UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JUDITH GODINEZ, on behalf of herself and all others similarly situated, Plaintiffs, v. ALERE INC., NAMAL NAWANA, JAMES F. HINRICHS, and CARLA R. FLAKNE, Defendants.	Civil Action No. 16-10766-PBS

MEMORANDUM AND ORDER

August 23, 2017

Saris, C.J.

INTRODUCTION

Plaintiffs sued Alere and three of its corporate officers alleging violations of Section 10(b) of the Exchange Act and Securities and Exchange Commission (SEC) Rule 10b-5. The suit also brings derivative claims against the officers, Chief Executive Officer Namal Nawana, Chief Financial Officer James Hinrichs, and Chief Accounting Officer Carla Flakne, under Section 20(a) of the Exchange Act. Two related cases have been consolidated with this one.

Before the Court is Defendants' motion to dismiss Plaintiffs' supplemental and amended consolidated class action

complaint for failure to state a claim under Federal Rules of Civil Procedure 9(b) and 12(b)(6) and the Private Securities Litigation Reform Act (PSLRA) (15 U.S.C. § 78u–4). Docket No. 80. At its core, resolution of the motion hinges on whether or not the complaint meets the PSLRA's heightened pleading standard for scienter. For the reasons stated below, after hearing, the motion to dismiss is **ALLOWED IN PART** and **DENIED IN PART**.

FACTUAL BACKGROUND

The facts are drawn from Plaintiffs' amended complaint (Docket No. 78), documents attached to or expressly incorporated into the complaint, as well as documents the authenticity of which are not disputed by the parties, documents central to the plaintiffs' claims, and documents sufficiently referred to in the complaint. See Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 232 & n.2 (1st Cir. 2015).

I. Background

Alere is a Delaware corporation with its principal place of business in Waltham, Massachusetts. Alere provides diagnostic testing for diseases and toxicology. It has manufacturing facilities in North America, Europe, and Asia, and its distribution network is global, with offices in thirty-two countries. One of Alere's products was INRatio, a mobile device that tested a patient's blood coagulation rate, allowing doctors to provide the correct dose of blood thinning medication to

reduce the risk of stroke (too much clotting) or hemorrhage (too little clotting). Alere's other lines of business include drug testing and medical device supply.

Plaintiffs advance four categories of conduct to support the allegation of securities fraud: 1) Alere had material weaknesses in its internal controls related to revenue recognition but only made limited disclosures of what the corporation knew; 2) Alere failed to disclose the need to recall INRatio products; 3) Alere failed to disclose billing "improprieties" in two of its divisions; and 4) Alere failed to disclose that its foreign offices regularly engaged in conduct that violated the Foreign Corrupt Practices Act (FCPA). To support the allegations of scienter, Plaintiffs highlight the decision by Alere executives to sell the company and the fact that Nawana and Hinrichs stood to receive change-of-control payments totaling $29 million if Alere was acquired. Defendants counter the inference by pointing out that Nawana and Hinrichs increased their holdings of Alere common stock during the proposed class period.

A. Desire to Sell

In October 2014, Nawana was promoted from Interim CEO to CEO and President. From December 2012 to July 1, 2014, Nawana had served as Alere's Chief Operating Officer. Hinrichs became Executive Vice President and CFO on April 6, 2015. Part of his

compensation package entitled him to a bonus equal to the aggregate increase in the exercise price of his stock options during the first year he was CFO. Also in October 2014, Alere put in place change of control provisions which guaranteed payouts to certain corporate officers in the event of "qualifying termination." Alere's SEC filings indicate that Nawana was entitled to a $20.5 million change-in-control payment, and Hinrichs was due $8.7 million if a qualifying termination occurred. In February 2015, Alere adopted a new compensation plan for executives, which included a short-term incentive plan based on two performance-based metrics.

As Plaintiffs tell it, by mid-2014 Alere executives decided to sell the company and began exploring options. On August 4, 2014, Alere announced that the company intended to refocus on its core business. In September 2014, former Alere CEO Ron Zwanziger indicated that he and other former Alere executives were interested in acquiring the company for $46 per share. Alere noted this offer in a September 15, 2014 press release and Form 8-K filed with the SEC. The press release identified J.P. Morgan as financial advisor to Alere's board regarding potential corporate transactions. Although Alere rejected the Zwanziger offer, the company sold subsidiaries on October 14, 2014 and January 9, 2015 as part of its effort to refocus on its core business.

In December 2015, an executive from Abbott Laboratories (Abbott), a large pharmaceutical corporation in the same market space as Alere, contacted Nawana to inform him that Abbott was interested in making a proposal to acquire Alere. Four days later, the Alere board authorized J.P. Morgan to contact other potential acquirers. On January 11, 2016, Alere presented at a J.P. Morgan healthcare conference at which Alere stated income for the first three quarters of 2015 that was later revised down. At the conference, Nawana also discussed Alere's INRatio2 medical device, which was later recalled. Docket No. 101, Ex. C.

B. Alleged Weaknesses in Internal Controls

1. Taxes

On March 5, 2015, Alere filed its 2014 Annual Report (2014 10-K), which disclosed that it had a "material weakness related to the failure to design controls to assess the accounting for deferred tax assets which became recognizable" when it sold its health management business in January 2015. On May 28, 2015, Alere amended its 2014 10-K, notifying the market that it had made material errors in its prior disclosures by incorrectly accounting for income taxes associated with two divestitures during 2014. As a result, Alere revised some previously reported quarterly financial statements, and annual financial statements for the years ending December 31, 2012, December 31, 2013, and December 31, 2014.

On November 9, 2015, in its 2015 third quarter SEC filing (2015 3Q 10-Q), Alere disclosed an internal control problem, stating that the company "did not maintain a sufficient complement of resources with adequate experience and expertise in accounting for income taxes." On November 13, 2015, Alere made a third amendment to its 2014 10-K to reflect its internal control issue related to income tax accounting.

According to a confidential witness, labeled in the complaint as a former Alere Senior Accountant in Western Europe from 2011 through 2014, there was a lack of internal controls at Alere, in part due to the vastness of the corporation, made up of approximately 200 entities operating in dozens of different countries and tax systems. As such, the confidential witness believed that Alere's financial information system could not ensure that all necessary information was compiled accurately, and accountants used basic spreadsheet software to reconcile revenue. The witness related that, in November 2013, Alere's tax auditing firm, PricewaterhouseCoopers (PwC), learned of a proposed $2.6 million adjustment related to internal transfer pricing. PwC advised Alere against the adjustment, but France-based employees contacted headquarters and took the adjustment.

2. Revenue Recognition

Other confidential witnesses -- a National Sales Manager in India from 2013 through early 2015 and a Global Vice President

of Customer Experience from June 2012 through May 2014 -- also reported deficiencies in Alere's internal reporting systems in various countries, including improper revenue recognition -- the practice of claiming revenue for accounting purposes in one quarter even though Alere did not actually transfer risk of loss of the goods until after that quarter closed. The Global Vice President of Customer Experience said that at the end of financial quarters, Alere "stuffed" distribution channels by selling products at a steep discount in order to boost sales figures for that quarter. None of the confidential witnesses is alleged to have had contact with senior management. Some confidential witnesses left the company before Nawana and Hinrichs took executive roles.

Throughout the relevant time period, Alere's annual (10-K) and quarterly (10-Q) SEC filings, including amended filings, contained the certifications required by the Sarbanes-Oxley Act (SOX), in which Nawana (once he became CEO) and Hinrichs (once he became CFO) attested that the Company's internal and disclosure controls were effective.

C. INRatio Recall Forewarnings

Plaintiffs allege that Alere was on notice for many years that its leading medical device, the INRatio blood clotting time measurement tool, had severe deficiencies that would probably result in a recall. According to the Global Vice President of

Customer Experience, in 2007 then-CEO Zwanziger called the device “crude,” and Alere’s standard practice regarding consumer complaints about the device was to attribute issues to “user error,” even when employees did not believe customers caused the issue. Another confidential witness, labeled as a former Quality Assurance Product Support Associate from March 2014 through February 2016, but who began in customer service at Alere in February 2010, said the device “didn’t work,” thus necessitating a recall. She said customers complained about “fluctuat[ions]” and that complaints about INRatio were “known” years prior to the 2016 recall and were “continuous.” The former Quality Assurance employee reported that Alere had to hire outside employees to handle the volume of complaints, and from October 2015 to February 2016, the company nearly doubled the internal quality assurance staff to field INRatio complaints.

Plaintiffs allege that Alere was on notice of the INRatio issues beginning in May 2014, when the company issued a partial recall of the device’s test strips, a fact memorialized in Alere’s 2014 10-K. In that filing, Alere noted the test strip recall, but stated that its “emphasis on quality during 2014 has enabled us to respond to these developments more effectively than in the past and will help to mitigate any negative impact.” In November 2015, the institute which coordinated the study of the blood-thinning medicine Xarelto was investigating whether

its use of INRatio devices had distorted results. That study resulted in the Food and Drug Administration (FDA) approving Xarelto. In late 2015, Alere submitted a proposed software enhancement to the FDA. Thereafter, although the precise date is not alleged in the complaint or revealed in Alere's SEC filings, the FDA informed Alere that the proposed INRatio software update failed to adequately demonstrate effectiveness. According to the complaint, the FDA advised Alere to submit a proposal to voluntarily remove INRatio devices from the market. This information was not disclosed to the market until Alere announced its voluntary recall of INRatio in July 2016.

Plaintiffs allege that Alere became aware of additional adverse information concerning INRatio in late January 2016, based on a private complaint filed in Delaware Chancery Court to which Plaintiffs lacked access. In February and March 2016, the New York Times published articles about INRatio, including information that the FDA was investigating whether use of INRatio compromised results in clinical trials, and more generally led doctors to give patients the wrong dose of warfarin. One article reported that the FDA had received more than 9,000 reports of INRatio product malfunctions, and more than 1,400 reports of INRatio causing injuries -- far more than market leader Roche's similar product, which had just ninety-five injury reports over the same period.

D. Billing Issues at Alere Subsidiaries

Alere's Toxicology Division provides drug testing for employers and government bodies. Plaintiffs allege that Alere knew of problems with billing practices in its Toxicology Division, since August 2013, when Horizon Blue Cross and Blue Shield filed a complaint in New Jersey Superior Court. The New Jersey complaint alleged that Alere and a company it acquired defrauded Horizon of at least $36 million by making false and fraudulent insurance claims for unnecessary tests. A confidential witness, labeled as a former Medicaid Accounts Resolutions Specialist, who worked for Alere in Florida from 2010 through October 2012, stated that Alere would conduct and bill for unnecessary toxicology screenings. Another confidential witness, the former Alere Toxicology Billing and Pricing Supervisor from March 2014 through August 2014 stated that, during those five months, there were two Medicare audits and one internal audit. The confidential witness stated that, based upon these audits, Alere learned of problems with its billing practices.

Alere's Arriva subsidiary, which sells diabetes testing supplies and other durable medical equipment, also allegedly had a history of violating Medicare billing requirements, and was subject to multiple government investigations. In particular, Plaintiffs allege Alere, via Arriva, was on notice of billing

issues in that subsidiary because Arriva previously acquired AmMed Direct, LLC (AmMed), which was the subject of a Federal False Claims Act suit in Tennessee. According to the complaint, the suit subsequently settled. Furthermore, in March 2015, Alere disclosed that Arriva was responding to a Civil Investigative Demand (CID) from the U.S. Attorney for the Middle District of Tennessee in connection with an investigation into possible improper claims submitted to government healthcare programs.

E. FCPA Improprieties

Plaintiffs allege that Alere was on notice of FCPA improprieties no later than fall 2013. The complaint recites statements from a confidential witness, the National Sales Manager in India from 2013 through early 2015. The National Sales Manager stated that, in late summer or early fall 2013, Deloitte conducted an internal investigation into Alere's government bidding practices in India. The confidential witness stated that the government bidding process was "highly corrupted," with state contracts facilitated by "under the table" dealings between Alere distributors and government officials. The complaint does not allege that the confidential witness's determination that the government bidding process was "highly corrupted" was a conclusion reached in the alleged Deloitte audit.

II. The Alleged Fraud is Revealed

On February 1, 2016, Abbott announced its intention to purchase Alere for $56 per share, a premium of $18.80 per share. If the deal closed, Nawana and Hinrichs stood to collect approximately $29 million in change-of-control payments. Alere filed a Form 8-K with the SEC on the date the merger was announced, which attached the merger agreement as an exhibit. Within the merger agreement Alere warranted that it had complied with securities laws and SEC regulations since January 1, 2014, and that none of the "Company SEC documents" since that date "contained any untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in light of the circumstances in which they were made, not misleading." The merger agreement also warranted that Alere had disclosed all liabilities, "whether accrued, absolute, contingent or otherwise," that would "individually or in the aggregate, reasonably be expected to have a Material Adverse Effect." Finally, the merger agreement warranted that Alere was not aware of pending or threatened legal or administrative proceeding, suit, claim, investigation, arbitration or action against the company or its subsidiaries that would be expected to have a material adverse effect.

Soon after the merger was announced, however, and throughout the remainder of 2016, Plaintiffs recite a series of

events and disclosures that illuminate the scope of the fraud alleged in this lawsuit.

A. February 26, 2016 and March 15, 2016 – Alere's Delayed 2015 10-K amid Accounting Woes and Potential FCPA Violations

On February 26, 2016, Alere first disclosed that its 2015 Annual Report (2015 10-K) would be delayed, because it was "conducting an analysis of certain aspects of revenue recognition in Africa and China and any potential implications on . . . internal controls over financial reporting for the year ended December 31, 2015." At the same time, Alere disclosed that it received a SEC subpoena on January 14, 2016 in connection with a previously-disclosed formal SEC investigation into sales practices in Africa. On March 15, 2016, Alere filed a Form 8-K disclosing that the company would need a further extension of the time to file its 2015 10-K, because its analysis of revenue recognition accounting practices in Africa and China was continuing. That Form 8-K also disclosed that on March 11, 2016, Alere received a grand jury subpoena from the Department of Justice (DOJ) "requiring the production of documents relating to . . . sales, sales practices[,] and dealings with third-parties in Africa, Asia and Latin America and other matters related to the [FCPA]."

Traders and market analysts reacted negatively. Alere shares fell eight percent from $53.46 per share to $49.32 per

share from March 14, 2016 to the close of the trading day on March 15, 2016. Market analyst BTIG, LLC downgraded Alere from "Buy" to "Neutral" on March 15, 2016. A report from Canaccord Genuity noted that the DOJ subpoena might cover a portion of the world (Asia, Africa, and Latin America) comprising one quarter of Alere's revenues.

B. April 20, 2016 and April 28, 2016 – Abbott Balks

During Abbott's quarterly earnings conference call on April 20, 2016, Abbott's CEO failed to affirm his company's commitment to acquiring Alere. Alere did not respond until April 28, 2016. In the interim, market analysts issued negative reports, and on April 20, 2016, Alere stock fell twelve percent from its April 19, 2016 ($49.47 per share to $43.36 per share). When Alere did respond on April 28, it did so in a press release stating that Abbott had relayed its serious concerns about the accuracy of Alere's various representations, warranties and covenants in the merger agreement. The press release also stated that Abbott had asked Alere to agree to terminate the merger in exchange for $30 to $50 million. Abbott's CEO again refused to commit to the merger during the company's next quarterly earnings conference call on July 20, 2016, noting Alere's long-delayed 10-K filing and Abbott's ongoing lack of access to information from Alere.

C. July 11-12, 2016 – INRatio Recalled

In May 2016 separate class action lawsuits alleging personal injury from INRatio defects were filed in Massachusetts and California state courts. Also that month, the United States Attorney for the District of New Jersey issued a subpoena seeking documents related to Alere's interactions with the FDA and INRatio's accuracy, reliability, and performance.

After the markets closed on July 11, 2016, Alere issued a press release announcing that it was removing INRatio products from the market, stating that in certain cases the devices provided blood clotting time results that are "clinically significantly lower than" laboratory results. In a related Form 8-K filed on July 12, 2016, Alere disclosed that it expected to record $70 to $90 million in charges related to the INRatio recall. On July 12, 2016, Alere's stock declined from $39.95 at close on July 11 to $38.61, a drop of three percent.

D. July 14, 2016 – Alere Discloses Material Weaknesses in Internal Controls

On July 14, 2016, Alere filed a Form 8-K and also issued a press release. The press release disclosed that Alere expected to conclude that one or more material weaknesses existed with respect to the company's internal controls over financial reporting. According to Alere's press release, the material weaknesses led to improper timing of revenue recognition in

Fiscal Years 2013 and 2014, as well as the first three quarters of Fiscal Year 2015.

E. July 27, 2016 – Alere's Toxicology Unit Receives a Criminal Subpoena

On July 27, 2016, Alere disclosed that the DOJ's Criminal Fraud Unit issued it a subpoena on July 1, 2016, related to billing records for Medicare, Medicaid, and Tricare patients. The Wall Street Journal additionally reported that the DOJ was investigating whether Alere provided illegal kickbacks to doctors who ordered tests from the unit. The market reacted to this disclosure, with Alere shares falling twenty-nine percent (from $44.06 to $31.47) during the trading day.

F. August 8, 2016 – Alere Releases its Long-Awaited 2015 Annual Report

On August 8, 2016, Alere filed its long-delayed 2015 Form 10-K, which showed financial performance below Alere's previous estimates (revenue for the fourth quarter of fiscal year 2015 was $4.8 million less than consensus estimates). The 2015 10-K also included financial statement revisions for prior reporting periods. As a result, Alere revised its income from continuing operations for the first nine months of 2015 from $18.2 million to $6 million. Alere's revisions also reflected that some previously reported financial results, which at the time exceeded market expectations, were, in fact, below analyst expectations after the revisions. For example, the initially

reported net revenue for the second quarter of 2015 was $629 million, above analyst expectations of $627 million, but the revisions brought results below expectations to $623 million.

The 2015 10-K also reported that Alere had material weaknesses in internal controls over revenue recognition and financial reporting. The filing included a report from the company's outside auditor, PwC, which stated that "the Company did not maintain, in all material respects, effective internal control over financial reporting." Alere's filing included a section setting forth the procedures the company would follow to remediate internal control deficiencies, including hiring more employees, reorganizing operations, and enhancing the review process for contracts and purchase orders.

The 2015 10-K also noted that the withdrawal of INRatio products would negatively impact Alere's fourth quarter 2015 financial results, and that the company had recorded a charge of $38 million against the year ended December 31, 2015 as a result of the recall. A press release further reported that Alere expected to record approximately $70 to $90 million in charges relating to the voluntary product withdrawal in 2016.

That same day, Abbott stated that Alere's 2015 10-K did not relieve its concerns about business controls and practices at Alere. Abbott expanded on those concerns in an August 10, 2016 public statement, rehashing many of the relevant events since

the merger announcement. On August 17, 2016, in its First Quarter 2016 10-Q, Alere reported results that showed revenue decreasing from the prior year and a net loss from continuing operations of $10 million. Alere's Second Quarter 2016 10-Q, released on September 6, 2016, showed decreased revenue as compared to the prior year, and showed a $35 million net loss from continuing operations.

G. August to December 2016 – The Alere-Abbott Delaware Chancery Court Actions

On August 25, 2016, Alere sued Abbott in Delaware Chancery Court to enforce the merger agreement. On November 3, 2016, Abbott sued Alere in Delaware Chancery Court alleging breach of contract for failure to provide access to information as required by the merger agreement. On November 15, 2016, Abbott and Alere settled the breach of contract action. However, on December 7, 2016, Abbott sued Alere to terminate its obligation to consummate the merger agreement.

H. November 4, 2016 – The Centers for Medicare & Medicaid Services Terminates Arriva's Medicare Enrollment

On November 4, 2016, Alere announced in its Third Quarter 2016 10-Q that, on October 12, 2016, Medicare revoked its subsidiary, Arriva's, enrollment for improper billing related to 211 claims submitted for deceased patients over a five-year period. Alere acknowledged the potentially severe consequences on its revenue if Medicare did not reinstate Arriva, as that

subsidiary accounted for $88 million in revenue during the first nine months of 2016. Plaintiffs allege that Arriva had compliance issues dating back to at least March 2012, when it acquired a Tennessee-based company, AmMed, which was subject to false claims allegations related to Medicare claims for diabetes testing supplies.

III. The Alleged Materially False and Misleading Statements

Plaintiffs allege the following materially false and misleading statements:

- SEC filings in fiscal year 2014 and the first three quarters of 2015 improperly recognized and reported revenue in violation of Generally Accepted Accounting Principles (GAAP). Docket No. 78 ¶¶ 173–81.
- The company had material weaknesses in internal controls over financial reporting, resulting in material errors and the need to restate them. Docket No. 78 ¶ 182
- The company failed to accrue or disclose a loss contingency regarding INRatio products. Docket No. 78 ¶¶ 183–91.
- The company failed to disclose material adverse facts relating to Arriva. Docket No. 78 ¶¶ 192–205.
- The company's SOX certifications were materially false and misleading. Docket No. 78 ¶¶ 206–12.

- The company's risk disclosures omitted material facts. Docket No. 78 ¶¶ 213–19.
- The Alere-Abbott merger agreement was materially false and misleading, and omitted certain material facts that were in existence at the time. Docket No. 78 ¶¶ 220–25.

IV. Loss Causation

Plaintiffs point to stock price declines on seven particular dates showing a decrease in stock price on the dates of the disclosures described above. Docket No. 78 ¶ 256. Plaintiffs also rely on a fraud on the market theory of causation. Docket No. 78 ¶¶ 258–62.

DISCUSSION

I. **Standard of Review**

To survive a Rule 12(b)(6) motion to dismiss, the factual allegations in a complaint must "possess enough heft" to state a claim to relief that is plausible on its face. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 557 (2007). "Plaintiffs alleging violations of Section 10(b) must plead (1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." In re Biogen Inc. Sec. Litig., 857 F.3d 34, 41 (1st Cir. 2017) (citing Fire & Police Pension Ass'n of Colo., 778 F.3d at 240). Under the PSLRA, the complaint must "specify each statement alleged to have been

misleading" as well as "the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1).

To meet the scienter element, the PSLRA requires that a complaint state with particularity specific facts giving rise to a "strong inference," id. § 78u-4(b)(2)(A), either of "intentional or willful conduct designed to deceive or defraud investors by controlling or artificially affecting the price of securities," City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 757 (1st Cir. 2011) (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 199 (1976)), or of "a high degree of recklessness," id. (quoting Aldridge v. A.T. Cross Corp., 284 F.3d 72, 82 (1st Cir. 2002)). "Recklessness, as used in this context, 'does not include ordinary negligence, but is closer to being a lesser form of intent.'" Fire & Police Pension Ass'n of Colo., 778 F.3d at 240 (quoting Greebel v. FTP Software, Inc., 194 F.3d 185, 188 (1st Cir. 1999)). Generally, "[a] plaintiff may not plead 'fraud by hindsight'; i.e., a complaint 'may not simply contrast a defendant's past optimism with less favorable actual results' in support of a claim of securities fraud." ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 62 (1st Cir. 2008) (quoting Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1223 (1st Cir. 1996), abrogated on other grounds by 15 U.S.C. § 78u-4(b)(2)).

To be specific, "whatever the characteristic pattern of the facts alleged, those facts must now present a strong inference of scienter. A mere reasonable inference is insufficient to survive a motion to dismiss." Greebel, 194 F.3d at 196. For an inference of scienter to be strong, "a reasonable person would [have to] deem [it] cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 324 (2007). The First Circuit has "found this exacting standard satisfied where the complaint contains clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so." In re Ariad Pharm., Inc. Sec. Litig., 842 F.3d 744, 751 (1st Cir. 2016).

II. Allegations

To track the complaint, the Court addresses each alleged materially false or misleading statement or omission and then considers the totality of the circumstances analysis urged by Plaintiffs.

A. Revised Financial Statements

Defendants argue that Plaintiffs' claim based on incorrect revenue recognition in fiscal years 2013 and 2014 fails to state

a cause of action because there are not particularized facts giving rise to a strong inference of conscious intent to defraud or a high degree of recklessness. See Local No. 8 IBEW Ret. Plan & Tr. v. Vertex Pharm., Inc., 838 F.3d 76, 80 n.6 (1st Cir. 2016) ("allegations of merely unreasonable conduct do not sufficiently plead scienter"). The Defendants do not deny that the original statements were false on account of a failure to comply with GAAP standards for revenue recognition, but argue that, in this context, these standards implicate complex accounting principles. Plaintiffs, conversely, argue that the GAAP errors support a strong inference of scienter because revenue recognition principles are clear and objective. See Docket No. 86 at 26–27.

Whether or not revenue recognition principles are clear and objective, Defendants are correct that the complaint is devoid of allegations that senior Alere officers knew of the revenue recognition errors before February 2016. To sufficiently plead scienter, Plaintiffs must allege GAAP violations coupled with corresponding fraudulent intent. See Day v. Staples, Inc., 555 F.3d 42, 57 (1st Cir. 2009) (quoting Novak v. Kasaks, 216 F.3d 300, 309 (2d Cir. 2000)). Although confidential witnesses quoted in the complaint suggested that there were issues with internal controls, there are insufficient allegations in the pleadings that the company or the individual defendants were or should

have been aware of the revenue recognition issues. See Local No. 8 IBEW Ret. Plan & Tr., 838 F.3d at 83 (affirming dismissal where complaint lacked allegations that anybody responsible for receiving, reviewing, and reporting results noticed error before discovery that led to amendment). Here, no confidential witnesses alleged that senior management knew prior to disclosure that revenue was being improperly recognized, i.e. by recognizing the revenue in the improper quarters or by "channel stuffing." See In re Biogen, 857 F.3d at 43 (citing Fire & Police Pension Ass'n of Colo., 778 F.3d at 245).

Plaintiffs attempt to reframe the scienter argument, positing that Defendants were on notice of internal control problems in other accounting areas, which raised red flags for problems in revenue recognition, thus supporting a strong inference of scienter. See Varghese v. China Shenghuo Pharm. Holdings, Inc., 672 F. Supp. 2d 596, 608 (S.D.N.Y. 2009). The roadblock to this scienter argument is that the prior internal control issues involved corporate taxation issues, not revenue recognition. That fact distinguishes this case from Vargehese, where, throughout the class period, the internal control issues involved treatment of uncollected trade receivables. Id. at 603. Plaintiffs do not convincingly argue that an internal control problem in one accounting area puts a company or its senior management on notice of internal control problems in all other

aspects of the company's accounting procedures. Further negating scienter is the fact that the prematurely recognized revenue was, in fact, real revenue.

Plaintiffs' stronger argument is that the acknowledgement of internal control issues followed so closely after the merger announcement, such that the merger agreement's warrant to the accuracy of all financial statements over the preceding two years must have been false. In other words, if Alere knew it had serious revenue recognition problems at the end of February 2016, it must have known of them at the beginning of February 2016, when the merger was announced. However, the fraudulent intent inference is not strong because, as the investigation revealed, Alere recognized revenue too soon, but did not recognize fake revenue. Also, although the Court may consider temporal proximity, the mere fact that the corrective disclosure occurred soon after the merger announcement does not necessarily give rise to a strong inference of scienter. See Shaw, 82 F.3d at 1225 ("[T]he short time frame between an allegedly fraudulent statement or omission and a later disclosure of inconsistent information does not, standing alone, provide a sufficient factual grounding to satisfy" a fraud standard).

B. INRatio Recall

Before the Court delves into the allegations related to INRatio, a brief timeline of relevant events is useful.

- In May 2014, Alere ordered a recall of certain INRatio testing strips.
- In December 2014, Alere issued a "voluntary urgent medical device correction" to inform users with certain medical conditions not to use the product.
- In late 2015, Alere submitted to the FDA a software enhancement it hoped would resolve ongoing issues.
- In December 2015, Abbott expressed interest in acquiring Alere.
- Sometime between the submission to the FDA and July 2016, the FDA informed Alere that it did not believe the software enhancements adequately demonstrated effectiveness, and the FDA advised Alere to submit a "proposed plan to voluntarily remove" INRatio from the market.
- Alere announced its voluntary withdrawal of INRatio products on July 11, 2016.
- In its 2015 10-K, released August 8, 2016, Alere recorded a $38 million loss related to the INRatio recall in the fourth quarter of its 2015 Fiscal Year, "due to the fact that the circumstances giving rise to the voluntary withdrawal . . . existed as of December 31, 2015."

Additionally, published newspaper articles in February and March 2016 revealed that the FDA had received thousands of reports of INRatio product malfunctions, and over 1,400 reports of INRatio causing injuries. The press also reported that the FDA was investigating whether INRatio faults compromised results of clinical trials. Finally, a confidential witness stated that Alere hired outside employees to handle the volume of INRatio complaints, and "nearly double[d]" the number of quality assurance staff tasked with fielding INRatio complaints.

Against that backdrop, Defendants argue that there is no factual basis for Plaintiffs' argument that Alere knew or should

have known that it would need to state a loss contingency for the INRatio recall prior to July 2016. Defendants argue that the company tried to resolve INRatio issues (e.g. the 2014 recall of certain testing strips and voluntary correction for users with certain medical conditions) prior to July 2016, but that those problems did not make the eventual recall of the entire product line inevitable or even probable. Accounting standards call for an entity to accrue a loss contingency when it is both probable that a liability has been incurred and the amount can reasonably be estimated. See Accounting Standards Codification (ASC) ¶ 450-20-25-2. Alternatively, ASC 450 requires disclosure of a loss contingency when the likelihood that a loss will occur is "more than remote but less than likely." In re Lions Gate Entm't Corp. Sec. Litig., 165 F. Supp. 3d 1, 21 (S.D.N.Y. 2016) (quoting ASC ¶¶ 450-20-50-3; 450-20-20 Glossary)). Alere also argues that it would not have invested substantial time and money in trying to fix the product if it knew in 2015 that a recall would be necessary, negating a strong inference of scienter. See Fire & Police Pension Ass'n of Colo., 778 F.3d at 244–45 (finding no scheme to defraud where company balanced its need to market product and find a solution amenable to FDA). As such, Defendants paint Plaintiffs' INRatio claims as "fraud by hindsight" insufficient to raise a strong inference of scienter.

See Ganem v. Invivo Therapeutics Holdings Corp., 845 F.3d 447, 457 (1st Cir. 2017).

Several factors rebut Defendants' argument that a disclosure or an accrual with respect to a loss contingency was not required. First, Alere recorded some of the loss claimed in July 2016 against a reserve (retroactively) taken in 2015. Specifically, Alere noted in its recall announcement that part of the loss was recorded in Fiscal Year 2015 because "the circumstances giving rise to the voluntary withdrawal . . . existed as of December 31, 2015." If so, Plaintiffs argue, the facts for recording a loss under accepted accounting standards were known at least seven months before Alere disclosed them. Second, at some time between Alere's submission of the software update to the FDA in late 2015 and the recall in July 2016, the FDA informed Alere that its software enhancements did not satisfactorily address the issues, and, as such, the FDA advised Alere to submit a proposal for a voluntary removal of INRatio products from the market.[1] Third, confidential witness statements about significantly increased quality assurance hiring to handle

[1] The pleadings do not state the date on which the FDA advised Alere to prepare for a voluntary recall. It was sometime between Alere's submitting a proposed software enhancement to the FDA and the July 11, 2016 recall announcement. However, the fact is that Alere charged part of the loss to the fourth quarter of 2015, stating that the circumstances necessitating the recall existed in the fourth quarter of 2015.

INRatio complaints, and published news stories in early 2016 suggesting that the FDA received thousands of complaints related to INRatio, including approximately 1,400 complaints of injury, all raise an inference that Defendants were on notice of consistent and ongoing problems with the product line. Plaintiffs also cite, in a supplemental declaration filed after argument on the pending motion, Nawana's statement at a January 11, 2016 industry conference that "historical headwinds" facing product lines including INRatio were abating. See Docket No. 101, Ex. C at 4. Taken together, Plaintiffs have alleged sufficient facts to demonstrate that Defendants knew or should have known prior to July 2016 that a recall of INRatio products was sufficiently likely such that accrual or disclosure of a loss contingency in 2015 was appropriate under generally accepted accounting standards.

The next question is whether Alere knowingly withheld this adverse information until after the merger announcement with Abbott (and longer still). Such a delay would give rise to a strong inference of scienter. Defendants essentially argue that the losses were recorded partly in the fourth quarter of fiscal year 2015 because that quarter had not "closed" until August 2016 for accounting purposes. See Docket No. 88 at 13 & n.13. In other words, Defendants claim they recorded the loss in the quarter that was unreported when the recall occurred. This

argument is not persuasive. If the facts necessitating the recall were actually known earlier than the recall announcement -- as the statement that "the circumstances giving rise to the voluntary withdrawal . . . existed as of December 31, 2015" suggests -- Alere failed to disclose the information in the Form 8–Ks it filed in early 2016.

Defendants cite passages from Alere's 2014 10-K which discuss the risks associated with INRatio in light of the FDA's strict regulatory scheme. See Docket No. 81 at 24–25 (citing Ezra Charitable Tr. v. Tyco Int'l, Ltd., 466 F.3d 1, 8 (1st Cir. 2006)). In that filing, Alere noted that:

> [t]he discovery of problems with a product may result in restrictions on the product, including notices of correction or product recalls, such as our December 2014 voluntary urgent medical device correction initiated with respect to our Alere INRatio and Alere InRatio2 systems and our April 2014 recall of our Alere InRatio2 PT/INR Professional Test Strips, or even withdrawal of the product from the market.

2014 10-K at 19. Although this warning made the unremarkable point that discovery of further issues may result in a recall, it does not adequately disclose the extreme problems with the product which led the FDA to advise Alere to undertake a voluntary recall. The statement does not make the market fully aware of the failure rate associated with INRatio product malfunctions, necessitating the FDA's suggestion of a full

recall. See Miss. Pub. Emps.' Ret. Sys. v. Bos. Sci. Corp., 649 F.3d 5, 28–29 (1st Cir. 2011) (distinguishing between facts suggesting commercial failure and those going to lesser risks).

In light of the surrounding allegations, at the motion to dismiss stage, the Court accepts as true the confidential witness statements about the high volume of complaints and increased quality assurance staffing in 2015. See In re Cabletron Sys., Inc., 311 F.3d 11, 29–30 (1st Cir. 2002). Defendants argue that the company was trying to fix the INRatio problems and would not have known before July 2016 that a recall would be sufficiently probable to require accrual of a loss charge under accepted accounting principles in advance of the July 2016 announcement. See In re Carter-Wallace Inc., Sec. Litig., 220 F.3d 36, 42 (2d Cir. 2000) (dismissing securities fraud claim for lack of scienter because company could not be expected to abandon its product immediately at early signs of problems). But the loss was attributed to circumstances in existence before the end of 2015, and the ongoing consumer issues with INRatio served to put senior management on notice of a looming recall. The Court will await a summary judgment record to determine whether Alere knew INRatio was a commercial failure and intentionally or recklessly hid that fact from the market to make sure that the deal with Abbott went through.

Here, the facts giving rise to a strong inference of scienter include the 2014 partial recall and correction, the high volume of consumer complaints, consumer injuries, and increased quality assurance staffing, the FDA's advice to prepare for a voluntary recall, and the timing of potentially lucrative merger discussions with Abbott (which could have been scuttled by disclosure of a likely recall), after which Nawana and Hinrichs stood to receive a combined $29 million in change-in-control payments. See Tellabs, 551 U.S. at 325 ("personal financial gain may weigh heavily in favor of a scienter inference"). Taken together, the inference that Alere and its senior management knew or recklessly hid the facts necessitating an INRatio recall-related loss reserve from the market is at least as likely as the opposing inference that Alere would not have made substantial efforts and investments to fix the problem if it knew a recall was likely or probable. See id. at 328–29 (holding that plaintiff must plead facts rendering inference of scienter at least as likely as plausible opposing inference).

The question of materiality remains. The "materiality requirement is satisfied when there is '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.'" Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 38 (2011) (quoting Basic Inc.

v. Levinson, 485 U.S. 224, 231–32 (1988)). This issue was lightly briefed by both sides. Defendants argue the recall was immaterial because INRatio products accounted for less than two percent of net revenue in 2015, and the charge in the fourth quarter of 2015 was "only" $38 million. See Docket No. 81 at 29. Plaintiffs argue that the INRatio nondisclosure was material because Abbott called it one of Alere's showcase products, the total charges related to the recall were between $70 and $90 million, and the recall caused between a 3.2 percent and eight percent decrease in gross profits. See Docket No. 86 at 25, 35 (citing Docket No. 78 (Compl.) ¶¶ 59, 94; Docket No. 87, Ex. D at 4). It is plain that the recall itself was material, as evidenced by Alere filing a Form 8-K to notify the market of the news. But that is not the question in this case, and, on this motion to dismiss record, the question of materiality cannot be resolved as a matter of law.

C. Toxicology Unit Billing Practices

Defendants argue that the fact of a regulatory investigation into the Toxicology Unit's billing practices in 2016 is insufficient to plead scienter in securities fraud litigation. The mere existence of an investigative subpoena in 2016 has limited probative value where there are no allegations that the issues being investigated were previously disclosed to senior management. See Brophy v. Jiangbo Pharm., 781 F.3d 1296,

1304 (11th Cir. 2015); Loos v. Immersion Corp., 762 F.3d 880, 890 (9th Cir. 2014). The confidential witness statements do not support an inference of scienter at the senior management level, because the statements were made by witnesses who did not hold senior positions within Alere, and there are no allegations that they communicated with senior management about the issues. See In re Biogen, 857 F.3d at 43 (holding that confidential witness statements do not give rise to a strong inference of scienter as to senior management "if none of the witnesses were senior managers and they had little contact with such managers"). Indeed, both confidential witnesses quoted in this section of the complaint left Alere before Nawana and Hinrichs had their respective roles. After briefing concluded, Defendants filed a declaration with the Court including an excerpt of Alere's newly filed First Quarter 2017 10-Q. See Docket No. 96. That excerpt stated that, on June 8, 2017, the DOJ informed Alere that it was closing its investigation into the Toxicology Unit without taking action against Alere or the subsidiary. Id. at ¶¶ 3–5.

With regard to Plaintiffs' allegation that the Horizon Blue Cross & Blue Shield lawsuit in New Jersey state court put Defendants on notice, these allegations from another complaint regarding a predecessor corporation, without more, do not establish a strong inference of scienter by senior management. Cf. In re Nat'l Century Fin. Enterprises, Inc., Inv. Litig., 580

F. Supp. 2d 630, 643 (S.D. Ohio 2008) (finding no strong inference of scienter where red flag allegation was attributable to a fellow defendant's predecessor). Defendants claim the lawsuit was never adjudicated, see Docket No. 88 at 15, which Plaintiffs do not rebut. Thus, Defendants' argument has all the more force in this case where the earlier lawsuit was filed against a predecessor corporation (Avee Laboratories) for alleged conduct that occurred, at least in part, prior to its acquisition by Alere, and entirely before Nawana and Hinrichs had their current titles.

D. FCPA Compliance

Defendants argue the FCPA allegations fail to adequately plead scienter because the mere fact of a government investigation does not give rise to a strong inference of scienter on the part of senior management. Plaintiffs point to the statements from the National Sales Manager in India from 2013 to early 2015 that the government bidding process was "highly corrupted" and that Deloitte conducted an internal investigation. However, the allegations as to the timing or result of the investigation are vague and there is no allegation that senior management was aware of any unlawful conduct. See In re Biogen, 857 F.3d at 43. Plaintiffs also point to the DOJ's subpoena of Alere regarding FCPA compliance. However, the existence of a subpoena does not, without more, give rise to a

strong inference of scienter on the part of senior management. See Washtenaw Cty. Emps.' Ret. Sys. v. Avid Tech., Inc., 28 F. Supp. 3d 93, 114 (D. Mass. 2014) (noting that a government investigation is "insufficient in and of itself" to establish a strong inference of scienter). Unlike Avid Tech, where the Court held that there were more allegations relating to scienter than just one government investigation, see id. at 115, in the context of the FCPA, the only allegation relating to scienter on the part of senior management is the government subpoena. Thus, the complaint fails to adequately plead scienter related to FCPA compliance.

E. Arriva's Medicare Eligibility Revocation

Defendants argue that although Arriva billed Medicare for 211 deceased patients, there are no facts supporting an inference that senior management knew or recklessly disregarded specific false claims or defects in Arriva's Medicare claims practices. Defendants urge the Court to find Plaintiffs' claims implausible, where nominal revenues from 211 fraudulent claims put at risk huge sums of billings to government-funded healthcare programs. Plaintiffs assert that Defendants were on notice of significant compliance issues at Arriva since March 5, 2015, when it responded to a CID involving possible improper

claims to government healthcare programs.[2] Significantly, this investigation was promptly disclosed in Alere's 2014 10-K. Even though Arriva's predecessor had prior claims of false billing against it, there is no allegation that the parent company was aware that the subsidiary had actually submitted claims on behalf of dead beneficiaries. See In re Comshare Inc. Sec. Litig., 183 F.3d 542, 553–54 (6th Cir. 1999) (declining to presume recklessness or internal controls from a parent corporation's reliance on its subsidiary's internal controls). This allegation does not raise a strong inference of scienter on the part of senior management.

F. The Abbott Merger Agreement and Delaware Litigation

On February 1, 2016, Alere filed a Form 8-K with the SEC announcing that it had agreed to be acquired by Abbott and stating that Alere's recent SEC filings prior to the acquisition did not contain any untrue statement or omission of material fact, that its financial statements were in accordance with GAAP and SEC rules, that it maintained a system of adequate internal

[2] There is little to support Plaintiffs' claim that Alere senior management was aware that Medicare restricted Arriva's access to the HETS billing system in 2015, nor is there a specific factual allegation that this restriction was related to the improper billing for deceased patients. Indeed, the CMS decision to prohibit Arriva from billing Medicare implies, at times, that Arriva had limited access to HETS through no fault of its own. See Docket No. 101, Ex. A, at 3, 19.

controls over financial reports, and that it was in compliance with state and federal laws, including the FCPA.

Plaintiffs devote substantial portions of the complaint to allegations made by Abbott in the Delaware Chancery Court litigation to argue that the representations and warranties in the merger agreement were materially false and misleading. Plaintiffs contend that the fact that Abbott accused Alere of failing to disclose information required under the merger agreement supports a strong inference of scienter under securities law. But in the Delaware litigation, Abbott focused largely on violations of the terms of the contract such as refusal to provide financial and business information, not securities laws violations. Though some of Alere's representations turned out to be untrue (i.e. compliance with GAAP), Plaintiffs' allegations from the Delaware litigation, with one exception, do not state significant additional information suggesting that senior management knew or recklessly disregarded that the statements in the merger agreement were materially false or misleading at the time they were made. Abbott did assert that "company management" put Alere India's Director of Finance on "long leave" and that he was "suspended" "with pay" so that Abbott could not interview him as part of the due diligence process. This allegation is one paragraph in the complaint, and it is not clear whether the alleged conduct was

directed by Alere India management, or by the parent company's senior management, including the individual defendants in this case. Furthermore, the single paragraph does not allege that the Alere India Director of Finance had particular information that Alere was obligated to disclose under securities law, rather than as a matter of contract.

For the interested reader, in the end, Alere and Abbott consummated the merger, with Alere agreeing to a reduced purchase price of $51 per share (approximately $500 million less in total than the originally agreed purchase price) on April 14, 2017, the same day Abbott dismissed all of its claims in Delaware Chancery Court with prejudice. See Docket No. 88 at 2; Docket No. 91 at 1.

III. Totality of the Circumstances

Plaintiffs argue that the Court should not examine the factual premises for each materially false and misleading statement or omission separately. Instead, Plaintiffs urge the Court to examine whether "all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." Tellabs, 551 U.S. at 323. Plaintiffs' argument rests on the fact that nearly all of the allegations stem from a general inability to implement adequate internal controls, albeit in disparate areas of a large corporation's

reporting structure. In their view, the accounting errors, FCPA violations, billing irregularities, and more, fit into a general pattern reflecting a lack of internal controls. Plaintiffs also argue that although an individual government investigation, standing alone, may not support a strong inference of scienter, here there were numerous government investigations across many departments. See Avid Tech., 28 F. Supp. 3d at 115 (D. Mass. 2014) ("government investigation can be seen as one more piece of the puzzle . . . add[ing] up to a strong inference of scienter").

There is no denying that a steady drumbeat of negative information about Alere was disclosed to the market beginning soon after the merger announcement. 2016 was a bad year for Alere. However, most of the internal control problems involved far-flung operations all over the world and very different kinds of government regulatory problems facing different subsidiaries. With the exception of the problems related to INRatio, the complaint does not support a strong inference of prior knowledge on the part of senior management. Thus, even considering the non-INRatio related allegations holistically, the complaint does not give rise to a strong inference of scienter on the part of senior management.

IV. Section 20(a) Claims

Section 20(a) of the Exchange Act imposes joint and several liability on persons in control of entities that violate securities laws. 15 U.S.C. § 78t(a). A section 20(a) claim is derivative of an underlying violation of the securities laws. ACA Fin. Guar. Corp., 512 F.3d at 67–68. Because the Court dismisses the claims under Rule 10b–5, it also dismisses the section 20(a) claims except with respect to the INRatio allegations.

ORDER

The Court **DENIES** the motion to dismiss (Docket No. 80) as to the alleged materially false and misleading statements and omissions related to INRatio. The Court **ALLOWS** Defendants' motion to dismiss (Docket No. 80) as to all other alleged materially false or misleading statements or omissions. Furthermore, the Court **DISMISSES** Carla Flakne as to all claims, as Plaintiffs did not pursue any theory of Flakne's individual liability. The parties shall propose a joint scheduling statement within thirty days.

/s/ PATTI B. SARIS
Patti B. Saris
Chief United States District Judge