IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge Robert E. Blackburn

Civil Case No. 11-cv-00165-REB-KMT

JOHN WOLFE, individually and on behalf of all others similarly situated,
MIKE MARNHOUT, individually and on behalf of all others similarly situated, and
SHAZI IQBAL, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

ASPENBIO PHARMA, INC., a Colorado corporation,
RICHARD G. DONNELLY,
GREGORY PUSEY,
JEFFREY G. McGONEGAL,
MARK COLGIN, and
ROBERT CASPARI,

Defendants.

ORDER GRANTING MOTION TO DISMISS

Blackburn, J.

The matters before me are (1) **Defendants' Combined Motions and Brief To Dismiss Plaintiffs' Amended Class Action Complaint** [#39],[1] filed October 7, 2011; (2) **Defendants' Motion Requesting Judicial Notice in Support of Defendants' Combined Motions and Brief To Dismiss Plaintiffs' First Amended Class Action Complaint** [#41], filed October 7, 2011; and (3) plaintiffs' **Request for Judicial Notice in Opposition To Defendants' Combined Motion To Dismiss the Amended Complaint** [#44], filed November 21, 2011. I grant the motions for judicial notice and

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[1] "[#39]" is an example of the convention I use to identify the docket number assigned to a specific paper by the court's electronic case filing and management system (CM/ECF). I use this convention throughout this order.

grant defendants' motion to dismiss.

I. JURISDICTION

I have subject matter jurisdiction pursuant to 28 U.S.C. § 1331 (federal question).

II. STANDARD OF REVIEW

When ruling on a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), I must determine whether the allegations of the complaint are sufficient to state a claim within the meaning of Fed. R. Civ. P. 8(a). For many years, "courts followed the axiom that dismissal is only appropriate where 'it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" ***Kansas Penn Gaming, LLC v. Collins***, 656 F.3d 1210, 1214 (10th Cir. 2011) (quoting ***Conley v. Gibson***, 355 U.S. 41, 45-46, 78 S.Ct. 99, 102, 2 L.Ed.2d 80 (1957)). Noting that this standard "has been questioned, criticized, and explained away long enough," the Supreme Court supplanted it in ***Bell Atlantic Corp. v. Twombly***, 550 U.S. 544, 562, 127 S.Ct. 1955, 1969, 167 L.Ed.2d 929 (2007). Pursuant to the dictates of ***Twombly***, I now review the complaint to determine whether it "'contains enough facts to state a claim to relief that is plausible on its face.'" ***Ridge at Red Hawk, L.L.C. v. Schneider***, 493 F.3d 1174, 1177 (10th Cir. 2007) (quoting ***Twombly***, 127 S.Ct. at 1974). "This pleading requirement serves two purposes: to ensure that a defendant is placed on notice of his or her alleged misconduct sufficient to prepare an appropriate defense, and to avoid ginning up the costly machinery associated with our civil discovery regime on the basis of a largely groundless claim." ***Kansas Penn Gaming***, 656 F.3d at 1215 (citation and internal quotation marks omitted).

As previously, I must accept all well-pleaded factual allegations of the complaint as true. ***McDonald v. Kinder-Morgan, Inc.***, 287 F.3d 992, 997 (10th Cir. 2002). Contrastingly, mere "labels and conclusions or a formulaic recitation of the elements of a cause of action" will not be sufficient to defeat a motion to dismiss. ***Ashcroft v. Iqbal***, 556 U.S. 662, 678, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009) (citations and internal quotation marks omitted). ***See also Robbins v. Oklahoma***, 519 F.3d 1242, 1247-48 (10th Cir. 2008) ("Without some factual allegation in the complaint, it is hard to see how a claimant could satisfy the requirement of providing not only 'fair notice' of the nature of the claim, but also 'grounds' on which the claim rests.") (quoting ***Twombly***, 127 S.Ct. at 1974) (internal citations and footnote omitted). Moreover, to meet the plausibility standard, the complaint must suggest "more than a sheer possibility that a defendant has acted unlawfully." ***Iqbal***, 129 S.Ct. at 1949. ***See also Ridge at Red Hawk***, 493 F.3d at 1177 ("[T]he mere metaphysical possibility that *some* plaintiff could prove *some* set of facts in support of the pleaded claims is insufficient; the complaint must give the court reason to believe that *this* plaintiff has a reasonable likelihood of mustering factual support for *these* claims.") (emphases in original). For this reason, the complaint must allege facts sufficient to "raise a right to relief above the speculative level." ***Kansas Penn Gaming***, 656 F.3d at 1214 (quoting ***Twombly***, 127 S.Ct. at 1965). The standard will not be met where the allegations of the complaint are "so general that they encompass a wide swath of conduct, much of it innocent." ***Robbins***, 519 F.3d at 1248. Instead "[t]he allegations must be enough that, if assumed to be true, the plaintiff plausibly (not just speculatively) has a claim for relief." ***Id.***

The nature and specificity of the allegations required to state a plausible claim will vary based on context and will "require[] the reviewing court to draw on its judicial experience and common sense." ***Iqbal***, 129 S.Ct. at 1950; ***see also Kansas Penn Gaming***, 656 F.3d at 1215. Nevertheless, the standard remains a liberal one, and "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely." ***Dias v. City and County of Denver***, 567 F.3d 1169, 1178 (10th Cir. 2009) (quoting ***Twombly***, 127 S.Ct. at 1965) (internal quotation marks omitted).

In addition to these basic pleading precepts, allegations of securities fraud are subject to the more exacting requirements of the Private Securities Litigation Reform Act of 1995 ("PSLRA"). Under the PSLRA, a complaint asserting a violation of section 10(b) of the Securities Exchange Act of 1934 (the 1934 Act), 15 U.S.C. § 78j(b),

> shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding a statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.

15 U.S.C. § 78u-4(b)(1).[2] In addition, the complaint must allege scienter with more precision than is required for allegations of fraud generally, such that plaintiffs "with respect to each act or omission alleged to violate this chapter, [must] state with

[2] These heightened standards were adopted in an effort "to eliminate some of the abuses experienced in private securities litigation, such as 'the routine filing of lawsuits . . . whenever there is a significant change in an issuer's stock price,' the 'abuse of the discovery process to impose costs so burdensome that it is often economical for the victimized party to settle,' and the 'manipulation by class action lawyers of the clients they purportedly represent.'" ***City of Philadelphia v. Fleming Companies, Inc.***, 264 F.3d 1245, 1258-59 (10th Cir. 2001) (quoting **H.R. Conf. Rep.** No. 104-369 at 31, ***reprinted in*** 41 Cong. Rec. H13692 (daily ed. Nov. 28, 1995)).

particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." ***Id.*** § 78u-4(b)(2). ***See also City of Philadelphia v. Fleming Companies, Inc.***, 264 F.3d 1245, 1258 (10th Cir. 2001) ("The PSLRA thus mandates a more stringent pleading standard for securities fraud actions in general, and for scienter allegations in particular.") (footnote omitted).

The parties have appended to their briefs various communications which form the basis of plaintiffs' claims in this lawsuit, as well as documents publicly filed with the SEC and/or the courts, and publications of federal agencies. It is well-settled that in resolving a motion to dismiss, the court may consider documents referenced in the complaint or that otherwise inform the basis of the plaintiff's claims. ***See Prager v. LaFaver***, 180 F.3d 1185, 1189 (10th Cir.), ***cert. denied***, 120 S.Ct. 405 (1999). In addition, "a court is permitted to take judicial notice of . . . facts which are a matter of public record." ***Folks v. State Farm Mutual Insurance Co.***, 299 Fed. Appx 748, 756 n.12 (10th Cir. Oct. 20, 2008). I thus grant the parties' respective motions to take judicial notice of these documents and consider them as relevant in my analysis of the substantive motion.

III. FACTUAL BACKGROUND

This is a putative class action brought by plaintiffs on behalf of themselves and all other persons who purchased common stock of defendant AspenBio Pharma, Inc. ("AspenBio Pharma"), between February 22, 2007, and July 19, 2010, inclusive.[3] Plaintiffs claim they purchased stock in AspenBio Pharma at prices that were artificially

[3] The operative pleading is the **Amended Class Action Complaint for Violations of the Securities Laws** [#29], filed August 23, 2011 [hereinafter "**Am. Compl**."].

inflated by the company's allegedly fraudulent and misleading public statements about one of its developing products, "AppyScore," a diagnostic test designed to detect elevated levels of a protein – MRP 8/14 – in blood plasma to help rule out appendicitis in patients who present with lower right quadrant pain, but do not in fact have appendicitis. (***See* Am. Compl.** ¶ 6 at 2.)[4]

AspenBio Pharma began developing AppyScore in July 2003 and optimized it in late 2004 or early 2005. (***Id.*** ¶¶ 50 & 53 at 11.) The company's founder Roger Hurst originally sought to develop a test that would identify proteins "differentially associated" with appendicitis. (***Id.*** ¶ 41 at 9.) However, testing allegedly revealed that MRP 8/14 was produced in response to many other types of inflammatory conditions as well, thus making it "useless as a clinical test for appendicitis." (***Id.*** ¶¶ 7-8 at 2-3 & ¶ 44 at 10.) Plaintiffs allege that in August 2005 Hurst informed AspenBio Pharma's then-CEO, defendant Richard Donnelly, that "AppyScore wouldn't work" (***id.*** ¶ 45 at 10), or alternatively, that it "just wasn't working" (***id.*** ¶ 97 at 22). A week later, Mr. Hurst was fired. (***Id.*** ¶ 45 at 10 & ¶ 100 at 23.)

Although AspenBio Pharma subsequently continued to develop AppyScore, it allegedly did nothing to increase the accuracy of the test thereafter. (***Id.*** ¶ 97 at 22-23.) Melinda Sogo, a research scientist who worked on AppyScore from 2003 to 2007, alleges that "when tested by trained professionals using exclusion criteria not disclosed

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[4] According to the Amended Complaint, "[d]istinguishing appendicitis from other diseases that present the same symptoms is a difficult clinical task." Under the current standard-of-care, doctors sometimes cannot definitively rule out appendicitis in patients who present with symptoms and thus sometimes remove healthy appendices, exposing patients to the risks associated with surgery. (***See* Am. Compl.** ¶¶ 3-5 at 2.)

to her, AppyScore was at best 75% accurate initially," and showed no better than 80 per cent sensitivity[5] when optimized and tested under clinical conditions. (***Id.*** ¶ 54 at 11.)

On February 22, 2007, the date on which the class period begins, AspenBio Pharma issued a press release headlined "AspenBio Pharma's New Human Appendicitis Blood Test Continues To Show High Accuracy in Clinical Trials." (***See id.*** ¶ 106 at 24-25; **Motion App.**, Foster Decl., Exh. 1 at 1.) The document announced the results of three different trials of AppyScore:

> 1. **The Early Study**. A study of pre-operative blood samples of 34 patients who ultimately underwent appendectomies. AppyScore correctly identified all 24 of the patients who in fact had appendicitis, as well as all 10 of the patients who did not.
>
> 2. **The Retrospective Study**. Of the 68 confirmed cases of appendicitis in a second study of 220 test subjects, AppyScore correctly identified 47 out of the 48 cases in which CT scans also were undertaken – a 97.9% success rate – whereas CT scans correctly identified only 43.
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> 3. **The 2007 Pilot Study**. An ongoing study of 400 blood samples from patients at six hospital emergency rooms, including both suspected cases of appendicitis and normal donors. At that point in the study, AppyScore had correctly identified 34 of the 36 cases that had been confirmed as presenting with appendicitis, a 94.4% success rate, while its success in detecting non-appendicitis cases was 76.9% (30 out of 39 cases).

(**Am. Compl.** ¶ 106 at 24-25; **Motion App.**, Foster Decl., Exh. 1 at 2-3.)[6] Mr. Donnelly

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[5] "Sensitivity" refers to the percentage of true positives that are accurately identified. (**See Am. Compl.** ¶ 76.e. at 16.)

[6] AspenBio Pharma allegedly restated the results of the Early Study at a presentation to investors on May 22, 2007 (***see*** **Am. Compl.** ¶ 143 at 35), as well as the preliminary results of the 2007 Pilot Study in an April 9, 2007, SEC filing (***id.*** ¶ 139 at 34), and in May 17, August 20, and August 23, 2007, press releases (***id.*** ¶ 142 at 35, ¶¶ 144-145 at 37). The company reported the final results of the 2007 Pilot Study, showing 98% sensitivity, on September 28, 2007. (***Id.*** ¶¶ 146-147 at 37-38). This same statement

also was quoted as saying: "To be the first to offer a blood test like this to ER doctors worldwide will be a major event not only for AspenBio, but for the entire healthcare community." (**Am. Compl.** ¶ 133 at 33; **Motion App.**, Foster Decl., Exh. 1 at 2.)

AspenBio Pharma conducted a second pilot study of 183 subjects in 2008 (the "2008 Pilot Study"), the satisfactory completion of which allowed it to run its first full-fledged, FDA-monitored clinical trial (the "2008 Clinical Trial"). (***Id.*** ¶ 157 at 41.) However, the results of the 2008 Clinical Trial, announced on January 20, 2009, "were devastating," showing no better than 89% sensitivity by any measure.[7] (***Id.*** ¶¶ 169 & 171 at 43.)[8] AspenBio Pharma offered a possible explanation for the results of the 2008 Clinical Trial in a March 12, 2009, press release, noting that the "study included an unexpected number of patients who presented with mild appendicitis when compared to peer reviewed published literature statistics. This was especially prevalent at one of the

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was reiterated in a Power Point presentation made to a group of investors on December 20, 2007 (***id.*** ¶ 154 at 40), as well as in an attachment to a Form 8-K statement on December 27, 2007 (***id.*** ¶ 154 at 40), and in an April 29, 2008, slide show filed with the SEC and made available on defendant's website (***id.*** ¶ 161 at 42). An April 23, 2008, press release also claimed that AppyScore's negative predictive value "was shown in pre-clinical research to be >95%." (***Id.*** ¶ 159 at 41.)

[7] Plaintiffs further allege that these results pertained despite AspenBio Pharma's use of different "cut-offs" – the level at which it was determined that MRP 8/14 was elevated enough to indicate the potential presence of appendicitis – to maximize AppyScore's performance on any given test. (**Am. Compl.** ¶ 170 at 43.)

[8] Plaintiffs allege that it was at this point that defendant consistently began to refer to AppyScore as potentially useful only "in conjunction with other standard diagnostic approaches," rather than as a stand-alone test for detection of appendicitis. (**Am. Compl.** ¶ 172 at 43.) The claim that this shift in position is significant because "[a] test that, standing alone, can revolutionize standard-of-care has a much greater market than a test that can only, at best, marginally increase diagnosis"(***id.*** ¶ 174 at 44 (emphasis omitted), and further, "runs the risk of multicollinearity," that is, being so highly correlated with the results of another test that the additional test simply becomes duplicative (***id.*** ¶ 175 at 44 (emphasis omitted)).

In addition, defendant continued to represent that AppyScore's sensitivity was 90% or greater when combined with other tests, such as white blood cell ("WBC") count (***id.*** ¶¶ 190-191 & 195 at 47), and that its negative predictive value in conjunction with other tests was 95% (***id.*** ¶ 206 at 49).

hospital sites which enrolled the largest number of patients in the study." (***Id.*** ¶ 182 at 45-46.) A conference call that same day made similar representations, indicating that the hospital site was not representative. (***Id.*** ¶ 189 at 46-47.) Regardless, AspenBio Pharma's stock plunged by more than 75 per cent that day, from $32.50 at the open to $6.50 when the market closed. (***Id.*** ¶ 181 at 45 & n.25.)

Undeterred, AspenBio Pharma filed a Form 510(k) with the FDA seeking commercial clearance for AppyScore in June 2009. (***Id.*** ¶ 195 at 47.) In response to an FDA request for further information, the company hired Jeffrey Magouirk, a biostatistician, to retrospectively analyze the data from the 2008 Clinical Trial. (***Id.*** ¶ 59 at 13 & ¶¶197-198 at 48.) The results of Mr. Magouirk's work allegedly showed that AppyScore's sensitivity was actually worse than reported in January 2009. (***Id.*** ¶¶ 62.a. & b.) In addition, the test's negative predictive value as measured by Mr. Magouirk was only 82-83 per cent, and only 88-89 per cent when combined with white blood cell ("WBC") count, rendering it too unreliable to be useful as predictor of low-risk cases of appendicitis and thus commercially unviable. (***Id.*** ¶ 62.c. at 13 & ¶¶ 199-200 at 48.)

On December 29, 2009, AspenBio Pharma announced in a press release that it had created a Statistical Analysis Plan to be used in a forthcoming FDA study of AppyScore (the "2010 Clinical Trial"). (***Id.*** ¶ 205 at 49.) Yet on June 7, 2010, the company reported that it would not be able to complete the study by July 2010 as previously planned. AspenBio Pharma's stock opened that day at $9.20, down from $16.90 the previous day. (***Id.*** ¶¶ 211-212 at 50.) On July 19, 2010, the final day of the class period, AspenBio Pharma issued a press release revealing that the 2010 Clinical

Trials showed less specificity[9] than the 2008 Clinical Trial, and sensitivity and negative predictive values of 91 per cent and 89 per cent, respectively, consistent with the 2008 Clinical Trial. (***Id.*** ¶ 215 at 51.)[10] In addition, the press release stated that AppyScore was found not to enhance clinical utility when used in combination with either WBC or neutrophil count. (***Id.*** ¶ 216 at 51.) The company's stock fell an additional 27 per cent, from $4.85 to $3.55, that day. (***Id.*** ¶ 281 at 51.)

IV. ANALYSIS

A. Section 10(b) and Rule 10b-5

Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful for any person to employ any manipulative or deceptive device, in contravention of the rules and regulations of the Securities and Exchange Commission (SEC), in connection with the purchase or sale of a security. 15 U.S.C. § 78j(b). SEC Rule 10(b)(5) provides that it is unlawful for a person "to make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5.

As noted earlier, the PSLRA imposes "[e]xacting pleading requirements" in order for a plaintiff to maintain a viable suit for violation of section 10(b) and/or Rule 10b-5. ***Tellelabs, Inc. v. Makor Issues & Rights, Ltd.***, 551 U.S. 308, 313, 127 S.Ct. 2499,

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[9] "Specificity" refers to the "percentage of actual negatives that are correctly identified as such." (**Am. Compl.** ¶ 76.f. at 17))

[10] AspenBio Pharma suggested that the disappointing results of the 2010 Clinical Trial were related to "(1) variables related to the transportation shipping conditions; and (2) the length of sample delivery time from the hospital sites across the country where the samples were drawn to the central laboratory that analyzed the samples." (**Am. Compl.** ¶ 213 at 50.) Relatedly, it also reported that samples were not sufficiently stable within a 48-hour window as previous determined. (***Id.*** ¶ 213 at 51.)

2504, 168 L.Ed.2d 179 (2007). To state a claim, plaintiffs must allege particular and sufficient facts to suggest that AspenBio Pharma and/or the individual defendants: (1) made an untrue statement of material fact or failed to state a material fact; (2) in connection with the purchase or sale of a security; (3) with scienter; (4) on which plaintiffs relied; and (5) as a proximate result of which, plaintiffs sustained damages. ***See, e.g.***, ***Anixter v. Home-Stake Products***, 77 F.3d 1215, 1225 (10th Cir. 1996). Defendants argue that the Amended Complaint fails to allege facts with sufficient particularity to sustain the first, third, and fifth of these essential elements. Because I find that the Amended Complaint does not allege adequate facts to plausibly assert a misrepresentation or omission of material fact as required by the first element, I do not examine the other two elements – the third and fifth elements.

1. False or Misleading Statement of Material Fact

To withstand scrutiny under the PSLRA, the Amended Complaint must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1). In addition, "if an allegation regarding a statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." ***Id.*** Merely because a representation proves in retrospect to have been wrong does not support a conclusion that it was false. The court may not "assume that what is true at the moment plaintiff discovers it was also true at the moment of the alleged misrepresentation, and that therefore simply because the alleged misrepresentation conflicts with the current state of facts, the charged statement must have been false." ***Grossman v. Novell, Inc.***, 120

F.3d 1112, 1124 (10th Cir. 1997). Instead, and to eschew the danger of inferring fraud based on hindsight, plaintiffs' allegations "must set forth, as part of the circumstances constituting fraud, an explanation as to why the disputed statement was untrue or misleading *when made*." ***Id***. (citation omitted; emphasis in original).

Defendants' motion challenges three categories of allegedly false and misleading statements set forth in the Amended Complaint: (1) statements regarding the results of AppyScore's 2007 testing; (2) statements regarding the results of the 2008 Clinical Trial; and (3) statements regarding the uniqueness and stand alone capabilities of the test. I examine each of these in turn.

a. The 2007 Studies

Plaintiffs allege that statements regarding the successes of early testing on AppyScore were false and misleading because they greatly exaggerated AppyScore's true predictive value. The Amended Complaint sets forth several bases for this belief.

First, plaintiffs allege that the Early Study "either never took place or was rigged" (**Am. Compl.** ¶ 108 at 26), based on the fact that Ms. Sogo has no memory of any such test having taken place and recalls AppyScore never achieving a better than 75-80 per cent success rate. (***Id.*** ¶ 108.a. at 26.) Yet no averment in the Amended Complaint affirmatively links any test Ms. Sogo performed while employed at AspenBio Pharma with the Early Study or either of the other two 2007 trials, and in fact, the allegations regarding her recollection of the results of testing stem from 2004 and 2005, not 2007. (***See id.*** ¶¶ 51-52 at 11.) In addition, the allegedly less accurate tests of which Ms. Sogo does aver knowledge were conducted by "trained professionals using exclusion

criteria not disclosed to [Ms. Sogo.]" (***Id.*** ¶ 54 at 11.) These allegations provide no plausible basis to conclude that the assumptions and testing conditions of the Early Study were substantially similar to any test of which Ms. Sogo may be aware.

Moreover, I cannot find one witness's failure to recall whether a particular event occurred adequate to support a plausible conclusion that it did not under the heightened pleading standards of the PSLRA. Although the Amended Complaint alleges that Ms. Sogo was one of only three of four research scientists working on AppyScore, it fails to plead facts suggesting that her position made her privy to knowledge of every trial and study that might have been undertaken from 2003 to 2007.[11] In any event, nothing but pure speculation could support the inference that Ms. Sogo's lack of memory is due to the fact that the Early Study never occurred, rather than some other, less sinister, explanation.

For similar reasons, allegations of another former employee, Jill Waters, that "AppyScore's sensitivity was far below 100%" (***id.*** ¶ 108.b. at 26), do not support a plausible conclusion that AspenBio Pharma's statements regarding the Early Study were fabricated or misleading.[12] Likewise, the fact that the Early Study was not

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[11] Although plaintiffs do allege that, as Manager of Quality Documents and Special Projects from June, 2007, to March, 2008, Ms. Sogo "reviewed all of the documentation regarding testing of AppyScore" (**Am. Compl.** ¶ 48 at 10), they do not suggest that this review was retrospective to include any studies prior to Ms. Sogo's assumption of the position, including, most significantly, the Early Study.

Moreover, accepting as true plaintiffs' allegations that AspenBio Pharma discouraged its scientists from discussing their work on AppyScore with one another (***see*** **Am. Compl.** ¶¶ 117-125 at 29-30), and that the lab manager specifically told Ms. Sogo in early 2007 that company policy forbade employees from discussing their work with colleagues (***id.*** ¶ 118 at 29), the Amended Complaint appears to support the opposite inference.

[12] Moreover, the exact date of the Early Study remains unspecified, and there is nothing in the Amended Complaint otherwise suggesting that it coincided with Ms. Waters's brief tenure with AspenBio Pharma. (***See*** **Am. Compl.** ¶ 63 at 14) (alleging that Ms. Waters worked for the company part-time

mentioned by certain of the individual defendants when describing a 2008 "pilot trial" on MRP 8/14 supports no plausible inference that reports on the results of the study were misleading or fabricated. (***See id.*** ¶ 108.d. at 27.)

Plaintiffs also suggest that it is virtually impossible, statistically speaking, for AppyScore to have received100 per cent accuracy and that "this result cannot be explained by chance alone." (***See id***. ¶ 108.e. at 27.) They rely for this allegation on the opinion of Nancy Chew, president of Regulatory Affairs North America, Inc., which "guides companies through the regulatory approval process for drugs and devices." (***Id.*** ¶ 74 at 15.) Assuming *arguendo* that an allegation of statistical improbability is sufficient to support an inference of falsity, an assumption for which plaintiffs provide no authority, nothing in the Amended Complaint or Ms. Chew's *curriculum vitae* appended thereto makes it apparent that she is a statistician or otherwise qualified to render or interpret statistical analyses in the manner contemplated by her proffered opinion. Moreover, the opinion is wholly conclusory and unsupported by any actual facts.[13] Plaintiffs' invocation of "basic statistics" to shore up this allegation, aside from not being included in the Amended Complaint, likewise is unsupported by any authority.

This leaves only plaintiffs' allegation that statements regarding the results of the Early Study were misleading or false because the results of the 2008 and 2010 Clinical

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testing AppyScore from January to March, 2007).

[13] Plaintiffs seek to bolster this allegation by reference to Ms. Chew's suggestion of three possible scenarios that may explain the differences between the Early Study's results and AppyScore's "true capabilities" as revealed by the 2008 and 2010 Clinical Trials. (**Am. Compl.** ¶ 115 at 29 (opining that company either used improper exclusion criteria, threw out some results, or lied about the results); ***see also id.*** ¶ 116 at 29 ("If any of these facts are true, and in Ms. Chew's opinion at least one is almost certainly true, then AspenBio made material misstatements of fact.").) This allegation, however, begs the question whether the initial purported statistical assumptions on which Ms. Chew relies are proper.

Trials revealed much lower, and allegedly more accurate, levels of specificity, sensitivity, and negative predictive value. Clearly, however, this argument is nothing more than impermissible fraud-by-hindsight. ***See Grossman***, 120 F.3d at 1124. Plaintiffs attempt to evade this conclusion by reference to their allegation that the Clinical Trials were "run on the same product as the initial experiments, and therefore should return the same results." (**Am. Compl.** ¶ 108.c. at 26.) Aside from the fact that this allegation appears to contradict other allegations in the Amended Complaint,[14] it plainly is based on fallacious logic. Even if the product tested was the same, there is nothing in the Amended Complaint to suggest that the testing *conditions* were consistent between any two or more trials.[15]

For these reasons, I find and conclude that these allegations, either singly or in combination, do not support an inference that any statement regarding the results of the Early Test were false or misleading.

b. Statements Regarding the Results of the 2008 Clinical Trial

During a March 12, 2009, conference call, defendant Mark Colgin allegedly confirmed that, despite the apparently disappointing results of the 2008 Clinical Trial, when combined with WBC, AppyScore's sensitivity rate "would go back up to 90." (**Am. Compl.** ¶¶ 190-191 at 47.) Relatedly, a December 29, 2009, press release announced that, when combined with WBC or neutrophil, AppyScore obtained a negative predictive

[14] Specifically, plaintiffs elsewhere allege that AspenBio Pharma "used different 'cut-offs' in every test – in essence, they were testing different products in every test." (**Am. Compl.** ¶ 170 at 43.)

[15] For this same reason, plaintiffs' allegations that Mr. Hurst told Mr. Donnelly in 2005 that AppyScore "didn't work" or "just wasn't working" do not speak to the viability of the test in 2007.

value of 95 per cent. (***Id.*** ¶ 206 at 49.) Plaintiffs allege that these statements were false based on the results of Mr. Magouirk's retrospective testing of the data from that trial, which found that AppyScore's sensitivity "was worse than standard-of-care" (***Id.*** ¶ 62.a. at 13), and that it had a negative predictive value was only 89-90 per cent even when combined with WBC (and no better than 83 per cent standing alone). (***Id.*** ¶¶ 199-200 at 48.)[16]

Defendants maintain that these statements are not rendered false or misleading based on Mr. Magouirk's findings. I agree. "[I]nterpretations of the results of various clinical studies . . . are essentially no different than opinions," because "[r]easonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions." ***In re Sanofi-Aventis Securities Litigation***, 774 F.Supp.2d 549, 567 & n.20 (S.D.N.Y. 2011): Reasonable professionals "may well differ with respect to what constitutes acceptable testing procedures, as well as how best to interpret data garnered under various protocols," and thus "[i]nterpretations of scientific data are not misleading where the interpretation finds reasonable support in the data." ***Noble Asset Management v. Allos Therapeutics, Inc***., 2005 WL 4161977 at *11 (D. Colo., Oct. 20, 2005) (citation omitted). Thus,

> [t]o properly plead that such statements were materially misleading, Plaintiffs must allege with particularity provable facts to demonstrate that the statement of opinion is both objectively and subjectively false. That is, Plaintiffs must show both that the [Defendants] did not actually hold the belief or opinion stated, and that the opinion stated was in fact incorrect.

[16] Given that Magouirk was hired specifically to analyze the data from the 2008 Clinical Trial, it matters not that he was not hired until after that trial had been completed.

In re Sanofi-Aventis Securities Litigation, 774 F.Supp.2d at 567 (citations and internal quotation marks omitted).

The Amended Complaint fails in this regard, alleging no facts regarding what testing methodologies Mr. Magouirk used or whether they differed, and if so, how, from those initially employed in the 2008 Clinical Trial. (***See* Am. Compl.** ¶ 199 at 48 (stating only that Mr. Magouirk used "standard analytical tools").)[17] In the absence of such detail, it is not possible to conclude that statements regarding the results of the 2008 Clinical Trial were false or materially misleading at the time they were made.

Plaintiffs also claim that AspenBio Pharma's purported explanation that the results of the 2008 Clinical Study were attributable to an unexpectedly high number of mild appendicitis cases at one of the hospitals involved in the study was false because AppyScore continued to perform poorly in subsequent trials. (**Am. Compl**. ¶ 183 at 46.) As noted above, however, such fraud-by-hindsight does not satisfy the requirements of the PSLRA.[18]

c. Statements Regarding AppyScore's Uniqueness

[17] The Amended Complaint also refers to a December 29, 2009, press release in which AspenBio Pharma announced that it had developed a Statistical Analysis Plan ("SAP"), to be used in a forthcoming FDA study, that when applied retrospectively to the data from the 2008 Clinical Trial obtained a negative predictive value of 95 per cent in combination with WBC or neutrophil. (**Am. Compl.** ¶¶ 205-206 at 49.) There are no facts pleaded, however, to suggest any relationship or even correlation between the SAP and Mr. Magouirk's analysis of the 2008 Clinical Trial data.

[18] The facts that Mr. Magouirk cannot remember this explanation having been included in the materials he reviewed and Ms. Chew being unaware of what peer-reviewed literature may have been referenced in the statement do not support an inference of falsity either. (***See* Am. Compl.** ¶ 62(h) at 14 & ¶¶ 184-185 at 46.) Nor can plaintiffs demonstrate falsity by reasoning backwards from their conclusion that AppyScore contributes nothing to standard of care because cases of mild appendicitis are most problematic. (***See id.*** ¶ 186 at 46.)

Plaintiffs allege that although AspenBio Pharma knew that AppyScore was not designed or intended to be a stand-alone test for appendicitis, it did not report that fact to the investing public until October 2008. (**Am. Compl.** ¶ 73 at 15 & ¶¶ 163-164 at 42.)[19] Plaintiffs claim that earlier statements that AppyScore was "unique" as the "world's first appendicitis screen or rule-out test," and that it had "no known competitors," were false and misleading because there were two or three other blood-based tests then in existence that could be used to detect and rule out appendicitis. (***Id.*** ¶¶ 101-102 at 23 & ¶ 134 at 33.)

Initially, statements that AppyScore was "unique" or the "first to offer a blood test like this" are not actionable. Rather, they are mere puffing, that is, "generalized statements of optimism that are not capable of objective verification," and thus not considered material for purposes of a section 10(b) claim. ***Grossman***, 120 F.3d at 1119. Such "enthusiastic but vague" characterizations of a product or process are not sufficient to state a claim. ***See, e.g.***, ***Galati v. Commerce Bancorp, Inc.***, 220 Fed. Appx. 97, 102 (3rd Cir. Mar. 29, 2007); ***In re Bank of America Corp. Securities, Derivative, and Employee Retirement Income Security Act (ERISA) Litigation***, 2012 WL 1353523 at *10 (S.D.N.Y. Apr. 12, 2012); ***In re Cytyc Corp.***, 2005 WL 3801468 at *23 (D. Mass. Mar. 2, 2005); ***In re Sun Healthcare Group, Inc. Securities Litigation***, 181 F.Supp.2d 1283, 1291 (D.N.M. 2002).

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[19] Plaintiffs argue that the marketing of AppyScore as "novel" has implications for the test's regulatory pathway and concomitant financing needs, with that designation suggesting a longer and more difficult route to approval. (***See*** **Am. Compl.** ¶¶ 237-243 at 57-58 & ¶ 252 at 59.) The Amended Complaint seems to contradict itself in this regard, however, in suggesting that AspenBio Pharma led investors to believe that AppyScore "could be approved without too much trouble from the FDA." (***Id.*** ¶ 137 at 34.)

Moreover, the Amended Complaint alleges no facts from which it can be discerned that AppyScore in fact was not unique in comparison to these other predictive measures. For example, it is not alleged that WBC or neutrophil tests measure the specific protein, MRP 8/14, that AppyScore is designed to detect. Indeed, the fact that AspenBio Pharma was issued a patent on the test establishes a presumption that AppyScore was "novel" and "non-obvious." ***See Microsoft Corp. v. i4i Ltd. Partnership***, – U.S. –, 131 S.Ct. 2238, 2242-43, 180 L.Ed.2d 131 (2011).

With regard to statements suggesting that AppyScore had no known competitors, no facts set forth in the Amended Complaint establishes that WBC or any other blood-based test is a competitor of AppyScore. Moreover, in the same 2007 document in which AspenBio Pharma stated that the test had "no known competitors," it also disclosed that the then-current standard of care included the taking of a WBC and envisioned that AppyScore could "easily be incorporated within the initial routine laboratory work in the emergency room." (***See* Def. Motion App.**, Exh. 14 at 2.) Taking the statement in the context in which it was made, it clearly was not false or misleading. ***See In re Level 3 Communications, Inc. Securities Litigation***, 2010 WL 5129524 at *9 (D. Colo. Dec. 10, 2010), ***aff'd***, 667 F.3d 1331 (10th Cir. 2012).

For these reasons, I find and conclude that the Amended Complaint fails to allege facts sufficient to plausibly suggest that AspenBio Pharma or any individual defendant made false or misleading representations of material fact. The failure to

adequately plead this essential element is fatal to their claims.[20]

B. Section 20(a)

Liability under section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), is premised on a primary violation of the securities laws.[21] ***See Adams v. Kinder-Morgan, Inc.***, 340 F.3d 1083, 1107-08 (10th Cir. 2003); ***In re ICG Communications, Inc. Securities Litigation***, 2006 WL 416622 at *16 (D. Colo. Feb. 7, 2006). Because I find and conclude that plaintiffs have failed to allege facts sufficient under the PSLRA to state a plausible claim under section 10(b) and Rule 10b-5, the motion to dismiss the section 20(a) claim also must be granted.

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[20] I note, however, that it appears equally unlikely that plaintiffs have pleaded facts sufficient to support a "strong inference" of scienter, either. ***See*** 15 U.S.C. § 78u-4(b)(2). Plaintiffs acknowledge in their response brief that the Amended Complaint fails to include allegations adequate to plead primary violations of the securities laws against defendants Robert Caspari and Mark Colgin. (**Plf. Resp.** at 30.) The allegedly "very high" salaries of the other individual defendants are not sufficient to support the required inference of scienter. ***See Fleming Companies, Inc.***, 264 F.3d at 1269-70; ***Grossman v. Novell, Inc.***, 909 F.Supp. 845, 851 (D. Utah 1995), ***aff'd***, 120 F.3d 1112 (10th Cir. 1997). Nor is the allegation that it would be "absurd" to suggest that the individual defendants were unaware of AppyScore's performance or market position, as the presumption on which it is premised has not been recognized in this circuit, ***see Fleming Companies***; 264 F.3dd at 1264; ***In re Crocs Securities Litigation***, 774 F.Supp.2d 1122, 1149 (D. Colo. 2011), and the facts alleged do not appear to bring the case within the limited "narrow conditions" in which it is applicable in any event, ***see Zucco Parnters LLC v. Digimarc Corp.***, 552 F.3d 981, 1000-01 (9th Cir. 2009) (exception recognized when either (1) complaint contains "detailed and specific allegations about management's exposure to factual information within the company;" or (2) "the falsity of the information was obvious from the operation of the company"). ***Cf. Berson v. Applied Signal Technology***, 527 F.3d 982, 988 n.5 (9th Cir. 2008) (scienter presumed where allegedly fraudulent stop-work orders halted tens of millions of dollars worth of work , caused the company to reassign 50–75 employees, and required defendant to complete voluminous paperwork). Finally, Hurst's 2005 opinion that AppyScore "just wasn't working" is so vague and global as to be unhelpful as a benchmark for scienter.

[21] This section provides for "control person" liability, to wit:

> Every person who, directly or indirectly, controls any person liable under any provision of this chapter or any rule or regulations thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, ...

15 U.S.C. § 78t(a).

V. CONCLUSION

Although long and detailed, plaintiffs' Amended Complaint still fails to set forth facts sufficiently particularized enough to withstand scrutiny under the PSLRA's exacting pleading standards. Specifically, the allegations of the Amended Complaint do not reference specific facts establishing that the statements on which plaintiffs' claims under section 10(b) and Rule 10b-5 rest were false or misleading. Moreover, in the absence of a primary violation of the securities laws, plaintiffs' section 20(a) control person claims fail as well.

VI. ORDERS

THEREFORE, IT IS ORDERED as follows:

1. That **Defendants' Combined Motions and Brief To Dismiss Plaintiffs' Amended Class Action Complaint** [#39], filed October 7, 2011, is **GRANTED**;

2. That **Defendants' Motion Requesting Judicial Notice in Support of Defendants' Combined Motions and Brief To Dismiss Plaintiffs' First Amended Class Action Complaint** [#41], filed October 7, 2011, is **GRANTED**;

3. That plaintiffs' **Request for Judicial Notice in Opposition To Defendants' Combined Motion To Dismiss the Amended Complaint** [#44], filed November 21, 2011, is **GRANTED**;

4. That plaintiffs' claims against defendants are **DISMISSED WITHOUT PREJUDICE** for failure to state claims on which relief may be granted; and

5. That judgment **SHALL ENTER** on behalf of defendants, AspenBio Pharma, Inc., a Colorado corporation; Richard G. Donnelly; Gregory Pusey; Jeffrey G.

McGonegal; Mark Colgin; and Robert Caspari, against plaintiffs, John Wolfe, individually and on behalf of all others similarly situated; Mike Marnhout, individually and on behalf of all others similarly situated; and Shazi Iqbal, individually and on behalf of all others similarly situated, as to all claims and causes of action asserted herein; provided, however, that the judgment shall be without prejudice.

Dated September 13, 2012, at Denver, Colorado.

BY THE COURT:

Robert E. Blackburn
United States District Judge