UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: ARIAD PHARMACEUTICALS, INC., SECURITIES LITIGATION	)	CIVIL ACTION 13-12544-WGY

YOUNG, D.J. March 24, 2015

MEMORANDUM AND ORDER

I. INTRODUCTION

This is a shareholder class action brought by Joseph Bradley, the City of Fort Lauderdale Police & Fire Retirement System, Pension Trust Fund for Operating Engineers and Automotive Industries Pension Trust Fund, and William A. Gaul, D.M.D. (collectively, "the Lead Plaintiffs"), on behalf of themselves and all similarly-situated shareholders, against ARIAD Pharmaceuticals, Inc. ("ARIAD"), several officers and directors of ARIAD (Chief Executive Officer Harvey Berger, Chief Financial Officer Edward Fitzgerald, Chief Medical Officer Frank Haluska, and Chief Scientific Officer Timothy Clackson) ("the Individual Defendants," together with ARIAD, the "ARIAD Defendants"), and seven underwriters. The underwriter defendants are J.P. Morgan Securities LLC, Cowen and Company, LLC, Jefferies & Company, Inc., BMO Capital Markets Corp.,

Leerink Swann LLC, RBC Capital Markets, LLC, and UBS Securities LLC (collectively, "the Underwriters").

The Lead Plaintiffs bring this proposed class action on behalf of themselves and all other persons or entities who purchased or acquired (1) any publicly-traded ARIAD securities between December 12, 2011 and October 30, 2013 (the "Class Period"), or (2) any of ARIAD's common stock pursuant or traceable to the secondary offering that occurred on or about January 24, 2013 ("2013 Stock Offering") and were damaged thereby. Corrected Consol. Compl. Violations Fed. Secs. Laws ("Compl.") 1, ECF No. 131. They allege that the ARIAD Defendants made a series of false and misleading statements and omissions in regards to the safety, efficacy, and commercial prospects of ARIAD's main product, a cancer medication called ponatinib, which is used to treat chronic myeloid leukemia. Id. As a result of these statements and omissions, the Lead Plaintiffs allege that the price of ARIAD common stock traded at artificially high values, while ARIAD concealed the full extent of adverse events arising from their clinical trials. Id. ¶¶ 5-6. Arguing that the Individual Defendants knew the full extent of the negative results stemming from the ongoing clinical trials, the Lead Plaintiffs allege that the Individual Defendants engaged in suspicious and unusual stock sales during the Class Period. Id. ¶ 327. They also bring a claim against

the ARIAD Defendants and the Underwriters under Section 11 of the Securities Act of 1933 ("Section 11") for alleged misstatements and omissions in stock offering materials. Id. ¶¶ 416-17.

The ARIAD Defendants and the Underwriters seek dismissal of all claims against them.

A. Procedural History

This litigation began on October 10, 2013 upon the filing of a class action complaint by Jimmy Wang against ARIAD and four of its officers. Class Action Compl. for Violations of Fed. Secs. Laws, ECF No. 1. The case was initially drawn to Judge Joseph Tauro, Elec. Notice, Oct. 11, 2013, ECF No. 3, but was reassigned to this Court shortly thereafter, Elec. Notice, Dec. 10, 2013, ECF No. 38.

On January 9, 2014, the Court entered an order consolidating several related actions into this single litigation, selecting lead plaintiffs, and approving the selection of lead counsel. Order, Jan. 9, 2014, ECF No. 95. The operative complaint was filed as a corrected consolidated complaint by the Lead Plaintiffs on March 25, 2014. Compl. The complaint is divided into two distinct and stand-alone parts, the first of which contains fraud allegations arising under Section 10(b), Rule 10b-5 promulgated thereunder by the United States Securities and Exchange Commission ("SEC"), and Section

20(a) of the Securities Exchange Act of 1934, Compl. ¶¶ 20-415 and the second of which contains allegations and claims arising under Section 11 of the Securities Act of 1933. See Compl. ¶¶ 416-85.

The two motions addressed by the Court here are motions to dismiss for failure to state a claim brought by the ARIAD Defendants and the Underwriters on April 14, 2014. ARIAD Defs.' Mot. Dismiss Corrected Consol. Compl., ECF No. 147; Mem. Supp. ARIAD Defs.' Mot. Dismiss Corrected Consol. Compl. ("ARIAD Defs.' Mem."), ECF No. 148; Underwriter Defs.' Mot. Dismiss, ECF No. 144; Underwriter Defs.' Mem. Law Supp. Mot. Dismiss ("Underwriter Defs.' Mem."), ECF No. 145. The Lead Plaintiffs filed an omnibus memorandum of opposition to the motions to dismiss on May 21, 2014. Pls.' Omnibus Mem. Law Opp. Defs.' Mot. Dismiss Corrected Consol. Compl. ("Pls.' Opp'n"), ECF No. 157. On June 4, 2014, the Underwriters submitted a reply in further support of their motion to dismiss, Underwriter Defs.' Reply Mem. Law Further Supp. Mot. Dismiss ("Underwriter Defs.' Reply"), ECF No. 162, and on June 5, 2014, the ARIAD Defendants submitted their own reply memorandum. ARIAD Defs.' Reply Mem. Further Supp. Mot. Dismiss Corrected Consol. Compl. ("ARIAD Defs.' Reply"), ECF No. 166.

B. Facts Alleged[1]

ARIAD is a biotechnology company based in Cambridge, Massachusetts, specializing in the development and sale of cancer drugs. Compl. ¶ 429. For several years, the company primarily has focused on developing the drug ponatinib, also known as Iclusig, as a treatment for chronic myeloid leukemia ("CML"). Id. In particular, ARIAD focused on developing a front-line drug to compete with existing drugs to treat CML, noting that front-line drugs are more lucrative products than second-line drugs. Id. ¶ 11 (explaining that front-line drugs "typically outsell second-line treatments by many orders of magnitude"). In the course of seeking approval by the U.S. Food and Drug Administration ("FDA"), ARIAD commenced a clinical trial on September 13, 2010, referred to by the parties as the PACE 2 trials. Id. ¶ 47. The trial was "designed to assess the

[1] The factual pleadings were divided into two parts, the first relating to the Exchange Act claims and the second relating to Section 11 claims. The facts supporting the Lead Plaintiffs' Section 11 claims are contained in paragraphs 429 through 472 of the corrected consolidated complaint, and they traverse much less territory than the factual allegations supporting the Lead Plaintiffs' Exchange Act claims sounding in fraud. Compare Compl. ¶¶ 36-393 (supporting Exchange Act claims) with id. ¶¶ 429-72 (supporting Securities Act claims). The complaint is structured as two independent parts, and the second part contains no statements incorporating by reference any statements from the first part of the complaint. The analysis and conclusions regarding the Section 11 claims are based solely on the pleadings made in the second part of the complaint. The facts relevant to both sets of claims are summarized in this section.

efficacy and safety of ponatinib in a larger subject group" consisting of "second-line" CML patients, meaning those with a demonstrated resistance to other, more established treatments. Id. ¶¶ 47-49, 431. The PACE 2 protocol provided for 449 test subjects to be treated with a recommended daily dose of 45 milligrams of the drug. Id. ¶ 49. Seeking funding for their ongoing clinical trials, ARIAD held its first of two stock offerings in December 2011, raising $258,000,000. Id. ¶ 62.

On June 4, 2012, ARIAD announced favorable interim results at a medical conference, citing "clear evidence of a favorable safety and tolerability profile in ponatinib in resistant or intolerant CML patients." Id. ¶ 50-51. ARIAD also submitted an interim report to the FDA containing data through the end of July 2012 (the "July 2012 Interim Report"). Id. ¶ 433. The results of this interim report documented adverse cardiovascular events in test subjects, including the incidence of "serious arterial thrombosis" in eight percent of patients. Id. ¶¶ 433, 435.

Shortly after the submission of the July 2012 Interim Report, ARIAD began a new clinical trial (the "EPIC" trial), which "was designed to support FDA approval of ponatinib in newly-diagnosed, never-treated CML patients, a.k.a. 'front-line' CML." Id. ¶ 434. The prescribed dosage for the EPIC trial was also 45 milligrams daily. Id.

On December 14, 2012, ARIAD filed a Form 8-K and announced in a press release that the FDA had granted accelerated approval to market ponatinib for second-line use. Id. ¶¶ 76-79, 435 (noting that the FDA relied on and publicized the data evinced in the July 2012 Interim Report). This press release included the list of serious adverse events that had occurred, including an eight percent occurrence of "serious arterial thrombosis" and four percent occurrence of serious congestive heart failure, with four fatalities. Id. ¶¶ 78-79. The FDA's approval was conditioned on two requirements: first, that each bottle of ponatinib include a "black box" warning label disclosing the occurrence of serious adverse cardiovascular events in users, and second, that ARIAD submit follow-up PACE 2 data to the FDA. Id. ¶¶ 110, 435-36. A "black box" warning is the strongest warning level for a prescription drug under FDA guidelines. Id. ¶¶ 81-82. The same day as the press release, ARIAD's share price fell twenty-one percent. Id. ¶ 88.

One month later, ARIAD conducted a public secondary offering of common stock ("the Offering") on January 24, 2013, id. ¶ 439, with the intention that the proceeds of the Offering be earmarked for developing and manufacturing ponatinib, id. ¶ 63. In connection with the Offering, the Underwriters prepared materials, including a prospectus supplement, to accompany existing materials such as a shelf registration statement, a

prospectus, and a number of SEC filings (collectively, "the Offering Materials"). Id. ¶ 441. ARIAD issued 15,307,000 shares in the Offering and raised $310,000,000. Id. ¶¶ 439-40.

In August 2013, ARIAD submitted follow-up data from the PACE 2 trials to the FDA. Id. ¶ 437. The new data, which covered the trial period from August 2012 to August 2013, "showed [among other things] that the rate of serious arterial thrombosis associated with ponatinib had increased from 8 [percent] to 11.8 [percent] in the time since" July 2012. Id.

Two months later, ARIAD announced that the FDA had terminated the EPIC trial, foreclosing ponatinib's approval for front-line use, which resulted in a stock value drop of forty-one percent. Id. ¶ 17. Shortly thereafter, ARIAD announced that the FDA had suspended marketing of ponatinib, resulting in a further forty-four percent drop in market value. Id. The FDA disclosed a number of serious adverse side effects occurring in ponatinib patients and stated that "[a]t this time, [the] FDA cannot identify a dose level or exposure duration that is safe." Id. ¶ 438.

After the Class Period ended, ARIAD announced on December 20, 2013 that the FDA was now allowing the marketing and distribution of ponatinib under a new label which included additional language on vascular occlusive events and heart failure. Id. ¶¶ 309-10. This re-labeling significantly

narrowed the eligible population of CML-patients, as it was relegated for third and fourth-line usage. Id. ¶ 312. The FDA issued independent safety findings on December 18, noting that "similar rates of serious vascular events have not been observed in several other drugs of this class." Id. ¶ 313.

II. ANALYSIS: Claims Against the Defendant ARIAD

A. Standard of Review

1. The Motion to Dismiss Standard

Under the Federal Rules of Civil Procedure, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). To survive a Rule 12(b)(6) motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). A mere recital of the legal elements supported only by conclusory statements is not sufficient to state a cause of action. Id. at 555.

Relatedly, "courts increasingly insist that more specific facts be alleged where an allegation is conclusory." Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp., 632 F.3d 762, 773 (1st Cir. 2011) (citing Maldonado v. Fontanes, 568 F.3d 263, 266, 274 (1st Cir. 2009)). Even at the motion to dismiss stage, "'naked assertion[s]' devoid of

'further factual enhancement'" are not entitled to a presumption of truth. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 557). "[I]t is only when . . . conclusions are logically compelled, or at least supported, by the stated facts, that is, when the suggested inference rises to what experience indicates is an acceptable level of probability, that 'conclusions' become 'facts' for pleading purposes." Cooperman v. Individual, Inc., 171 F.3d 43, 47-48 (1st Cir. 1999) (quoting Dartmouth Review v. Dartmouth College, 889 F.2d 13, 16 (1st Cir. 1989)).

2. Standard of Review in Securities Actions

In many securities actions, a heightened pleading standard applies. This is so because claims alleging fraud are subject to the stricter standards of Federal Rule of Civil Procedure 9(b), and because the Private Securities Litigation Reform Act ("PSLRA"), Pub. L. No. 104-67, codified at 15 U.S.C. § 78u-4, imposes an even more rigorous standard on scienter allegations, a required element of fraud claims under Section 10 of the Exchange Act. See Lenartz v. Am. Superconductor Corp., 879 F. Supp. 2d 167, 180 (D. Mass. 2012). PSLRA, enacted as a "check against abusive litigation by private parties," requires that plaintiffs "state with particularity both the facts constituting the alleged violation, and the facts evidencing scienter, i.e., the defendant's intention 'to deceive, manipulate, or defraud.'"

Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 313 (2007) (internal citation omitted).

Plaintiffs pleading a violation of Section 11 of the Securities Act, however, typically "need only satisfy the notice-pleading standard of Fed. R. Civ. P. 8(a)," since scienter is not an element of Section 11. Silverstrand Invs. v. AMAG Pharm., Inc., 707 F.3d 95, 102 (1st Cir. 2013). The First Circuit recognizes one exception to the "relatively minimal burden" of pleading a Section 11 claim: when the allegations supporting a Section 11 claim sound in fraud, . . . they are subject to the heightened requirements of Rule 9(b). Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1223 (1st Cir. 1996). "[C]ourts must ensure that [Section 11 allegations] truly do 'sound in fraud' before the heightened pleading standard . . . attaches." In re Number Nine Visual Tech. Corp. Sec. Litig., 51 F. Supp. 2d 1, 12 (D. Mass. 1999).

Here, the Plaintiffs' Section 10b, Rule 10b-5, and Section 20 claims sound in fraud and must therefore meet the rigorous scienter standards under the PSLRA. The Plaintiffs' Section 11 claims, however, do not sound in fraud. Compl. ¶ 417 ("Lead Plaintiffs do not allege or intend to allege any claims or assertions of fraud in connection with their claims in this section of the Complaint, which are rooted exclusively in theories of innocent and/or negligent conduct to which the

strict liability provisions of the §§ 11 and/or 15 apply . . . .”). Although the first part of the complaint contains extensive allegations of fraudulent representations and concealment by ARIAD and its management, there are no allegations in the second part of the complaint suggesting that any of the Underwriters affirmatively knew of or attempted to cause incomplete and misleading disclosures in the Offering Materials. The second part of the complaint addressing the Section 11 claims, then, is subject to the ordinary pleading standard applicable to a Rule 12(b)(6) motion to dismiss . . . See In re WebSecure, Inc. Sec. Litig., 182 F.R.D. 364, 367 (D. Mass 1998) (O’Toole, J.) (holding that Section 11 claims against underwriters do not sound in fraud because “[n]owhere in the complaint is there any allegation of scienter with regard to the underwriter defendants”).

B. Count 1: Section 10(b) and Rule 10b-5 Violations

The Plaintiffs allege that ARIAD, throughout the Class Period, provided an overly positive outlook on safety and efficacy data from the ongoing PACE 2 trial, describing the drug as “well tolerated” without full disclosure of dosage reductions and serious cardiovascular side effects that occurred in the pre-approval period. See Compl. ¶¶ 146-239. In December 2012, ARIAD’s tune changed with the disclosure of serious adverse events through ARIAD’s FDA approval announcement, resulting in

ARIAD stock price dropping more than twenty percent in a single day. Pls.' Opp'n 12. The Plaintiffs allege that ARIAD continued to make positive statements in the post-approval period, with the "full truth" only emerging in October 2013. Compl. 16.

Section 10 of the Exchange Act provides:

> It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange . . . (b) To use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

15 U.S.C. § 78j(b). To state a claim under Section 10(b) of the Exchange Act, and Rule 10b–5 promulgated thereunder, the Plaintiffs must allege that: "(1) in connection with the purchase or sale of securities, (2) the defendant made a false statement or omitted a material fact, (3) with the requisite scienter, and that (4) plaintiff relied on the statement or omission, (5) with resultant injury." Lenartz, 879 F. Supp. 2d at 180-81; see also Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 341 (2005). Materiality requires that there be "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." Basic

Inc. v. Levinson, 485 U.S. 224, 231–32 (1988) (quoting TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976)). Because these claims sound in fraud, the Plaintiffs must plead with particularity, pursuant to Rule 9(b) and PSLRA. To survive a motion to dismiss, "the plaintiff must 'specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading,'" Hill v. Gozani, 638 F. 3d 40, 55 (1st Cir. 2011) (quoting ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008)), and each alleged act or omission must "state with particularity [the] facts giving rise to a strong inference that the defendant acted with the required state of mind." Id. (quoting 15 U.S.C. § 78u-4).

1. Scienter Requirements

Section 10(b) requires the plaintiff to show scienter, i.e. that the speaker "acted with fraudulent intent or knowing or reckless disregard of his obligation to disclose." In re Boston Sci. Corp. Sec. Litig., 686 F.3d 21, 29 (1st Cir. 2012) (citing Automotive Indus. Pension Trust Fund v. Textron, Inc., 682 F.3d 34, 38–39 (1st Cir. 2012)). PSLRA requires that a strong inference of scienter be pled, amounting to a "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Tellabs, 551 U.S. at 324.

The First Circuit in N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc., 537 F.3d 35, 55 (1st Cir. 2008),

established that "[i]f there is reason to be concerned about material omissions or misrepresentations, the presence of insider trading can be used, in combination with the other evidence, to establish scienter." See also Smith v. First Marblehead Corp., No. 13-12121-PBS, 2014 WL 5460484, at *6 (D. Mass. Oct. 28, 2014) (Saris, J.) ("A strong inference of scienter can also be supported by indirect evidence," including evidence of "[i]nsider trading, or sudden sales of shares by the defendants," which is "highly probative of scienter."); cf. Mississippi Pub. Emps. Ret. Sys. v. Boston Sci. Corp., 649 F.3d 5, 29 (1st Cir. 2011) ("Insider trading cannot establish scienter on its own, but rather can only do so in combination with other evidence.").

The Plaintiffs allege that false and misleading statements were made, essentially by omission, about ponatinib and its adverse cardiovascular effects, widespread dosage reduction, and potential for front-line approval throughout the Class Period, causing ARIAD stock to trade at inflated prices. Pls.' Opp'n 19. The ARIAD Defendants counter these allegations by arguing that the Plaintiffs are unable to show that "at the time these statements were made, the ARIAD Defendants knew that the statements were false or that additional disclosures were necessary to make them not misleading." ARIAD Defs.' Mem. 7. They also posit that alleged omissions surrounding the PACE

trial and dosage reductions were, in fact, disclosed and non-material. Id. at 12. Finally, the ARIAD Defendants state that allegations of the Individual Defendants' insider trading were motivated by normal, financial incentives under allowable "Rule 10b5-1 plans," rather than by a personal profit motive, and do not support an inference of scienter. Id. at 16-17.

Upon review of the alleged misrepresentations regarding serious adverse events, dosage reductions, and forecasts on the long-term safety and efficacy of ponatinib, the Court determines that while certain material misstatements and omissions were indeed made by the ARIAD Defendants, the Plaintiffs fail to establish that they were made with scienter.

2. Pre-Approval Statements: Omissions Regarding Dosage Reduction

In the first ponatinib clinical trial, the FDA approved a maximum dosage of 45 milligrams of ponatinib for late-stage CML patients. Pls.' Opp'n 7, 23 (resulting from the PACE 1 trial which tested safety and efficacy across different dosage levels). As admitted by Harvey Berger, the chairman and CEO of ARIAD, the only way to ensure ponatinib's success as a front-line drug would be to have a successful trial using the 45 milligram dosage. Id. at 23-24 (". . . if there was widespread reduction of the dosage level below 45 mg, then ponatinib stood

virtually no chance of being approved as a 'front-line' CML treatment.").

In December 2012, ARIAD announced it had received FDA approval for ponatinib to treat patients with TKI-resistant or intolerant CML, although they had to publish a strong warning label disclosing serious cardiovascular events and lower dosage levels in the clinical study. Compl. ¶¶ 76-79, 87. The Plaintiffs argue that up to this point, investors had been kept in the dark about the overall rate of dosage reductions (amounting to approximately seventy-three percent) that occurred in the PACE 2 trial. Pls.' Opp'n 24 (describing ARIAD's statements on dosage reductions as "vague," and made in an effort to "convey that dose reductions were a relatively rare occurrence."). They point to the drop in share price from $23.88 to $18.93 on the day of the announcement as evidence that investors were surprised by the news. Compl. ¶ 88.

The ARIAD Defendants counter that dosage reductions had been made known to investors, and that alternatively, the reductions were not material information. ARIAD Defs.' Mem. 11. It is evident from the Defendants' own explanation, however, that their disclosures were lacking in substance and delivered in limited fora. The disclosures were described as follows: On December 12, 2011, Chief Medical Officer Frank Haluska mentioned that three dosage levels were used in the PACE 2 trial and that

"[i]n some cases, you go down to the next lowest level." Id. (answering an analyst's question during a webcast which was later posted to ARIAD's website). His answer made no mention of the rate of dosage reduction. In June 2012, a clinical investigator stated that "a few" patients had their ponatinib dosages reduced in order to control adverse events. Id. at 11-12 (responding to an audience member's question during an investor event). It is questionable how these two disclosures, the latter of which did not even come from an ARIAD officer, constituted meaningful disclosure of the total rate of dosage reduction affecting more than half the participants in the PACE 2 study.

The ARIAD Defendants also argue that even if the dosage reductions were not disclosed, they did not constitute material information under the "total mix of information" standard, because the overall results of the PACE 2 trial "undisputably showed ponatinib to be efficacious, a conclusion endorsed by FDA when it approved the drug in December 2012." ARIAD Defs.' Mem. 12.

This argument, that eventual FDA approval excused the disclosure of certain facts in hindsight, is problematic because it ignores the "total mix" framework for materiality. Although the Plaintiffs concede that adverse event reports were made available (albeit "buried" in the FDA website in July 2012), and

were discussed in part in ARIAD's December 11th press release, the fact that the stock value plummeted twenty-one percent on December 14th, when ARIAD announced that eight percent of patients suffered serious cardiovascular adverse events, suggests that this information had a palpable impact on the market. Compl. ¶¶ 78-79, 88. These specific disclosures omitted material information to ARIAD investors, especially in light of how important the 45 milligram dosage level was for obtaining front-line approval. See Hill, 638 F. 3d at 55 (1st Cir. 2011) ("[T]he plaintiff must 'specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading.'") (quoting ACA Fin. Guar., 512 F.3d at 58). While dosage reduction rates were material information, whether the Plaintiffs have alleged this material misrepresentation with scienter is less clear, and is discussed in Section IIB4 below.

3. Pre-Approval Statements: Positive Forecast on Ponatinib's Safety and Efficacy

Throughout the pre-approval stage, ARIAD regularly updated investors regarding the potential approval and marketability of ponatinib, noting ongoing incidents of adverse events in the PACE 2 population. ARIAD's forecast remained sunny throughout the Class Period, describing adverse events as "manageable" and "well-tolerated." Compl. ¶ 3. Early in the Class Period,

Berger told investors that he expected ponatinib to generate more than $600,000,000 in shortterm sales and over $900,000,000 in long-term sales. Pls.' Opp'n 7. In a December 2011 press release, ARIAD announced that preliminary data from the PACE trial presented a "favorable safety and tolerability profile of ponatinib in resistant or intolerant CML patients," Compl. ¶ 146-47 (noting that the Class Period began on December 12, 2011, one day after the filing of ARIAD's Form 8-K and press release). This press release listed common adverse events as including "rash," "thrombocytopenia," "dry skin," "abdominal pain," and "headache," and noted four on-study deaths as possibly related to ponatinib. Id. ¶ 146 (omitting any mention of cardiovascular side effects). On January 12, 2012, Berger spoke at a healthcare conference "distinguish[ing] ponatinib from its competitors" as a "new class of drugs." Pls.' Opp'n 7-8. On February 13, 2012, Berger commented that "[i]t appears certainly from the preliminary data . . . [a]dverse events . . . are quite manageable and . . . not something the physicians are concerned about." Compl. ¶ 163.

On December 11, 2012, an investment bank, Cowen and Company, published an analyst report which opined that "[p]onatinib's profile continues to look very benign, with few worrisome signals." Compl. ¶ 233. The most severe side effect discussed was a five percent rate of pancreatitis, but the

report noted that "only one patient discontinued therapy because of pancreatitis." Id.

Emphasizing that Berger and other company officers had "real time access" and "daily data to the patient level," Pls.' Opp'n 20, the Plaintiffs argue that the ARIAD Defendants knew of much more severe side effects that were not disclosed until December 2012, including serious arterial thrombosis in eight percent of trial patients, congestive heart failure or left ventricular dysfunction in four percent of patients (with four fatalities), and "treatment-emergent hypertension" in sixty-seven percent of patients, Compl. ¶ 148. These adverse events were reported in the July 2012 Interim Report, which formed the basis of the December 2012 FDA approval and black box warning requirement. Id. ¶¶ 433, 435.

Was ARIAD under an obligation to disclose the serious adverse events to investors prior to the December 2012 press release? This Court concludes that it was. In Matrixx Initiatives, Inc. v. Siracusano, 131 S. Ct. 1309, 1321 (2011), the Supreme Court affirmed that Section 10(b) "do[es] not create an affirmative duty to disclose any and all material information." Rather, the plaintiff must prove that "the defendant made a statement that was 'misleading as to a material fact,'" which would have created "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the

reasonable investor as having significantly altered the 'total mix' of information made available.'" Id. at 1318 (quoting Basic, 485 U.S. at 231-32, 238; accord Boston Sci. Corp., 686 F.3d at 27 (1st-Cir. 2012). Addressing whether the disclosure of specific serious adverse events should have been disclosed, the Supreme Court in Matrixx held that the incidence of anosmia (loss of smell) in users of the drug, Zicam, although not arising to a level of statistical significance, was material information to the reasonable investor and ought thus have been disclosed. Matrixx, 131 S. Ct. at 1321 ("Given that medical professionals and regulators act on the basis of evidence of causation that is not statistically significant, it stands to reason that in certain cases reasonable investors would as well.").

The ARIAD Defendants argue that they were not obligated to disclose these serious adverse events because there was no proof that ponatinib caused the cardiovascular events at the time ARIAD spoke about ponatinib's safety and tolerability. ARIAD Defs.' Mem. 9. Specifically, they argue that serious arterial ischemic events and cardiovascular issues were due to preexisting risk factors in the study group and that the trial's single-arm design did not allow the FDA to conclude whether ponatinib caused the adverse events. Id. They acknowledge that even had they known of the adverse events prior to the December

2012 press release, they (and "independent clinical investigators") truly believed that ponatinib was not the cause. Id. (citing In re Rigel Pharm. Inc. Sec. Litig., 697 F.3d 869, 880 n.8 (9th Cir. 2012), which held "as long as the omissions do not make the actual statements misleading, a company is not required to disclose every safety-related result from a clinical trial, even if the company discloses some safety-related results and even if investors would consider the omitted information significant."). Second, the ARIAD Defendants claim that they had "no way of knowing that FDA would ultimately require a boxed warning for adverse events that neither ARIAD nor FDA linked to ponatinib," id., which as a result, renders their positive statements not misleading.[2]

[2] The Court rejects arguments based on what ARIAD or investors should have gleaned from available data, whether it was what ARIAD itself should have medically concluded or what investors should have figured out on their own. The Plaintiffs argue that as medical experts, the ARIAD Defendants were "highly skilled at interpreting drug data" and "should have reached essentially the same conclusion as the FDA's experts when presented with the same data" in regards to the boxed warning. Pls.' Opp'n 22. Arguing what the ARIAD Defendants "should have" concluded as to clinical data is no substitute for the specificity of facts needed at the motion to dismiss stage. This also applies to the Defendants, who weakly assert that ARIAD investors had access to all of the adverse events disclosed on December 11, 2011, and "[a]rmed with this data, investors had all the tools to draw their own conclusions regarding ponatinib's safety and efficacy profile." ARIAD Defs.' Reply 8. These arguments fail to support either parties' position.

Regardless, the Supreme Court has held that serious adverse events and fatalities can be deemed material to investors even at non-significant rates. Matrixx, 131 S. Ct. at 1322-23 (holding that the occurrence of anosmia in approximately ten Zicam users, was deemed material information to investors even though the rate of anosmia was not "statistically significant"). The fact that ARIAD's stock price dropped more than twenty percent on December 14, 2012 with the "revelation of the significant safety issues," Pls.' Opp'n 12, and dropped again on October 9, 2013, with the announcement of more cardiovascular adverse events and the suspension of the EPIC trial, id. at 16, strongly indicates that these adverse events were material to ARIAD investors. See also Compl. ¶¶ 283-85 (the October 2013 disclosure indicated a higher rate of serious arterial thrombosis in 11.8 percent of subjects, and a study-wide dosage reduction to 30 mg of ponatinib). Even analysts noted they were unaware of serious ischemic events until the December 2012 issuance of a black box warning, stating that "the large number of side effects and the severity of the side effects came as a surprise to the investment community." Pls.' Opp'n 12-13. Finally, ARIAD itself seemed to treat adverse events as having been caused by ponatinib, as evidenced by how ponatinib use was discontinued in patients experiencing arterial thrombotic

events, and by the noted occurrences of "treatment-emergent hypertension" in the trial. Compl. ¶¶ 78-79.

The market's reaction to the December 2012 disclosures strongly suggests that the rates of serious ischemic events altered the "total mix" of information relied on by investors. Even though ARIAD was not obliged to disclose all adverse events from their clinical trials, Matrixx, 131 S. Ct. at 1321, the market's sharp reaction to the black box warning, combined with ARIAD's own assessment of adverse events as having been caused by ponatinib, indicates that the rate of serious cardiovascular events should have been disclosed in a non-misleading manner.

Whether the ARIAD Defendants made these positive statements knowing they were misleading is not explicitly supported in the pleadings. The ARIAD Defendants argue that the Plaintiffs fail to specify when and what information was known at the times pre-approval statements were made to investors. ARIAD Defs.' Mem. 8. For example, early statements from December 2011 that ponatinib was "well tolerated" may have well been true at the time they were made, because serious ischemic events (disorders related to the deficiency of blood flow to a part of the body) were not observed until a full year later. Id. (citing to the July 23, 2012 "updated data cut-off date" where ischemic events were measured in eight percent of patients). Indeed, the Plaintiffs allege that the July 2012 Interim Report data were

"facts contemporaneously known" to ARIAD at the time the statements were made, Compl. ¶ 151, but how this constitutes a "conscious[] inten[t] to defraud" or a "high degree of recklessness," In re Genzyme Corp. Sec. Litig., 754 F.3d 31, 40 (1st Cir. 2014) (quoting Boston Sci. Corp., 523 F.3d at 85), is left unexplained. First, the fact that ARIAD was under the close supervision of the FDA in the run-up to its eventual approval cuts strongly against any inference that ARIAD was acting recklessly in hiding serious ischemic events from investors. Second, the complaint is devoid of specific allegations as to how ARIAD or the Individual Defendants actively sought to conceal negative information from investors or the FDA. While this Court views serious ischemic events as material information to investors, the Plaintiffs have not demonstrated how these pre-approval omissions were made with intent to defraud and, as a result, scienter is not here adequately alleged.

4. Post-Approval Statements: Continuing Positive Outlook on Ponatinib's Success

The Plaintiffs allege that after receiving second-line FDA approval in December 2012, the Defendants continued to make statements attempting to convince the market that the negative announcements regarding the black box warning label were minor setbacks, and that ponatinib was on its way to front-line

approval. Pls.' Opp'n 25. The Plaintiffs claim that partial, misleading disclosures were made in ARIAD's March 2013 Form 10-K and Form 8-K, in its April 2013 Investor Conference Call, in the May 2013 Form 10-Q, and at a healthcare conference and shareholder meeting. See Compl. ¶¶ 248-282. For example, analysts were told that "[adverse events] are likely due to the underlying disease and pre-existing condition of the patients," id. ¶ 247, and that "ARIA[D] noted no major hurdles to [ponatinib] adoption in the estimated 2,500 CML patients switching from alternative [tyrosine-kinase inhibitors], which we believe is illustrated by the early use of the drug in the 2nd-line setting." Id. ¶ 265. At a June 2013 healthcare conference hosted by Goldman Sachs, Berger stated that "the patients in the PACE trial were heavily skewed in terms of preexisting multiple cardiovascular risk factors . . . . So, this is not your average population." Id. ¶ 274.

The Plaintiffs claim the "full truth" was revealed to the market in October 2013, marking the end of the Class Period. Id. ¶ 380. The turning point came when ARIAD announced that it was pausing enrollment in all clinical studies of ponatinib pending changes in dose and other modifications, and that the dose for current patients enrolled in their Phase 3 EPIC trial would be reduced to 30 milligrams across the group. Id. ¶ 283. Further, ARIAD disclosed that the ponatinib trials would be

modified to exclude patients with a history of arterial thrombosis resulting in heart attack or stroke. Id. This is not surprising, in light of the additional PACE 2 results released on this date, which included an increased percentage of patients with serious arterial thrombosis (now 11.8 percent of trial subjects), serious venous occlusion in 2.9 percent of subjects, and a twenty percent combined rate of non-serious and serious cardiovascular adverse events. Id. ¶ 284 (reflecting data from twenty-four months of the clinical study). This news caused ARIAD's share price to drop sixty-six percent in value, from $11.31 to $5.83 per share. Id. ¶ 285. The same day, Haluska continued to blame pre-existing risk factors in the PACE 2 patient population, and stated that "we are very confident that at the end of the day, with the dose reduction scheme that we have and the high circulating levels that can be achieved with lower doses than 45 milligrams, that the EPIC [Phase 3] trial has an excellent likelihood of being a positive trial with an appropriate benefit/risk balance." Id. ¶ 288.

The ARIAD Defendants argue that their statements were not misleading because all of the challenged information regarding serious adverse events was disclosed in the December 2012 boxed warning and press release. ARIAD Defs.' Mem. 13. Because this information and warning included the rate of dose reduction and incidence of adverse events, the ARIAD Defendants argue that

they cannot be liable for subsequent statements expressing their continuing confidence in the drug. Id. They rely on In XM Satellite Radio Holdings Sec. Litig., 479 F. Supp. 2d 165, 181 (D.D.C. 2007), which stated: "[A] company has no duty to disparage its own competitive position in the market where it has provided accurate hard data from which analysts and investors can draw their own conclusions about the company's condition and the value of its stock." (internal citations omitted). The ARIAD Defendants further attack the Plaintiffs' allegations as failing to state what information ARIAD knew at the time they made the post-approval statements, specifically, what facts were "contrary to the optimism ARIAD was portraying publicly." ARIAD Defs.' Reply 9. In response, the Plaintiffs rely on general allegations that ARIAD "must have known, because it eventually knew, that the rate of cardiovascular events had increased." Id.

Here, the Defendants have the stronger argument. While the Complaint contains reports from analysts that mark frustration with the partial disclosures and the ensuing dips in stock price, Compl. ¶ 298 ("Management had repeatedly asserted safety concerns for [ponatinib] were a Wall Street misconception"), the Plaintiffs do not pinpoint exactly what clinical trial data was known by the Defendants in 2013 at the time they made post-

approval statements touting the safety and efficacy of ponatinib.

5. Scienter: Insider Trading Allegations

Accordingly, the Court takes a closer look at the Plaintiffs' allegations of insider trading to see if these claims bolster their scienter theory. The Plaintiffs attempt to bolster their scienter theory with allegations that the Individual Defendants, all ARIAD officers, engaged in sudden and unusual sales of stock during the Class Period. Compl. ¶¶ 93-97. Although the Plaintiffs provide a cogent argument that insider trading was taking place, this evidence, along with all other allegations of scienter, insufficiently supports that material misrepresentations were knowingly or recklessly made by the ARIAD Defendants.

The Plaintiffs support their scienter theory by highlighting the Individual Defendants' large and unusual Class Period stock sales which generated "enormous abnormal profits," especially in light of the fact that ponatinib was ARIAD's most important product. Pls.' Opp'n 28; see also Compl. 103.

It is clear that the four Individual Defendants engaged in vastly different sales practices before the Class Period as compared to during the Class Period: stock sales prior to the Class Period totaled $666,000, but sales during the Class Period exceeded $28,000,000. Pls.' Opp'n 28. Berger, for example, did

not sell any ARIAD shares in the twenty-two months prior to the Class Period, but sold approximately $16,964,700 in stock during the same amount of time during the Class Period. Id. at 29. The Plaintiffs also allege that the Individual Defendants' shares were sold in irregular amounts and intervals throughout 2012, rather than in the pre-determined amounts and intervals commonly found under Rule 10b5-1 trading plans. Compl. ¶¶ 366-367.[3]

Rule 10b5-1 trading plans provide an affirmative defense for insiders who trade before they become aware of insider knowledge, and do so in good faith "and not as a part of a plan or scheme to evade the prohibitions" against insider trading. See SEC Rule 10b5-1(c); Compl. ¶ 358. The Individual Defendants however, enacted their trading plans during the Class Period (Clackson, Fitzgerald, and Haluska enacted ten days into the Class Period, and Berger enacted his plan in December 2012). Pls.' Opp'n 31; see also Freudenberg v. E*Trade Fin. Corp., 712 F. Supp. 2d 171, 201 (S.D.N.Y. 2010) (holding that "[t]rading

[3] For example, Clackson acquired approximately 160,000 shares during the twenty-two months prior to the Class Period and sold 43 percent of his share acquisitions, but acquired 545,017 shares during the Class Period and sold 69 percent of his acquisitions. Id. ¶ 345 (both Fitzgerald and Haluska had similar jumps in shares acquired and sold before and during the Class Period). Further, none of the Individual Defendants purchased any ARIAD stock during the Class Period with their personal funds. Id. ¶ 343. The Plaintiffs describe these trades as "well-timed." Id. ¶ 351.

plans are not a cognizable defense to scienter allegations on a motion to dismiss where, as here, they were adopted during the Class Period"). Berger's trading plan, enacted in late December 2012 after the announcement of FDA approval, "was purportedly designed to sell 100,000-share blocks of stock at monthly intervals from March through August 2013 whenever ARIAD's share price rose above a pre-determined floor price" which allowed Berger to realize over $16,000,000 in profits. Compl. ¶ 94.

The Individual Defendants explain that the sharp contrasts in sales were based on tax reasons and were enacted after adverse events from the PACE trial were disclosed. ARIAD Defs.' Mem. 14 ("A generic profit motive . . . is too universal to demonstrate scienter in a specific case."); see also ARIAD Defs.' Reply 12-13. Moreover, they argue that the Plaintiffs fail to demonstrate how these trading plans were used "to avoid a stock price drop anticipated from their foreknowledge of a release of bad news." Id. at 13.

This Court acknowledges that the sheer contrast in trading volume and frequency before and after the Class Period supports an allegation of insider trading, suggesting that strategic sales were made in light of key non-public information arising from the PACE trial. But the allegations of insider trading do not amount to a strong inference of scienter, even coupled with other allegations in the complaint. As analyzed above, the

complaint generalizes claims that Individual Defendants knowingly withheld material information relating to results of the PACE 2 trial. The Plaintiffs fail to connect exact disclosures with specific conduct or inside knowledge of clinical data. Even with their stronger insider trading claim, the Plaintiffs are unable to connect exact trading periods with specific, negative results from the clinical trial. This leaves the Court unable to glean a strong inference of scienter from the facts alleged. On this basis, the Court GRANTS the ARIAD Defendants' Motion to Dismiss Section 10 and Rule 10b-5 claims for a failure to state a claim.

C. Count II: Section 20(a) Claims

Because claims brought under Section 20(a) of the Exchange Act are derivative of Rule 10b-5 claims, liability can attach only to a person who is liable for violating a substantive provision of the Exchange Act. See Hill, 638 F.3d at 53; see also Janus Capital Grp., Inc. v. First Derivative Traders, 131 S. Ct. 2296, 2310 (2011) ("More importantly, a person who is liable under § 20(a) controls another "person" who is "liable" for a securities violation.") (internal citation omitted). Because the Court dismisses Section 10 claims against the ARIAD Defendants, no Section 20 liability can be assigned to the four Individual Defendants named in this action.

D. Conclusion

The Court GRANTS the ARIAD Defendants' motions to dismiss Counts I and II under Section 10 and Section 20. The Plaintiffs' Section 11 and Section 15 claims are discussed below in conjunction with the same claims brought against the Underwriters.

III. ANALYSIS: Claims Against the Underwriters Defendant

The Plaintiffs allege that the ARIAD and Underwriter Defendants are liable under Section 11 of the Securities Act of 1933 for alleged misstatements and omissions in stock offering materials. Compl. ¶ 416. ARIAD and the Underwriter Defendants seek dismissal of all Section 11 claims against them on the basis that the Plaintiffs lack standing and that they fail to state a claim.[4] See ARIAD Defs.' Mem. 17-20; see also Underwriter Defs.' Mem. 1.

A. Legal Standard: Section 11 and Section 15 of the Securities Act

Section 11 of the Securities Act creates a cause of action empowering purchasers of securities offered under a false or misleading registration statement to sue certain enumerated parties. Specifically, the statute "impos[es] a stringent

[4] The Underwriters provided significantly more in-depth briefing on Section 11 claims than did the ARIAD Defendants. Accordingly, this section of the Memorandum and Order will focus heavily on the arguments presented in the Underwriters' briefs, although the Court will address both the ARIAD Defendants and Underwriters' motions to dismiss.

standard of liability on the parties who play a direct role in a registered offering," Herman & MacLean v. Huddleston, 459 U.S. 375, 381-82 (1983), a category which includes participating underwriters. See 15 U.S.C. § 77k(a)(5). As mentioned above, the Section 11 claims in this action do not sound in fraud and are subject to the ordinary pleading standards under Rule 12 of the Federal Rules of Civil Procedure.

Section 15 of the Securities Act imposes secondary liability on "control persons" of a company for violations of Sections 11 and 12 of the Securities Act. Joint and several liability attaches "only to the extent primary liability first attaches to a 'controlled person.'" Lenartz, 879 F. Supp. 2d at 188 ("Section 15 imposes joint and several liability on any person who, through stock ownership, agency or otherwise, controls any person liable under Section 11 or Section 12."). To prove a violation, the plaintiffs "must allege 1) an underlying violation by the controlled person or entity and 2) that the defendants controlled the violator." In re Evergreen Ultra Short Opportunities Fund Sec. Litig., 705 F. Supp. 2d 86, 96 (D. Mass 2010) (Gorton, J.) (citing Aldridge v. A.T. Cross Corp., 284 F.3d 72, 85 (1st Cir. 2002)).

B. Standing

The ARIAD Defendants and Underwriters challenge the Plaintiffs' standing to bring Section 11 claims against them.[5] See Underwriter Defs.' Mem. 4-8; see also ARIAD Defs.' Mem. 17-20. According to the Underwriters, the Plaintiffs have not sufficiently alleged that they purchased ARIAD shares issued under the challenged 2013 Offering, as opposed to ARIAD shares issued in previous stock offerings. Underwriter Defs.' Mem. 5-6.

Section 11 confers standing only on persons who acquired the specific securities issued under the challenged registration statement. 15 U.S.C. § 77k(a) (referring to "any person acquiring such security"). This requirement is satisfied whether the plaintiff purchased shares in the public offering itself or in the secondary market, so long as the plaintiff can trace the origin of his shares back to the offering in dispute. In re Number Nine, 51 F. Supp. 2d. at 11-12. It follows that a person holding shares issued in a different, undisputed offering does not have standing to join a Section 11 action, as he cannot be said to have relied on the purportedly fraudulent

[5] Challenges to Section 11 standing like this one attack statutory standing, not Article III standing. See Cooperman v. Individual, Inc., 171 F.3d 43, 47 n.3 (1st Cir. 1999). The jurisdiction of the Court is therefore not at issue when considering such a challenge. See In re Eaton Vance Corp. Sec. Litig., 219 F.R.D. 38, 41-42 (D. Mass. 2003) (Harrington, J.).

registration materials. See Plumbers' Union Local No. 12 Pension Fund, 632 F.3d at 768 n.5 (incorporating by reference and quoting the holding in Barnes v. Osofsky, 373 F.2d 269, 273 (2d Cir. 1967), that only "those who purchase securities that are the direct subject of the prospectus and registration statement" may bring a Section 11 claim).

At the motion to dismiss stage, the relevant issue for the Court to analyze is whether the Plaintiffs adequately have pled that they purchased securities traceable to the challenged offering. The parties in this action disagree as to the appropriate standard of pleading. The Plaintiffs contend that general allegations, akin to notice pleading, are sufficient in the First Circuit. Pls.' Opp'n 35-37. But the Underwriters argue that in the wake of Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), and Ashcroft v. Iqbal, 556 U.S. 662 (2009), more is required.

1. This Court's Rule Prior to Twombly and Iqbal

Case law preceding the publication of Twombly and Iqbal shows that in the District of Massachusetts prior to 2007, this issue was settled by a line of cases analyzing the impact of Gustafson v. Alloyd Co., Inc., 513 U.S. 561 (1995), on Section

11 standing.[6] This Court's practice has been to hold general allegations sufficient to survive a motion to dismiss for lack of standing. E.g. In re Number Nine, 51 F. Supp. 2d at 9, 11-12 (denying a motion to dismiss because the complaint alleged simply that the plaintiffs purchased securities "in or traceable to" the contested stock offering). This is consistent with the pre-2007 rulings of other sessions in the District of Massachusetts. See, e.g., In re Transkaryotic Therapies, Inc. Sec. Litig., 319 F. Supp. 2d 152, 159 (D. Mass. 2004) (Zobel, J.) (holding a plaintiff's allegation that he purchased shares traceable to a specific offering sufficient to state a Section 11 claim); In re WebSecure, 182 F.R.D. at 367-68 (D. Mass. 1998) (O'Toole, J.) (ruling that proper standing was pled by unvarnished allegations that plaintiffs "purchased their stock pursuant to or traceable to the defective Registration Statement") (quotation marks omitted); Cooperman v. Individual, Inc., No. 96-12272-DPW, 1998 WL 953726, at *7 (D. Mass. May 27, 1998) (Woodlock, J.) ("Plaintiffs have standing under Section 11

[6] In the wake of Gustafson, this Court and other sessions in the District of Massachusetts determined that holders of securities "traceable to" a fraudulent offering had Section 11 standing even if they did not directly purchase those securities from the issuer at the time of the offering. In coming to this conclusion, this Court and its colleagues consistently denied motions to dismiss for lack of standing in favor of plaintiffs who had made only allegations, without more, that their shares were traceable to a contested offering. These rulings indirectly affirm that general allegations of the kind pled in this action were enough to survive a motion to dismiss.

if they purchased shares . . . 'traceable to' the public offering. Because Plaintiffs allege as much in the Complaint, I will not grant the motion to dismiss on this ground.") aff'd on other grounds, 171 F.3d 43 (1st Cir. 1999). This issue has not been squarely addressed by the First Circuit or revisited in the District of Massachusetts since the publication of Twombly and Iqbal.

2. Developments Since Twombly and Iqbal

Jurisprudence is emerging in at least one other circuit holding that Section 11 standing must be pled with greater particularity than the standard articulated above. The most prominent decision promulgating this interpretation recently was rendered by the Ninth Circuit in In re Century Aluminum Co. Sec. Litig., 729 F.3d 1104 (9th Cir. 2013). In that case, the Ninth Circuit observed that although general allegations of traceable stock purchases were "probably" sufficient to survive a motion to dismiss before 2007, "Iqbal and Twombly moved us away from a system of pure notice pleading." Id. at 1107.

The Ninth Circuit applies this principle by requiring particular factual specificity when the plaintiffs hold shares that could have been issued in any one of multiple stock offerings. Under In re Century Aluminum, this standard expressly cannot be satisfied by a "conclusory allegation" that plaintiffs purchased stock directly traceable to a particular

offering. Id. at 1108. Because "experience and common sense tell us that . . . [such] aftermarket purchasers usually will not be able to trace their shares back to a particular offering," plaintiffs must "allege facts from which we can reasonably infer that their situation is different." Id. at 1107-08.

The In re Century Aluminum plaintiffs attempted to accomplish this by showing that they purchased shares during periods of extreme change in trading volume and stock price, likely attributable to the issuance of new shares flooding the secondary market. Id. at 1108. But the Ninth Circuit ruled that such evidence was insufficient to support a reasonable inference that the plaintiffs' shares were traceable to any particular offering. "[T]he 'obvious alternative explanation' [was] that [the shares] could instead have come from the pool of previously issued shares. Plaintiffs' allegations [were] consistent with their shares having come from either source." Id. (citing Twombly, 550 U.S. at 567) (internal citation omitted). Without "facts tending to exclude the possibility that the alternative explanation is true," the plaintiffs' explanation was "merely possible rather than plausible." Id.

At the district court level, a split on this issue is emerging. In addition to the decisions of district courts bound by this precedent, at least two district court decisions outside

of the Ninth Circuit have endorsed a similar approach to pleading Section 11 standing. See Ho v. Duoyuan Global Water, Inc., 887 F. Supp. 2d 547, 561 (S.D.N.Y. 2012); Grand Lodge of Pa. v. Peters, 550 F. Supp. 2d 1363, 1376 (M.D. Fla. 2008). Recent decisions of other district courts, however, hold that general allegations of traceability continue to be sufficient to allege Section 11 standing. See In re Mun. Mortg. & Equity, LLC, Sec. & Derivative Litig., 876 F. Supp. 2d 616, 657-58 (D. Md. 2012); In re Wachovia Equity Sec. Litig., 753 F. Supp. 2d 326, 373 (S.D.N.Y. 2011); see also Northumberland Cnty. Ret. Sys. v. Kenworthy, No. CIV-11-520-D, 2013 WL 5230000, at *6 (W.D. Okla. Sept. 16, 2013); Perry v. Duoyuan Printing, Inc., No. 10 Civ. 7235 GBD, 2013 WL 4505199, at *9-10 (S.D.N.Y. Aug. 22, 2013).

The Defendants more or less urge this Court to disregard any decision relying on pre-Twombly and pre-Iqbal cases. Underwriter Defs.' Reply 3. Twombly and Iqbal did not, however, so fundamentally alter the Rule 8 pleading standards so as to render all prior pleading jurisprudence immaterial. Surely the district court decisions holding that general allegations continue to suffice post-Twombly and Iqbal recognized those Supreme Court precedents. Those courts simply reached a conclusion different from the Ninth Circuit as to the effect of Twombly and Iqbal on Section 11 standing allegations.

3. Maintaining the Court's Previous Rule

In the absence of additional guidance or evidence that the Ninth Circuit is not an outlier among circuits on this issue, this Court takes a conservative approach to the Underwriters' challenge and hews to the established pre-Twombly standard. This Court holds that general allegations that the Plaintiffs hold traceable shares are sufficient to plead standing under Section 11, even if those allegations are unaccompanied by more specific corroborating allegations.

Under this rule, the Plaintiffs' complaint passes muster, and the Court DENIES the ARIAD and Underwriter Defendants' motion to dismiss for lack of standing.

C. Material Misstatements and Omissions

The Underwriters argue in the alternative that the Plaintiffs have failed to allege actionable misstatements or omissions made in the Offering Materials. To make out a Section 11 violation, the Plaintiffs "need only show a material misstatement or omission to establish [their] prima facie case." Herman & MacLean, 459 U.S. at 382 (1983). The First Circuit has identified four elements that must be alleged: "(1) that [the company's] prospectus contained an omission; (2) that the omission was material; (3) that defendants were under a duty to disclose the omitted information; and (4) that such omitted

information existed at the time the prospectus became effective." Cooperman, 171 F.3d at 47.

In their complaint, the Plaintiffs refer to misstatements and omissions in three areas: (1) the alleged increasing incidence of "serious cardiovascular adverse events" related to ponatinib throughout 2012, e.g., Compl. ¶ 446, (2) the alleged infeasibility of the recommended prescribed 45 milligram dose of ponatinib in the majority of patients, e.g., id. ¶ 447-48, and (3) the allegedly dwindling potential of ponatinib's approval for front-line use, e.g., id. ¶ 449. The Plaintiffs additionally allege that the Offering Materials failed to disclose "that the incidence of adverse cardiovascular events in PACE 2 had or was reasonably expected to have a material . . . unfavorable impact on . . . revenues," in violation of Item 303 of Regulation S-K. Id. ¶ 472 (internal quotation marks omitted).

According to the Underwriters, all material information related to these claims and existing as of January 2013 was fully and accurately disclosed. They contend that the Plaintiffs have failed adequately to allege that their assertions regarding adverse cardiovascular events, dosage, and ponatinib's potential for front-line use were true and known to the Underwriters at the time of the January 2013 stock offering. See Underwriter Defs.' Mem. 8-20.

1. Trends in Adverse Cardiovascular Events

The parties disagree as to whether information about adverse cardiovascular events related to ponatinib was fully disclosed in the Offering Materials. The Underwriters assert that such information was fully disclosed because the Offering Materials expressly incorporated, among other things, the results of ARIAD's July 2012 Interim Report on the progress of its PACE 2 trials. Id. at 8. The Plaintiffs counter that the Offering Materials contained no information on PACE 2 results between July 2012, the cut-off date of the interim report, and January 2013, the time of the stock offering. Pls.' Opp'n 38. During this time, the Plaintiffs say, the incidence of adverse events was worsening, which would have been material to prospective investors. Id.; see also Compl. ¶ 462.

a. The July 2012 Interim Results

It is undisputed that at the time of the January 2013 Stock Offering, the information available to investors about a possible link between ponatinib and adverse cardiovascular events was not uniformly positive. Recall that one month before the offering, on December 14, 2012, ARIAD issued a press release announcing the FDA's limited approval of the drug with a serious "black box" warning on its label. Compl. ¶ 435. The announcement of this development made public the results from the July 2012 Interim Report on the progress of the PACE 2

clinical trials, as that report was the basis for the FDA's decision to grant conditional approval. Id. According to the Plaintiffs' complaint, the July 2012 Interim Report "showed an increase in both adverse and 'serious' adverse cardiovascular events in patients taking ponatinib." Id. ¶ 433. Accordingly, the drug's black box warning was required to list several types of adverse cardiovascular events experienced by ponatinib-treated patients and specifically disclose that "serious arterial thrombosis occurred in 8 [percent] of . . . patients." Id. ¶ 435.

b. August 2013 Results as a Basis for Alleging Trends Between July 2012 and January 2013

The Underwriters vigorously attest that these developments and underlying data were fully disclosed in the Offering Materials. Underwriter Defs.' Mem. 8. The Plaintiffs do not dispute this, but they point out that by the time of the stock offering, ARIAD had collected approximately six months of additional clinical trial data beyond July 2012, none of which was provided to participating investors. Pls.' Opp'n 38. The December disclosure that eight percent of patients experienced arterial thrombosis was, according to the Plaintiffs, only a "snapshot in time of adverse event data" as of July 2012, "reveal[ing] nothing about the trends or uncertainties then known to Defendants" as of January 2013. Id. at 39. The

Plaintiffs' complaint and brief go on to allege that the PACE 2 data from July 2012 through January 2013 was unfavorable and "gave rise to material, adverse facts, trends, and uncertainties" requiring disclosure, "including that adverse events were increasing over time." Id. at 38; see also Compl. ¶¶ 446-49.

These characterizations are based on a report submitted to the FDA in August 2013, providing eleven months of follow-up data on the PACE 2 clinical trials after July 2012. Id. ¶ 437. The August 2013 report showed, for example, "that the rate of serious arterial thrombosis associated with ponatinib had increased from 8 [percent] to 11.8 [percent] in the time since the July 2012 Interim PACE 2 Report." Id.

The Underwriters point out that the August 2013 report provides aggregated data from both before and after the January 2013 stock offering. Underwriter Defs.' Mem. 12. The Plaintiffs' allegations rely on the report's results without differentiating between pre- and post-offering data. According to the Underwriters, this lack of specificity prevents the Court from being able to draw a reasonable inference that the adverse trends established as of August 2013 were known as of January 2013. Id.

c. Pleading Standard Under Shaw

The Underwriters' argument is a compelling one. Even though Rule 9(b) pleading standards do not apply here, this Court has held that when a complaint pleads "the alleged nondisclosure of information premised on a subsequent announcement or disclosure of such information," such allegations "address matters of projection or forecast to which a stricter standard of pleading attaches." In re Number Nine, 51 F. Supp. 2d at 24. Such heightened pleading is required in the First Circuit because of the risk that "the plaintiff's claim of nondisclosure may be indistinguishable from a claim that the issuer should have divulged its internal predictions about what would come of the undisclosed information." Shaw, 82 F.3d at 1211 (1st Cir. 1996). Thus, while allegations that disclosure was required in "relat[ion] to a specific, verifiable fact" are accepted as true under the classic dismissal standard, allegations that information should have been disclosed as "a matter of judgment or projection" are not entitled to the same benefit of the doubt. In re Number Nine, 52 F. Supp. 2d at 24.

Since the Plaintiffs' allegations regarding adverse cardiovascular events fall in the latter category, the question for the Court to resolve is whether "the allegedly undisclosed information is sufficiently remote in time or causation from the ultimate events of which it purportedly forewarned." Shaw, 82

F.3d at 1211. That means determining whether the increasing trend in adverse cardiovascular events "is of such a nature that it is reasonable to infer its existence at the time of the Offering from a disclosure some eight months later." In re Number Nine, 51 F. Supp. 2d at 16.

d. Fact-Specific Analysis

"As desirable as bright-line rules may be, this question cannot be answered by reference to such a rule." Shaw, 82 F.3d at 1210. Previous decisions addressing this subject turn on fact-intensive and contextual analysis. See, e.g., Cooperman, 171 F.3d at 48 (holding that the departure of the defendant company's CEO in July 1996 supported a reasonable inference that material information regarding conflict within the board of directors was omitted from March 1996 offering materials, because "[o]ur experience indicates that Board-level conflicts . . . do not arise or disappear overnight") (internal quotation marks and citation omitted); Shaw, 82 F.3d at 1211 (holding that disastrous end-of-quarter results supported a reasonable inference that material information was omitted from a prospectus filed eleven days before the end of the quarter, with no mention of the coming "extreme departure" from previous financial performance); In re Number Nine, 52 F. Supp. 2d at 17 (holding that an inventory markdown eight months after a public offering did not support a reasonable inference that material

information about the inventory's obsolescence was omitted from the prospectus, in part because "the computer industry is a field marked by rapid technological advances") (internal quotation marks and citation omitted).

The instant case presents a close call. On the one hand, the six months of data collected from August 2012 to January 2013 represents a significant, albeit not overwhelming, portion of the three-year PACE 2 study, and it covers half of the period tracked by the August 2013 follow-up study that caused the FDA to suspend sales and marketing of the drug. Further, the FDA's October 2013 safety announcement referred to an "increasing rate and pattern" of adverse events and warned that "[i]n some patients, fatal and serious adverse events have occurred as early as 2 weeks after starting Iclusig [ponatinib] therapy." Compl. ¶ 438. Given the alleged importance of ponatinib to ARIAD, see Compl. ¶ 429, it is likely that the progress of the PACE 2 was closely monitored, meaning that any trends presenting in the data likely would be known almost immediately. These facts are consistent with a conclusion that ARIAD knew at the time of the Offering that the prognosis for ponatinib was even worse than the July 2012 results suggested.

On the other hand, it is common sense that data collected over too short of an interval cannot be a basis for reliable conclusions about something so complex and multivariable as a

cancer treatment drug. If the Offering had occurred two weeks after the July 2012 interim report cut-off date, it is unlikely that the Plaintiffs would claim a Section 11 violation for the omission of two weeks of follow-up data. The question is therefore as follows: is six months of follow-up data enough to trigger a reasonable inference that a reliable trend was evident?

One possible touchstone could be the actions of the FDA. Again, the FDA based its December 2012 decision to approve ponatinib with a black box warning on ARIAD's results from July 2012. Compl. ¶ 435. In so doing, the agency did not examine data collected between July 2012 and the time of its decision. It instead required ARIAD to submit follow-up data over a twelve-month window after the interim report. Id. ¶ 436. This might suggest that in the FDA's judgment, data from July to December 2012 was not likely to be sufficient to alter the agency's assessment of ponatinib's safety profile.[7] The Court might reason from this that data over nearly the same time period, July 2012 to January 2013, similarly could not have been relied on to draw sound conclusions about ponatinib's safety.

[7] The FDA's actions could also suggest, however, nothing more than the fact that it is a government agency with limited resources to monitor pharmaceutical clinical trials. It could be that the agency does not have much capacity to check up on the progress of drug trials at intervals shorter than twelve months.

Further, the Plaintiffs plead few facts that would allow the Court to infer with any particularity how troubling the PACE 2 results were at the time of the Offering. The Complaint contains, for example, no allegations describing the nature of the rate of increase in adverse cardiovascular events. It could be that the incidence of such events steadily increased throughout the clinical trial, such that ARIAD could reasonably expect that results would only worsen beyond the disclosed July 2012 results. But it could also be that the adverse reactions to ponatinib presented at irregular intervals throughout the three-year trial, or that the majority of adverse events occurred at the tail end of the study after prolonged use of ponatinib.

Given these uncertainties, the Court rules that the PACE 2 results as of August 2013 do not support a reasonable inference that materially adverse trends -- beyond what was disclosed in the July 2012 Interim Report -- existed at the time of the Offering a full eight months prior. It is certainly possible that negative trends already had manifested in the data by that point, but absent more factual detail about the specific results collected through January 2013, these pleadings "stop[] short of the line between possibility and plausibility." Twombly, 550 U.S. at 546.

The Court rules that the complaint does not allege facts sufficient to support a reasonable inference that a materially worsened trend in adverse cardiovascular events existed in the PACE 2 trials at the time of the Offering.

2. Dosage Reductions

Plaintiffs further allege that the Offering Materials omitted material information regarding the dosages of ponatinib administered to patients in ARIAD's clinical trials. Specifically, the Offering Materials allegedly failed to disclose

> that the drug was toxic at the 45 mg dose; that the PACE 2 data in the July 2012 Interim Report showed that 73 [percent] of PACE 2 patients were given a less efficacious, lower dose in order to reduce adverse events and continue to tolerate the drug, or taken off ponatinib altogether; that therefore the more effective 45 mg "recommended dose" was not a feasible dose that could be maintained; and that follow-up data from the PACE 2 trial showed that patients continued to receive reduced doses of ponatinib.

Compl. ¶ 466. The Underwriters seek dismissal of claims based on these alleged omissions, arguing that the Plaintiffs' assertions here either are insufficiently pleaded or were fully disclosed in the Offering Materials.

a. "Toxic" and "Not a Feasible Dose"

Two of the Plaintiffs' alleged omissions are but conclusory allegations. The complaint does not plead any specific facts to support its allegations that the recommended 45 milligram dose

of ponatinib was "toxic" or "not a feasible dose that could be maintained." Compl. ¶ 466. The Plaintiffs' most concrete allegation in this area, that many patients had their dosage adjusted downward from 45 milligrams, does not support an inference that the 45 milligram dose was toxic or infeasible –- particularly if, as is suggested in the complaint, some patients did maintain the recommended dosing regimen. See Compl. ¶ 466 (referring to the PACE 2 interim results showing that 73 percent of patients received lower doses of ponatinib, implying that 27 percent of patients were able to maintain 45 milligram doses).

Without allegations laying out, for example, the clinical standard for toxicity, ponatinib's relationship to that standard at the 45 milligram dose, or other verifiable facts that ARIAD could have known that would make the drug "toxic," the Plaintiffs' allegations are baseless. See Oxford Asset Mgmt., Ltd. v. Jaharis, 297 F.3d 1182, 1193 (11th Cir. 2002) (rejecting a similar allegation on the basis that "[n]o studies are referred to, [and] no specific facts are pleaded that indicate any basis for Oxford's bald assertions that Niaspan elevates liver enzymes to an intolerable level").

The Court rules that there was no material misstatement or omission in the Offering Materials for failure to disclose that ponatinib was "toxic" or infeasible at the 45 milligram dose.

b. Dosage Reductions in July 2012 Interim Report

Second, the Plaintiffs allege that the Offering Materials failed to disclose that 73 percent of PACE 2 patients as of July 2012 were prescribed lower doses of ponatinib to mitigate adverse effects. The Underwriters contend "that this data was publicly disclosed prior to the Offering, including in materials that were incorporated into the Offering Materials." Underwriter Defs.' Mem. 15 (emphasis omitted). They refer to a number of sources that allegedly publicized the data, including (1) Full Prescribing Information prepared by the FDA, ECF No. 146-3, published on the FDA's and ARIAD's websites, and referred to in a December 14, 2012 press release which was in turn incorporated into the Offering Materials, Underwriter Defs.' Mem. 15; (2) a report of the FDA's Center for Drug Evaluation and Research ("CDER"), published on the FDA's website in late 2012, FDA CDER Report, ECF No. 146-4; and (3) a December 14, 2012 conference call in which ARIAD's chief medical officer fielded questions from a number of investment analysts, Transcript, ECF No. 146-5.

The Court is empowered, at the least, to take judicial notice of the FDA's Full Prescribing Information and the FDA CDER report as public records. See In re Colonial Mortg. Bankers Corp., 324 F.3d 12, 19 (1st Cir. 2003) ("[M]atters of

public record are fair game in adjudicating Rule 12(b)(6) motions, and a court's reference to such matters does not convert a motion to dismiss into a motion for summary judgment.") (citation omitted); see also Romani v. Shearson Lehman Hutton, 929 F.2d 875, 879 (1st Cir. 1991) (taking notice of offering documents submitted by the defendants in connection with their motion to dismiss a securities action). Further, the Plaintiffs do not address these documents in their reply brief, failing to challenge the public nature or authenticity of any of these documents. See Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993) (noting the willingness of courts adjudicating a motion to dismiss to consider "documents the authenticity of which are not disputed by the parties; for official public records; for documents central to plaintiffs' claim; or for documents sufficiently referred to in the complaint"). These records show that not only was the rate of down-dosing in the July 2012 Interim Report public knowledge by the time of the Offering, the statistic was at least indirectly incorporated into the Offering Materials.

The Court rules that as to dosage reduction data in the July 2012 Interim Report, no material omission was made from the Offering Materials.

c. Continued Dose Reductions After July 2012

The Plaintiffs allege that the Offering Materials were misleading because they failed to mention that patients in the PACE 2 study continued to have their ponatinib doses adjusted downward after July 2012. Compl. ¶ 466. The Underwriters respond that the complaint "allege[s] no facts supporting this allegation of 'continued' dose reductions, let alone facts suggesting any such reductions were in any way different in frequency or scope from the reductions disclosed in the Offering Materials." Underwriter Defs.' Mem. 16.

This element of the Plaintiffs' complaint is problematic for two reasons. First, as the Underwriters point out, the complaint contains virtually no facts that would support a reasonable inference that dose reductions continued in the six months prior to the Offering. The complaint does not even refer in this context to the results of the August 2013 study, making the continued dose reductions claim even more lacking in support than the Plaintiffs' claim of increased adverse cardiovascular events. The only basis offered to support the allegation that dose reductions continued is a perfunctory reference to confidential witnesses, Compl. ¶ 466, but no elaboration beyond the single use of the term "CWs" is provided. The Plaintiffs do not offer more than a conclusory assertion of continued dose reductions.

Second, even if the Court accepts this unsubstantiated assertion as true, the allegation as pled does not make out a claim of material omission. As discussed in the preceding section of this memorandum, the rate of dose reductions in the PACE 2 interim results as of July 2012 was public and available to potential investors at the time of the Offering. It was also evident to investors from ARIAD's disclosures throughout 2012 that actual dose administration could be expected to depart from the planned recommended dose of 45 milligrams. See Compl. ¶ 465 (quoting statements regarding the 45 milligram dose in Forms 8-K filed before the disclosure of the July 2012 interim results, which are virtually identical to statements made in the Offering Materials after the interim results became public). Disclosing that the rate of dose adjustments remained the same between July 2012 and January 2013 would have done nothing to "significantly alter[] the total mix of information made available" to investors. Basic, 485 U.S. at 232 (internal quotation marks and citations omitted).

The Court rules that the complaint does not plead sufficient facts to support a reasonable inference that dose reductions continued at the same rate from July 2012 to January 2013, and also rules that even if continued dose reductions occurred, it was not a material omission to fail to disclose them in the Offering Materials.

3. Ponatinib's Potential for Front-Line Use

The third category of misrepresentations alleged by the Plaintiffs deals with ponatinib's prospects for "front-line" treatment of CML. ARIAD's Prospectus Supplement contained statements describing the company's "initial commercial strategy" to market ponatinib to "second-line" CML patients, and estimating global sales that "may reach $1 billion by 2018." Compl. ¶ 467. According to the Plaintiffs, these statements were materially untrue because they did not disclose "that the drug's potential for front-line use was dramatically decreasing based on (1) the increasingly negative safety profile relating to cardiovascular events, and (2) the necessary down-dosing from the more effective 45 mg dose to the less effective 30 mg and 15 mg doses." Id. ¶ 468.

a. Reliance on Other Insufficient Allegations

In the same vein as the preceding sections of this memorandum, this part of the complaint offers weak support for its allegations. The relevant assertion here is even further undermined because it relies on allegations which are themselves poorly supported by the Plaintiffs' pleadings. That is, the idea that ponatinib's prospects for front-line use were "dramatically decreasing" expressly depends on the Plaintiffs' allegations that (1) a worsening trend in adverse cardiovascular events was cognizable as of January 2013 and (2) continued down-

dosing occurred -- premises that this Court does not accept as true, for reasons explained in the earlier sections of this memorandum. Since the factual allegations underlying this part of the complaint are not sufficiently pled to be accepted as true, the Court has ample reason to rule that the complaint's assertion about ponatinib's declining chances for front-line use approval is also insufficiently pled.

b. No Misrepresentation

This Court also rules that no actionable misrepresentation or omission has been made with regard to ponatinib's front-line potential. First, the Plaintiffs' allegation that ponatinib's front-line potential was rapidly declining at the time of the Offering, even if accepted as true, has no bearing on the truth of ARIAD's statement that its initial commercial strategy at the time of the Offering was to market ponatinib for second-line use (targeting patients with a demonstrated resistance to more established CML treatments). In fact, the complaint pleads numerous facts confirming the truth of ARIAD's statement at the time of the Offering, e.g. that ponatinib was approved by the FDA for second-line use, id. ¶ 435, and that the PACE trials assessing second-line use were much further along than the EPIC trial aimed at supporting front-line use, id. ¶¶ 430-34. It is difficult to see how the truth of a statement regarding ARIAD's

strategy in the present could be undermined by dim prospects for a completely different future strategy.[8]

The Court rules that no material misrepresentation or omission was made by the statement regarding ARIAD's "initial commercial strategy."

c. Forward-Looking Statements Under the PSLRA Safe Harbor

As for the statement regarding global sales projections identified by the Plaintiffs as misleading, Compl. ¶ 467, the Court rules that the statements are protected by the safe harbor provisions of the PSLRA. Under the safe harbor, defendants such as the Underwriters cannot be held liable for forward-looking statements, as long as such a statement is "(i) identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the

[8] The Underwriters go a bit too far, though, in arguing that "[n]othing in this [initial commercial strategy] statement . . . made any projection concerning the drug's 'potential for front-line use.'" Underwriter Defs.' Mem. 17. It could be argued, albeit not strongly, that an undisclosed decline in ponatinib's front-line potential made ARIAD's statement materially untrue because of the use of the word "initial." The framing of second-line use as merely an "initial" strategy could be read to imply that ARIAD's ultimate goal was to position ponatinib for front-line use. This implication would be materially untrue, then, if the drug's actual prospects for front-line use were as dismal as the Plaintiffs claim yet such data remained undisclosed. This is a tortured line of reasoning, however, and one that ignores the structure of the statement as an expression of present, not future, strategy.

forward-looking statement; or (ii) immaterial." 15 U.S.C. § 77z-2(c)(A). The statute further explains that the definition of a forward-looking statement includes:

> (A) a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, . . . or other financial items;
> (B) a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer;
> (C) a statement of future economic performance . . . ; [or]
> (D) any statement of the assumptions underlying or relating to any statement described in subparagraph (A), (B), or (C) . . . .

15 U.S.C. § 77z-2(i)(1).

ARIAD's estimate in the prospectus supplement that global sales of ponatinib could reach $1,000,000,000 by 2018 plainly falls within this portion of the statute. It is a classic example of a projection of revenues, captured by the definition of a forward-looking statement in 15 U.S.C. § 77z-2(i)(1)(A). The statement was also qualified by language referring investors to an extensive discussion in that same document of risk factors. See Prospectus Supplement S-3, S-8 through S-30, ECF No. 146-1. As the Plaintiffs advance no arguments even addressing the applicability of the PSLRA safe harbor, no further analysis is needed to conclude that the $1,000,000,000 revenue projection is a protected statement.

The Court rules that ARIAD's projected sales estimate for 2018 was a forward-looking statement protected by the PSLRA safe harbor.

4. Item 303 of Regulation S-K

Finally, the Underwriters seek to dismiss the Plaintiffs' Section 11 claim based on an alleged violation of Item 303 of SEC Regulation S-K. Underwriter Defs. Mem. 19. The goal of Item 303 is "to give the investor an opportunity to look at the company through the eyes of management, so that they may assess the financial condition and results of operations of the registrant, with particular emphasis on the registrant's prospects for the future." Silverstrand Invs., 707 F.3d at 102 (internal quotation marks and citations omitted). This requires management to "[d]escribe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." 17 C.F.R. § 229.303(a)(3)(ii). A plausible complaint stating a failure to disclose such trends or uncertainties "must allege (1) that a registrant knew about an uncertainty before an offering; (2) that the known uncertainty is reasonably likely to have material effects on the registrant's financial condition or results of operation; and (3) that the offering documents failed to

disclose the known uncertainty." Silverstrand Invs., 707 F.3d at 103 (internal quotation marks and citation omitted).

This part of the Plaintiffs' complaint fails for the same reasons discussed above. According to the complaint,

> Defendants were required to disclose: (i) that the incidence of adverse cardiovascular events in PACE 2 had or was reasonably expected to have a "material . . . unfavorable impact on . . . revenues," and (ii) to what extent that trend had impacted or was reasonably expected to impact ARIAD's revenue.

Compl. ¶ 472. These assertions rehash insufficient allegations made earlier in the complaint. Because the results of the July 2012 Interim Report were made public prior to the Offering, only uncertainties stemming from developments between July 2012 and January 2013 can be the subject of an alleged Item 303 violation. Again, at this stage of the litigation, the only available data point for assessing what ARIAD further knew about adverse cardiovascular events in January 2013 comes from the company's August 2013 follow-up report. As was discussed earlier in greater detail, general reference to the PACE 2 results as of August 2013 is insufficient to support a reasonable inference that management knew of a worsening trend eight months earlier.

The Court rules that the complaint fails to allege facts sufficient to support a reasonable inference that the Offering Materials violated Item 303 of Regulation S-K.

C. Section 11 and 15 Claims Against the ARIAD Defendants

1. Standing

The ARIAD Defendants seek to dismiss the Plaintiffs' Section 11 claims against them on the basis that the Plaintiffs lack standing because they are unable to trace their shares to the January 24, 2013 secondary offering. ARIAD Defs.' Mem. 18. They also assert that the Plaintiffs cannot establish any materially false or misleading statements in the offering materials. Pls.' Opp'n 35.

As discussed above, this Court adopts the pre-Twombly standard for Section 11 claims, which accepts general allegations that the Plaintiffs held traceable shares as sufficient to plead standing under Section 11, even if those allegations are unaccompanied by other facts. As stated in their complaint, the Plaintiffs purchased ARIAD common shares on the open market, "pursuant to or traceable to the [January 2013] Offering Materials," Compl. ¶ 480, which satisfies the standing requirements at the pleading stage. See Pls. Opp'n 37 (supplementing their argument with proof from Lead Plaintiff, Bradley, who filed a certification of his stock purchase on January 24, 2013, the day of the Offering). The Court, therefore, rules that the Plaintiffs have adequately

demonstrated statutory standing and DENIES the ARIAD Defendants' motion to dismiss based on the lack of standing.

2. Material Misstatements or Omissions

This Court references the discussion in Section IIIB above and rules that no inference of material misrepresentation or omission can be found against the ARIAD Defendants with regard to the Section 11 claims. In sum, this Court concludes that the supposed omission of six months of data, between the July 2012 Interim Report and the January 2013 Offering, offered no basis that cardiovascular adverse events were increasing or that there was a worsening trend in adverse events in the PACE 2 trial.

In addition to this analysis, the Court notes that the facts in Silverstrand, which the Plaintiffs argue are instructive here, are distinguishable from the facts pleaded in this case. Silverstrand Invs. v. AMAG Pharm., No. 10-10470-NMG, 2014 WL 1379792 (D. Mass. Apr. 7, 2014). In Silverstrand, the First Circuit held that the plaintiffs sufficiently pled a Section 11 claim because the defendant AMAG Pharmaceuticals failed to disclose reports of serious adverse effects linked to their drug, Feraheme, in their offering materials. 707 F.3d at 96-97. Feraheme is an intravenous iron-replacement drug used by patients with chronic kidney disease and like ARIAD, AMAG sought and received FDA approval for this drug leading up to their offering. Id. at 97-98. The plaintiffs alleged that AMAG

failed to disclose twenty-three serious adverse events, including life-threatening anaphylactic reactions and fourteen hospitalizations, even though they had disclosed this information to the FDA. Id. at 103. The First Circuit held that it constituted a material omission for AMAG to fail to disclose these events because they undoubtedly would have "[given] rise to . . . uncertainties AMAG reasonably knew would adversely affect future revenues," and "made the Offering risky and speculative." Id. at 97.

On the contrary, ARIAD disclosed the rates of serious cardiovascular events in their black box warning label in their December 2012 FDA approval announcement, making them publicly known, and incorporated this data into their January 2013 offering materials. ARIAD Defs.' Reply 10. The news of the eight percent rate of arterial thrombosis, which negatively affected ARIAD stock price upon announcement, had already been absorbed into the market at the time of the January Offering, and the Plaintiffs are unable to point to what adverse trends existed in the six months of PACE 2 study leading up to the offering. Accordingly, the Court rules that no material misstatements or omissions can be established against the ARIAD Defendants with regard to the Section 11 claims, and GRANTS the ARIAD Defendants' motion to dismiss based on a failure to state a claim under Section 11.

3. Section 15 Claims

Finally, the ARIAD Defendants move to dismiss the claims under Section 15 of the Securities Act, which imposes secondary liability for control persons who are liable under violations of Sections 11 or 12. ARIAD Defs.' Mem. 20. The Plaintiffs have established that the Individual Defendants, in their officer and director positions, "exercised direct control over ARIAD by acting as day-to-day managers of ARIAD . . . and had the power . . . to cause ARIAD to engage in the violations of law." Compl. ¶ 484. But because Section 11 liability cannot be established against the ARIAD Defendants, this Court must dismiss the Plaintiffs' Section 15 claims. See Lenartz, 879 F. Supp. 2d at 188 (holding that section 15 liability is "triggered only to the extent primary liability first attaches to a 'controlled person'").

As a result, this Court GRANTS the ARIAD Defendants' motions to dismiss the Plaintiffs' Section 11 and Section 15 claims.

IV. CONCLUSION

For the foregoing reasons, the Court makes the following rulings. As to the ARIAD Defendants, it GRANTS the ARIAD Defendants' motion to dismiss the Section 10(b), Rule 10b-5, and Section 20(a) claims, DENIES the motion to dismiss Section 11 claims on the basis of statutory standing, and GRANTS the motion

to dismiss Section 11 claims pursuant to Federal Rule of Civil Procedure 12(b)(6). As to the Underwriters' motions, the Court DENIES the motion to dismiss for lack of standing, and GRANTS the Underwriters' motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6).

SO ORDERED.

/s/ William G. Young
WILLIAM G. YOUNG
DISTRICT JUDGE