions, but provides
2 Plaintiffs with the opportunity to amend their complaint.

3 II. BACKGROUND

4 This is a proposed federal securities class action suit brought against Atossa Genetics,
5 Inc. (“Atossa”), several of its officers and directors, and the underwriters for Atossa’s
6 November 8, 2012, initial public offering (“IPO”). The Amended Complaint (“AC”) alleges
7 that various Defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of
8 1934 (“1934 Act”) and Rule 10b-5 promulgated by the Securities and Exchange Commission,
9 and Sections 11 and 15 of the Securities Exchange Act of 1933 (“1933 Act”). Dkt. #28. The
10 1933 Act claims allege that Defendants made materially untrue statements in the Registration
11 Statement and Prospectus used in connection with the IPO. The 1934 Act claims are based on
12 alleged materially false and misleading statements made by Atossa and the named officers and
13 directors in press releases, interviews, quarterly statements and other documents following the
14 IPO, between November 8, 2012, and October 4, 2013 (the “Class Period”). Dkt. #28 at ¶¶
15 144-173.

16 Atossa is a healthcare company located in Seattle, WA, focused on improving breast
17 health through the development of a suite of medical device products and Laboratory
18 Developed Test (“LDT”) services. Dkt. #28 at ¶¶ 3 and 25. During the relevant time period,
19 Atossa’s primary medical device product was the Mammary Aspirate Specimen Cytology Test
20 (“MASCT”) System, which consisted of a reusable breast pump and sample collection kit. *Id.*
21 at ¶ 4. The MASCT System uses negative pressure to aspirate and collect nipple aspirate fluid
22 (“NAF”) from breast milk ducts for cytological testing. *Id.* During the relevant time period,
23 Atossa used the ForeCYTE Breast Health test, which was conducted by its wholly-owned
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1 subsidiary The National Reference Laboratory for Breast Health (“NRLBH”), to perform
2 cytological analysis on NAF specimens, the results of which were then provided to treating
3 physicians to assist with breast health assessments. Dkt. #39, Ex. 1 at 9 and 13.

4 In 2003, prior to the date that Atossa acquired it, the MASCT System received pre-
5 market clearance from the FDA pursuant to a 510(k) clearance process. Dkt. #28 at ¶ 47. Once
6 a device has been cleared through the 510(k) process, a manufacturer may make minor changes
7 to the device without submitting a new 510(k). However, a new 510(k) is required if the device
8 is significantly changed or modified in design, components, method of manufacture, or
9 intended use. Dkt. #39, Ex. 1 at 28, Ex. 2 at 31 and Ex. 3 at 44.
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11 Prior to Atossa’s Initial Public Offering (“IPO”), Atossa made changes to the MASCT
12 System’s Instructions for Use. Dkt. #28 at ¶¶ 51 and 83. Atossa determined that this was a
13 minor change that did not require a new 510(k), and therefore did not submit one to the FDA.
14

15 In July 2012, an FDA inspector conducted an inspection at Atossa and issued a Form
16 483 inspection report. Dkt. #28 at ¶ 10 and Dkt. #39, Ex. 20. The form noted ten
17 “observations,” including one pertaining to design change procedures. Dkt. #39, Ex. 20.
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19 On November 8, 2012, Atossa conducted an IPO of 800,000 shares, raising
20 approximately \$3.1 million. Dkt. #28 at ¶ 69. In connection with the IPO, Atossa filed a
21 Registration Statement with the Securities Exchange Commission (“SEC”), and issued a
22 Prospectus. Dkt. #39, Exs. 1 and 13 and Dkt. #47, Ex. 11. The offering was a “firm
23 commitment” offering, meaning that neither Atossa nor its directors and officers sold any stock
24 to the public. Instead, all shares were sold to the offering underwriters, who in turn sold the
25 shares to the public. Dkt. #39, Ex. 13 at 118.
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1 On February 21, 2013, Atossa received a warning letter from the FDA, which
2 referenced the observations made by the inspector in July of 2012. Dkt. #28 at ¶ 83. The FDA
3 also posted the letter on its website. *Id.* On February 25, 2013, Atossa issued a press release
4 announcing that it had received the letter. Dkt. #28 at ¶ 83. On March 12, 2013, Atossa
5 responded to the letter. Atossa informed the FDA that it would submit a new 510(k) for the
6 MASCT System, and asked the FDA to post its response letter on its website. Dkt. #39, Ex. 17.

8 On October 4, 2013, Atossa announced a voluntary recall of the MASCT System device
9 and the ForeCYTE test. Dkt. #28 at ¶ 128. In response, Atossa shares declined \$2.47 per
10 share, approximately 46%, to close at \$2.85 per share on October 7, 2013. Atossa has
11 suspended all sales of the MASCT and ForeCYTE test and has generated no revenue since
12 production was suspended. Dkt. #28 at ¶ 135. Shares are currently selling at approximately
13 \$1.70.
14

15 III. DISCUSSION

16 A. Standard of Review for Securities Fraud Cases

17 In reviewing a motion to dismiss a case involving securities fraud allegations, this Court
18 must engage in a three-part analysis. First, on a motion to dismiss for failure to state a claim
19 under Federal Rule of Civil Procedure 12(b)(6), all allegations of material fact must be
20 accepted as true and construed in the light most favorable to the nonmoving party. *Cahill v.*
21 *Liberty Mut. Ins. Co.*, 80 F.3d 336, 337-38 (9th Cir. 1996). However, the court is not required
22 to accept as true a “legal conclusion couched as a factual allegation.” *Ashcroft v. Iqbal*, 556
23 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). The
24 Complaint “must contain sufficient factual matter, accepted as true, to state a claim to relief
25 that is plausible on its face.” *Id.* at 678. This requirement is met when the plaintiff “pleads
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1 factual content that allows the court to draw the reasonable inference that the defendant is liable
2 for the misconduct alleged.” *Id.* Absent facial plausibility, Plaintiffs’ claims must be
3 dismissed. *Twombly*, 550 U.S. at 570.

4 Second, when a complaint alleges violations under Section 10(b) of the 1934 Act and
5 Rule 10b-5, the Court must examine the pleadings for compliance with the particularized
6 pleading requirement found in Federal Rule of Civil Procedure 9(b). *Zucco Partners, LLC v.*
7 *Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009). The Ninth Circuit has long applied the
8 heightened pleading standard of Rule 9(b) to securities fraud complaints, and therefore requires
9 the element of falsity, or “a material misrepresentation or omission of fact,” to be pled with
10 particularity. *See id.* (citing *Semegen v. Weidner*, 780 F.2d 727, 729, 734-35 (9th Cir. 1985)
11 and *Ronconi v. Larkin*, 253 F.3d 423, 429 n.6 (9th Cir. 2001)).

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14 Third, the Court must examine the pleadings under the Private Securities Litigation
15 Reform Act of 1995 (“PSLRA”). Since 1995, courts have been required to scrutinize securities
16 fraud complaints under the more exacting standards of the PSLRA. The PSLRA amended the
17 Securities Exchange Act to require that a securities fraud complaint “plead with particularity
18 both falsity and scienter.” *Zucco*, 552 F.3d at 990 (quoting *Ronconi*, 253 F.3d at 429). To
19 properly allege falsity, a securities fraud complaint must now “specify each statement alleged
20 to have been misleading, [and] the reason or reasons why the statement is misleading.” 15
21 U.S.C. § 78u-4(b)(1). To the extent that an allegation regarding a statement or omission is
22 made on information and belief, “the complaint shall state with particularity all facts on which
23 that belief is formed.” *Id.* In doing so, the plaintiff must “reveal ‘the sources of [his]
24 information.’” *In re Daou Sys., Inc. Sec. Litig.*, 411 F.3d 1006, 1015 (9th Cir. 2005).
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1 In addition, under the PSLRA, to properly allege scienter the plaintiff must “state with
2 particularity facts giving rise to a strong inference that the defendant acted with the required
3 state of mind.” 15 U.S.C. § 78u-4(b)(2). In other words, the plaintiff must plead with
4 particularity the facts evidencing “the defendant’s intention ‘to deceive, manipulate, or
5 defraud.’” *Tellabs*, 551 U.S. at 313 (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194,
6 96 S. Ct. 1375, 47 L. Ed. 2d 668 (1976)). To satisfy the PLSRA’s rigorous pleading standards,
7 the complaint’s scienter allegations must give rise not just to a plausible inference of scienter,
8 but to an inference that is “cogent and at least as compelling as any opposing inference of
9 nonfraudulent intent.” *Id.* at 314; *see also id.* at 324.
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11 This scienter analysis is different from the ordinary Rule 12(b)(6) standard. On a
12 typical 12(b)(6) motion, the Court makes all reasonable inferences in favor of the plaintiff. *See*
13 *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570)). Under the PSLRA, the Court must
14 weigh competing inferences and “only allow the complaint to survive a motion to dismiss if the
15 malicious inference is at least as compelling as any opposing inference.” *Zucco*, 552 F.3d at
16 991.
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18 **B. Judicial Notice**

19 Though this Court limits its Rule 12(b)(6) review to allegations of material fact set forth
20 in the complaint, this Court may also consider documents of which it has taken judicial notice.
21 *See* F.R.E. 201; *Swartz v. KPMG LLP*, 476 F.3d 756, 763 (9th Cir. 2007). Here, both parties
22 ask this Court to take judicial notice of numerous documents. *See* Dkts. #40, #41, #57 and #60.
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24 With respect to the documents requested by the Atossa Defendants, Plaintiffs appear to
25 have objected only to the Form 483 which was issued after the July 2012 FDA inspection. *See*
26 Dkt. #49 at 22 fn. 11. Notably, Plaintiffs rely on this document both in their Amended
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1 Complaint and in their Opposition brief. *See* Dkts. #28 at ¶¶ 10, 58,59 and 83 and #49 at 8-9
2 and fn. 6. Accordingly, the Court will take judicial notice of all of the documents requested by
3 Atossa Defendants at Dkts. #40 and 57. Many of these documents have been incorporated by
4 reference into the Amended Complaint, including the majority of the SEC filings and
5 correspondence from the FDA, or are public record. Moreover, the authenticity of these
6 documents is not in dispute. Likewise, to the extent that they are not duplicative, the Court
7 takes notice of the documents requested by the Underwriter Defendants in Dkts. #41 at 3-4 and
8 #42.
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10 Although Plaintiffs have also submitted a request, asking this Court to consider a press
11 release issued by Atossa on September 23, 2014, the Court finds such request untimely. *See*
12 Dkt. #60. The briefing on the instant motions to dismiss was complete on August 15, 2014.
13 Moreover, the purpose of the press release is not clear given that it was issued outside of the
14 timeframe alleged in the Complaint, and the Court's notice and consideration of the document
15 would not have changed its analysis of the issues in any event.
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17 **C. Standing to Assert Section 11 Claims**

18 As an initial matter, the Court addresses Defendants' arguments with respect to the
19 Plaintiffs' standing to assert Section 11 claims. To have standing to bring a Section 11 claim,
20 Plaintiffs must be able to trace their shares back to an allegedly misleading registration
21 statement. *In re Century Aluminum Co. Secs. Litig.*, 704 F.3d 1119, 1120 (9th Cir. 2013)
22 (citing *Hertzberg v. Dignity Partners, Inc.*, 191 F.3d 1076, 1080 (9th Cir. 1999)). In *Century*
23 *Aluminum*, the Ninth Circuit Court of Appeals outlined two types of situations in which the
24 tracing issue arises, and explained what both situations require of a plaintiff seeking to allege
25 standing.
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1 In the first situation, “all of a company’s shares have been issued in a single offering
2 under the same registration statement.” *Id.* at 1120. In such circumstances, the tracing
3 requirement “generally poses no obstacle.” *Id.* Simply pleading that the plaintiff’s shares “are
4 directly traceable to the offering in question states a claim ‘that is plausible on its face.’” *Id.* at
5 1122 (quoting *Twombly*, 550 U.S. at 570). “No further factual enhancement is needed because
6 by definition all of the company’s shares will be directly traceable to the offering in question.”
7 *Id.* (emphasis in original) (citing *DeMaria v. Andersen*, 318 F.3d 170, 176 (2d Cir. 2003)).

9 The second situation occurs when “a company has issued shares in multiple offerings
10 under more than one registration statement.” *Id.* In such scenarios, “the plaintiff must prove
11 that her shares were issued under the allegedly false or misleading registration statement, rather
12 than some other registration statement.” *Id.* at 1121. “Courts have long noted that tracing
13 shares in this fashion is ‘often impossible,’ because ‘most trading is done through brokers who
14 neither know nor care whether they are getting newly registered or old shares,’ and ‘many
15 brokerage houses do not identify specific shares with particular accounts but instead treat the
16 account as having an undivided interest in the house’s position.’” *Id.* at 1121 (quoting *Barnes*
17 *v. Osofsky*, 373 F.2d 269, 271-72 (2d Cir. 1967)). Under that situation, at the pleading stage, a
18 plaintiff must allege facts from which the court can “reasonably infer that their situation is
19 different.” *Id.* at 1122. The Court may require “a greater level of factual specificity” in the
20 complaint before it may “reasonably infer that shares purchased in the aftermarket are traceable
21 to a particular offering.” *Id.* “Making this determination is ‘a context-specific task that
22 requires the reviewing court to draw on its judicial experience and common sense.’” *Id.*
23 (quoting *Iqbal*, 556 U.S. at 679).

1 In this case, Defendants point out that none of the lead Plaintiffs purchased their shares
2 in 2012, when the IPO issued. Rather, the Lead Plaintiffs purchased their shares in 2013, after
3 over one million unregistered shares came onto the market. *Id.* Further, Defendants argue that
4 the only Plaintiff who bought shares in 2012, Nicholas Cook, did so right after 50,122
5 unregistered shares became available for sale. *Id.* As a result, Defendants argue that the shares
6 came from a polluted pool and cannot be traced back to the initial offering. *Id.* Plaintiffs
7 respond that, despite the unregistered shares entering the market, because Atossa had a single
8 offering with a single registration statement, their allegations are sufficient to support standing
9 at this stage of the litigation. Dkt. #49 at 39. The Court is not persuaded by Plaintiffs.
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11 Indeed, Plaintiffs do not dispute that millions of unregistered shares were available to
12 buy publicly by the time the first Lead Plaintiff purchased shares on May 15, 2013. While it is
13 true that there was only one offering under a Registration Statement, ultimately 93% of the
14 shares available for purchase by the public were not issued through the IPO. *See* Dkt. #38 at
15 17-18. Other federal courts have consistently held that shares bought on the market after
16 unregistered shares have entered the market cannot be traced back to the IPO. *See, e.g., In re*
17 *Initial Public Offering Sec. Litig.*, 227 F.R.D. 65, 117-18 (S.D.N.Y. 2004), *vacated on other*
18 *grounds*, 471 F.3d 24 (2d Cir. 2006); *see also In re Flag Telecom Holdings, Ltd. Sec. Litig.*,
19 245 F.R.D. 147, 173 (S.D.N.Y. 2007).
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22 Therefore, the Court finds, standing alone, Plaintiffs' conclusory allegation that they
23 acquired Altosa shares "traceable to the Company's false and misleading Registration for its
24 IPO" does not allow this Court to draw a reasonable inference about that assertion because it is
25 devoid of factual content. *See* Dkt. #28 at ¶ 136. Accordingly, the Court finds that Plaintiffs
26 lack statutory standing for their Section 11 claims and the claims must be dismissed. As a
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1 result, the Court need not address at this time whether Defendant Guse is an appropriate
2 Defendant on the Section 11 claim against him, nor must the Court address any substantive
3 arguments with respect to the Section 11 claims.

4 **D. Alleged violations of Section 10(b) and Rule 10b-5**

5 The Court now turns to Plaintiffs' alleged violations of Section 10(b) and Rule 10b-5.
6 Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful for "any person . . .
7 [t]o use or employ, in connection with the purchase or sale of any security registered on a
8 national securities exchange . . . any manipulative or deceptive device or contrivance in
9 contravention of such rules and regulations as the Commission may prescribe as necessary or
10 appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). One
11 such rule promulgated under the Act is SEC Rule 10b-5, which provides, *inter alia*, that "[i]t
12 shall be unlawful for any person . . . [t]o engage in any act, practice, or course of business
13 which operates or would operate as a fraud or deceit upon any person, in connection with the
14 purchase or sale of any security." 17 C.F.R. § 240.10b-5(c). To prevail on a Rule 10b-5 claim,
15 a securities fraud plaintiff must prove five elements: "(1) a material misrepresentation or
16 omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4)
17 transaction and loss causation, and (5) economic loss." *Zucco*, 552 F.3d at 990 (quoting *In re*
18 *Daou*, 411 F.3d at 1014).

19 A misrepresentation or omission is material if there is "a substantial likelihood that the
20 disclosure of the omitted fact would have been viewed by the reasonable investor as having
21 significantly altered the 'total mix' of information made available." *Reese v. Malone*, 747 F.3d
22 557, 568 (9th Cir. 2014) (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 231-232, 108 S. Ct. 978,
23 99 L. Ed. 2d 194 (1988)). "Although determining materiality in securities fraud cases should
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1 ordinarily be left to the trier of fact, conclusory allegations of law and unwarranted inferences
2 are insufficient to defeat a motion to dismiss for failure to state a claim.” *In re Cutera Sec.*
3 *Litig.*, 610 F.3d 1103, 1108 (9th Cir. 2010). To plead materiality and falsity, Plaintiffs “must
4 (1) specify each allegedly misleading statement or omission, (2) explain why the statement is
5 misleading, and (3) if the allegation ‘regarding the statement or omission is made on
6 information and belief, the complaint shall state with particularity all facts on which that belief
7 is formed.’” *Id.* at 1109 (quoting 15 U.S.C. § 78u-4(b)(1)(B)).

9 In this case, the Court finds that Plaintiffs have failed to plead materiality or falsity with
10 sufficient particularity. Indeed, to the extent their claims are based on the statements allegedly
11 made in the Registration Statement for the IPO, the statements actually made were not false.
12 *See* Dkt. #28 at ¶¶ 64-77.² Plaintiffs allege that the Form S-1/A contained materially untrue
13 and misleading statements to the effect that the MASCT System and ForeCYTE tests had been
14 FDA-cleared. However, a review of the Form S-1/A reveals that Plaintiffs have
15 mischaracterized the statements. Indeed, while it is true that the Registration Statement did
16 state that the MASCT System had been FDA-cleared, that statement is true. Plaintiffs allege
17 themselves that the device received clearance in 2003. Dkt. #28 at ¶ 47. The Registration
18 Statement accurately stated that the System had been cleared for use as a “sample collection
19 device, with the provision that the fluid collected using the device can be used to determine
20 and/or differentiate of normal versus premalignant versus malignant cells.” *Compare* Dkt. #28
21 at ¶ 47 *with* Dkt. #39, Ex. 1 at 23. The Registration Statement does not state that the
22 ForeCYTE test has been FDA-cleared. Rather, it states that the ForeCYTE test uses the FDA-
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27 ² The Court examined only those statements made in the “effective” Registration Statement –
28 in this case, the Form S-1/A that became effective on November 8, 2012. 15 U.S.C. §77(k)(a).
Thus, the alleged representations made in an earlier S-1 Registration Statement are not at issue.
See Dkt. #28 at ¶¶ 64-66.

1 cleared MASCT System. Dkt. #39, Ex. 1 at 9 and 23. The Registration Statement also does
2 not represent that the ForeCYTE Breast Health test had been FDA-cleared for the screening or
3 diagnosis of breast cancer. Likewise, a review of the Prospectus reveals the same
4 mischaracterizations by Plaintiffs. *See* Dkt. #42, Ex. 11.

5 Similarly, Plaintiffs complain that the press release disclosing the FDA Warning Letter
6 misled the market by downplaying the significance of the Letter. Dkt. #28 at ¶¶ 83-89.
7 However, the press release specifically included language alerting potential investors that the
8 FDA may not agree with Atossa's position and may subject the company to additional
9 regulatory action. Dkt. #39, Ex. 4 at 48.
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11 In addition, in the March 15, 2013, interview Dr. Quay only refers to the MASCT
12 System as having been patented and regulated by the FDA, and differentiates the device from
13 the ForeCYTE test. Dkt. #39, Ex. 24 at 188. Dr. Quay also acknowledges the warning letter
14 from the FDA, and states that Atossa intends to respond and continue to work to clear up any
15 concerns. *Id.* Dr. Quay then looks forward to 2013 and 2014 as years wherein the Company
16 will achieve full FDA clearance. *Id.* at 189.
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18 Further, Plaintiffs allege that Atossa Defendants' continued positive statements even
19 after the FDA warning, and their failure to disclose its newly-submitted (and later withdrawn)
20 510(k) for the MASCT System, deceived investors throughout the class period. These
21 allegations ignore that positive statements and optimism are not misleading in circumstances
22 such as these. *See, e.g., City of Roseville Employees' Ret. Sys. v. Sterling Fin. Corp.*, 2014 U.S.
23 Dist. LEXIS 131628 (E.D. Wash. Sept. 17, 2014); *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1111
24 (9th Cir. 2010) (noting that statements of mere corporate puffery, "vague statements of
25 optimism like 'good,' 'well-regarded,' or other feel good monikers," are not actionable because
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1 “professional investors, and most amateur investors as well, know how to devalue the optimism
2 of corporate executives.”); *Glen Holly Ent., Inc. v. Tektronix, Inc.*, 352 F.3d 367, 379 (9th Cir.
3 2003) (finding no liability where the alleged misstatements “were generalized, vague and
4 unspecific assertions, constituting mere puffery upon which a reasonable consumer could not
5 rely.”). Moreover, “[i]t is clearly insufficient for plaintiffs to say that a later, sobering
6 revelation makes an earlier, cheerier statement a falsehood.” *Yourish v. California Amplifier*,
7 191 F. 3d 983, 997 (9th Cir. 1999); *see also In re Metawave Communs. Corp. Sec. Litig.*, 629
8 F. Supp.2d 1207, 1218 (W.D. Wash. 2009) (“Honest optimism followed by disappointment is
9 not the same as lying or misleading with deliberate recklessness.” (citation omitted)).
10

11 Plaintiffs’ allegations with respect to the Q3 2012 Quarterly Statement and Press
12 Release and Form 10-Q for the Period ending September 30, 2012, are a different matter. Dkt.
13 #28 at ¶¶ 78-80. The December 20, 2012, press release clearly contains statements referring to
14 the “FDA-cleared and marketed product, the ForeCYTE Breast Health Test for breast cancer
15 risk assessment,” as Plaintiffs allege. Dkt. #39, Ex. 31 at 316. The press release further states
16 under its “corporate highlights” that the ForeCYTE Breast Health Test for breast cancer risk
17 assessment is an FDA-cleared product that “launched through a field experience trial.” *Id.*
18 Further, in a February 2013 interview with Defendant Quay, Dr. Quay stated that the
19 ForeCYTE Breast Health Test “is literally a Pap smear for breast cancer.” Dkt. #39, Ex. 23 at
20 180. Dr. Quay went on to say that the test was cleared by the FDA:
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23 **What stage of development is this test currently at?**
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25 It has gone through all of the FDA clearance process, which is a multi-year,
26 multi-million dollar process.

27 Dkt. #39, Ex. 23 at 181 (bold text in original). These statements are not accurate as all parties
28 acknowledge that the ForeCYTE Breast Health test was never FDA-cleared. However, given

1 all of the information available to investors at the time, including the accurate information
2 discussed above, the Court cannot find that these limited statements by Dr. Quay “significantly
3 altered the ‘total mix’ of information made available.” *Reese*, 747 F.3d at 568. For all of these
4 reasons, Plaintiffs have failed to show materiality and falsity with sufficient particularity and
5 the 10(b) claims must be dismissed. Accordingly, the Court will not address the remaining
6 elements of the claims.
7

8 **E. Alleged Violations of Section 15 of the 1933 Act and Section 20(a) of the 1934**
9 **Act**

10 Section 15 of the 1933 Act and Section 20(a) of the 1934 Act, concerning control
11 person liability, both require proof of an underlying primary violation of the securities laws. 15
12 U.S.C. §§ 77o & 78t(a); *see also No. 84 Emp’r-Teamster Joint Council Pension Trust Fund v.*
13 *Am. W. Holding Corp.*, 320 F.3d 920, 945 (9th Cir. 2003). Because the Court has found that
14 Plaintiffs do not adequately allege primary violations under Section 11 and Section 10(b), the
15 Court grants Defendants’ motion to dismiss these claims as well.
16

17 **F. Leave to Amend**

18 Leave to amend must be granted with “extreme liberality” in securities cases. *Eminence*
19 *Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003) (reversing denial of leave to
20 amend even though complaint had been amended three times already). As such, if Plaintiffs
21 wish to amend their complaint, they are permitted to file a motion for leave to amend within 20
22 days of the date of this Order. The motion should attach any proposed Second Amended
23 Complaint. The motion should also cite relevant authority explaining why leave to amend is
24 appropriate, and why the proposed amendments will not fall victim to the legal authorities
25 discussed above.
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IV. CONCLUSION

Having reviewed the relevant pleadings, the declarations and exhibits attached thereto, and the remainder of the record, the Court hereby ORDERS:

- 1) Atossa Defendants' Motion to Dismiss (Dkt. #38) is GRANTED and all claims against Defendants are DISMISSED with leave to file a motion to amend as discussed above NO LATER THAN twenty (20) days from the date of this Order.
- 2) Underwriter Defendants' Motion to Dismiss (Dkt. #41) is GRANTED and all claims against Defendants are DISMISSED with leave to file a motion to amend as discussed above.
- 3) Atossa Defendants' Requests for Judicial Notice (Dkts. #40 and #57) are GRANTED.
- 4) Plaintiffs' Request for Judicial Notice (Dkt. #60) is DENIED.

DATED this 6 day of October 2014.



RICARDO S. MARTINEZ
UNITED STATES DISTRICT JUDGE