UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JUDITH GODINEZ, on behalf of herself and all others similarly situated,

Plaintiff,

v.

ALERE INC., NAMAL NAWANA, JAMES F. HINRICHS, and CARLA R. FLAKNE

Defendants.

Case No.: 1:16-cv-10766-PBS

SUPPLEMENTAL AND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Leave to File Granted on January 3, 2017 (Dkt. No. 76).

JURY TRIAL DEMANDED

TABLE OF CONTENTS

Lead Plaintiffs the Glazer Funds (defined below in ¶ 13 and plaintiffs OFI Asset Management and NECA-IBEW Pension Trust Fund (the Decatur Plan) (together with the Glazer Funds, "Plaintiffs"), by and through their attorneys, bring this action pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), and Rule 10b-5 promulgated thereunder, on behalf of themselves and all other persons or entities who purchased or otherwise acquired the publicly-traded common stock of Alere Inc. ("Alere" or the "Company") during the period from May 28, 2015 through December 7, 2016, inclusive (the "Class Period") and were damaged thereby (the "Class"). Plaintiffs bring this action against Defendants Alere, Alere's Chief Executive Officer ("CEO") Namal Nawana, Alere's Chief Financial Officer ("CFO") James F. Hinrichs, and Alere's former Chief Accounting Officer ("CAO") Carla R. Flakne (the "Individual Defendants" and, collectively with Alere, "Defendants").

Plaintiffs allege the following upon information and belief, except as to those allegations concerning Plaintiffs which are alleged upon personal knowledge. Plaintiffs' information and belief is based upon, among other things, their counsel's investigation, which includes, without limitation, a review and analysis of: (a) regulatory filings made by Alere with the U.S. Securities and Exchange Commission ("SEC"); (b) press releases and media reports issued by and disseminated by Alere; (c) other publicly available information concerning Alere including, without limitation, securities analyst reports and court filings; and (d) interviews of former employees. Plaintiffs believe that substantial additional evidentiary support is likely to exist for the allegations set forth herein after a reasonable opportunity for further investigation or discovery.

I. NATURE OF THE ACTION

1. Alere provides diagnostic testing for diseases and toxicology. Alere's diagnostic products include point-of-care and laboratory tests within the infectious disease, cardio-metabolic disease and toxicology markets, as well as patient self-testing services, which it distributes through its worldwide distribution network. Alere has manufacturing facilities in the United States, Canada, China, Germany, Japan, Norway, South Korea and the United Kingdom, and the distribution network supporting its professional diagnostics business includes offices in 32 countries. Alere has its own sales force in many countries, including most major markets. During 2015, Alere reported that it generated approximately 56% of its net revenue from continuing operations from the United States, approximately 18% from Europe and approximately 26% from other locations, including Africa and India.

2. This action arises out of Alere and the Individual Defendants' violations of the federal securities laws by making materially false and misleading statements and omissions of material facts concerning Alere's business, finances and operations. The material misrepresentations and omissions occurred at a time when the Individual Defendants were actively seeking to sell Alere and, to that end, creating the illusion that the Company was thriving and had adequate financial and internal controls, while complying with its legal requirements concerning the proper billing of its services and not bribing foreign officials in violation of the U.S. Foreign Corrupt Practices Act ("FCPA"). The Defendants' strategy proved successful when, on February 1, 2016, Abbott Laboratories ("Abbott") entered into a merger agreement (the "Merger Agreement") to acquire Alere for $56.00 per share (the "Merger"), which represented a substantial and highly lucrative premium to Alere's then-current trading price of $37.20 per share. Most notably, when consummated, the Merger would result in special one-time payments to Individual Defendants Nawana and Hinrichs of ***over $29 million***. Nawana and Hinrichs were

thus highly motivated to, and did, misrepresent the apparent financial and operational condition of Alere through a series of materially false and misleading statements, which artificially inflated Alere's stock price.

3. However, on February 26, 2016 – less than one month after the Merger Agreement was signed – Defendants' scheme began to unravel when they disclosed, for the first time, that the Company would be unable to timely file its 2015 Annual Report on Form 10-K (the "2015 Form 10-K") as required by the Exchange Act. This was followed by a series of material negative disclosures about Alere's business, which included: (a) the March 15, 2016 announcement by Alere that the reason for its delay in filing the 2015 Form 10-K related to the Company's "analysis of certain aspects of the timing of revenue recognition, more specifically, revenue cutoff, in Africa and China for the years ended December 31, 2013, 2014 and 2015 (and each of the quarters in those annual periods)," as well as Alere's disclosure that it received a grand jury subpoena from the U.S. Department of Justice ("DOJ") concerning, among other things, matters related to the FCPA; (b) the April 20, 2016 refusal by Abbott's CEO to comment publicly on the likelihood that Abbott would complete the pending Merger; (c) the April 28, 2016 disclosure by Alere that Abbott wished to cancel the Merger Agreement and had offered to pay the Company $30 to $50 million for its expenses if it agreed to do so; (d) the July 11, 2016 disclosure by Alere that, along with the FDA, it would be initiating a voluntary withdrawal of the Company's blood testing INRatio products from the market; (e) the July 27, 2016 disclosure that the Company received a criminal subpoena from the DOJ regarding Alere's Toxicology unit, requesting Medicare, Medicaid and Tricare billing records; (f) the November 3, 2016 disclosure (after the close of the markets) that Abbott was pursuing litigation against Alere for Alere's alleged failure to provide to Abbott all of the underlying documents it requested of Alere in

connection with the Merger; (g) the November 4, 2016 disclosure that Arriva Medical, LLC ("Arriva Medical"), a subsidiary of Alere, had received a notice from the Centers for Medicare and Medicaid Services ("CMS") on October 5, 2016 revoking Arriva's Medicare enrollment, because CMS had determined that, over a five-year period, Arriva Medical had submitted claims for reimbursement for 211 deceased patients; and (h) the December 7, 2016 disclosure that Abbott had filed suit against Alere to terminate its proposed acquisition of Alere based on multiple serious problems that amount to material adverse effects under the Merger Agreement and the substantial loss in Alere's value following the Merger Agreement that were "not isolated incidents brought on by chance" but the result of "systemic company-wide failures of internal controls."

4. These disclosures caused the price of Alere's common stock to decline significantly: (a) first by $4.14 per share to close at $49.32 per share on March 15, 2016; (b) then by $6.11 per share to close at $43.36 per share on April 20, 2016; (c) then by $4.50 per share to close at $39.00 per share on April 29, 2016; (d) then by $1.34 per share to close at $38.61 per share on July 12, 2016; (e) by $12.55 per share to close at $31.47 per share on July 27, 2016; (f) by $6.76 per share to close at $36.10 on November 4, 2016; and (g) by $3.01 per share to close at $36.67 on December 7, 2016. Collectively, by the end of the Class Period, the price of Alere common stock fell by approximately 34% from the $55.39 per share Class Period high closing price, and to approximately the same price at which it had traded before the Merger Agreement was announced.

5. Alere's internal financial controls were so deficient and inadequate that it was not until August 8, 2016 *i.e.,* almost ***five months*** after the March 15, 2016 deadline to file its 2015 Form 10-K, that the Company finally filed that document. The 2015 Form 10-K, combined with

other disclosures made by Alere, alerted investors to the following material facts that Defendants had previously withheld from investors:

(a) Alere had improperly reported revenue based upon the time its products were shipped rather than when they were actually purchased, as required by Generally Accepted Accounting Principles ("GAAP") and the Company's policies, enabling the Company to artificially inflate its income for the nine months ended September 30, 2015;

(b) Alere's internal controls over financial reporting had material weaknesses that caused the Company to, among other things, incorrectly report revenues during 2015 and ultimately required the Company to materially delay, by several months, the filing of its 2015 Form 10-K and its Form 10-Qs for the first and second quarters of 2016;

(c) Facts existed that would give rise to the DOJ investigating Alere's toxicology division and the DOJ seeking records related to Medicare, Medicaid and Tricare billings and payments made to physicians;

(d) The Company failed to timely disclose that it was required to take a substantial charge relating to its withdrawal from the market of its INRatio products in the final fiscal quarter of 2015, even though it knew that such a charge was highly probable and estimable at least by that time;

(e) Facts existed that would give rise to the DOJ investigating Alere in connection with improper overseas payments, *i.e.*, bribes, violating the FCPA;

(f) Facts existed that would give rise to the CMS revoking Alere's Arriva Medical subsidiary's Medicare enrollment; and

(g) Alere had failed to timely provide Abbott with information about its business that would assuage Abbott's concerns about the value of Alere as an acquisition target and the effectiveness of its internal controls, which led Abbott to sue Alere to end the Merger.

6. The August 8, 2016 material restatement of Alere's previously filed financial statements: (a) resulted in decreases in previously reported income from continuing operations of ***67%*** for the nine months ending September 30, 2015; (b) caused the Company's previously reported income from continuing operations in the third fiscal quarter of 2015 to be revised to a loss; and (c) resulted in the Company's previously reported income from continuing operations in the second fiscal quarter of 2015 to be reduced by more than one-third. ***Importantly, the***

ultimate disclosures by Alere concerning the severity of its internal control weaknesses and deficiencies, were so significant that, in fact, the Company has admitted that its unaudited financial statements and results, even as of this late date, may not be relied upon, as the Company is unable to ensure that its financial statements do not include material misstatements. In addition, Alere has reported that remedial measures, which it has undertaken to protect against material misstatements, may not be relied upon.

7. Alere's internal control failures were so severe that they had previously required the Company to restate its earnings for the fiscal year ended December 31, 2014, as well as for the three and nine months ended September 30, 2014. The recently-disclosed internal control failures were also not the first ones experienced by or reported upon by the Company. Instead, in May 2015, the Company publicly disclosed that it had a material weakness in internal controls relating specifically to taxes regarding dispositions, and in November 2015, acknowledged that it had a material weakness in internal controls relating specifically to U.S. taxes on foreign earnings and lacked sufficient qualified personnel to identify errors in those calculations.

8. In reaction to Alere's belated disclosures, Abbott initially publicly expressed doubt at proceeding with the Merger, and now has sought to extricate itself from the terms of the Merger Agreement. In this regard, on December 7, 2016, Abbott filed a Verified Complaint in the Court of Chancery of the State of Delaware, alleging, among other facts, that "Alere has announced an endless sequence of serious problems—making it a materially different company than the one Abbott agreed to buy—including but not limited to a major Alere division being barred from the Medicare program (*i.e.*, Arriva); the permanent recall of INRatio, an important product platform; multiple new government subpoenas (two of which are criminal); and a five-month delay in filing Alere's 10-K coupled with admissions of internal control failures requiring

a restatement of three years of previous financials from 2013-2015." *See Abbott Laboratories v. Alere, Inc.*, C.A. No. 12963-VCG (Del. Ch. Dec. 12, 2016) (public version) ("Abbott Complaint") ¶ 3. Abbott concluded that "[as] a direct consequence of these events, Alere has already been stripped of substantial businesses, product lines, and revenue streams," and that "[a]ny one of these striking developments would be troubling, but together they reveal a much deeper problem: a fundamental lack of controls throughout the company coupled with minimal transparency about these events." *Id.* ¶ 4.

9. Defendants, by contrast, are seeking to enforce the Merger Agreement and sued Abbott for injunctive relief in the Delaware Court of Chancery. In doing so, Defendants recognize that, given all the material adverse disclosures since the time of the Merger Agreement, no other company would be willing to acquire Alere for a price even close to the $56 price per share which Abbott had agreed to pay, depriving the Individual Defendants of the more than $29 million bounty they hoped to earn upon consummation of the Merger Agreement.

II. JURISDICTION AND VENUE

10. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5), giving this Court jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. §78aa).

11. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false or misleading information,

occurred in substantial part in this Judicial District. In addition, the Company's principal executive offices are located within this Judicial District.

12. In connection with the acts, transactions and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications and the facilities of a national securities exchange.

III. PARTIES

A. Plaintiffs

13. Lead Plaintiffs Glazer Capital Management, L.P., Glazer Enhanced Fund L.P., Glazer Enhanced Offshore Fund, Ltd., Glazer Offshore Fund, Ltd. and Highmark Limited, in respect of its Segregated Account Highmark Multi-Strategy 2 (collectively, the "Glazer Funds"), as set forth in the certification previously filed with this Court, purchased Alere securities during the Class Period, and suffered damages as a result of the federal securities law violations and the materially false and/or misleading statements and/or material omissions alleged herein.

14. Plaintiff OFI Asset Management, as set forth in the certification previously filed with this Court, purchased Alere securities during the Class Period, and suffered damages as a result of the federal securities law violations and the materially false and/or misleading statements and/or material omissions alleged herein.

15. Plaintiff NECA-IBEW Pension Trust Fund (the Decatur Plan), as set forth in the certification previously filed with this Court, purchased Alere securities during the Class Period, and suffered damages as a result of the federal securities law violations and the materially false and/or misleading statements and/or omissions of material facts alleged herein.

B. Defendants

16. Defendant Alere Inc. is a Delaware corporation with its principal executive offices located at 51 Sawyer Road, Suite 200, Waltham, Massachusetts 02453. Alere is a publicly traded company registered with the SEC pursuant to Section 12 of the Exchange Act. Alere's shares trade on the New York Stock Exchange ("NYSE"), an efficient market, under the ticker symbol "ALR." Alere relies heavily on its foreign operations with eight of its ten largest manufacturing operations located outside the U.S. For 2014, approximately 47% of its net revenue was derived from sales outside the U.S. In its Professional Diagnostics business, its largest business segment, U.S. revenue declined approximately 8% during 2014, while revenues from international sales increased because of continued strong performance from Africa, China and India, where revenues increased by approximately 17%. As stated in its 2014 Form 10-K/A (defined below): "Our high-performance diagnostics for infectious disease, cardiometabolic disease and toxicology are designed to meet the growing global demand for accurate, easy-to-use and cost-effective near-patient tests. Our goal is to make Alere products accessible to more people around the world, even those located in remote and resource-limited areas, by making them affordable and usable in any setting." 2014 Form 10-K/A at 40.

17. Defendant Namal Nawana ("Nawana") was the Company's Interim CEO from July 1, 2014 until October 25, 2014 and, after that time to the present, became CEO, President, and a Director of Alere. Nawana signed the Sarbanes Oxley Act of 2002 ("SOX") certifications included in Alere's 2014 Form 10-K (defined below), 2014 Form 10-K/A (defined below), 2015 1Q Form 10-Q (defined below), 2015 2Q Form 10-Q (defined below), 2015 3Q Form 10-Q (defined below) and 2015 Form 10-K.

18. Defendant James F. Hinrichs ("Hinrichs") is and has been since April 6, 2015, Alere's CFO. Hinrichs signed the SOX certifications included in Alere's 2014 Form 10-K/A, 2015 1Q Form 10-Q, 2015 2Q Form 10-Q, 2015 3Q Form 10-Q and 2015 Form 10-K.

19. Defendant Carla R. Flakne ("Flakne") was, at all relevant times, CAO of Alere until March 31, 2016, when she was replaced by Jonathan Wygant. Flakne signed Alere's 2014 Form 10-K, 2014 Form 10-K/A, 2015 1Q Form 10-Q, 2015 2Q Form 10-Q and 2015 3Q Form 10-Q.

20. Defendants Nawana, Hinrichs and Flakne are collectively referred to herein as the "Individual Defendants." The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Alere's reports to the market, including in Alere public filings filed with the SEC, and in press releases and presentations to securities analysts, money and portfolio managers and institutional investors.

IV. BACKGROUND AND NATURE OF THE FRAUD

A. Defendants Decided to Sell Alere and Set Up a Multi-Million Dollar Payday

21. Alere provides diagnostic tests for infectious disease, cardio-metabolic disease, and toxicology. As discussed below, by mid-2014, Alere executives decided to sell Alere to explore strategic alternatives, including a corporate transaction, then put in place change of control provisions that would guarantee them multi-million dollar payments in the event the Company was sold, and took repeated steps to sell off portions of the Company before Alere entered into the February 1, 2016 Merger Agreement with Abbott. The Individual Defendants were thus highly motivated to conceal, and did conceal, Alere's true financial state, the material weaknesses in its internal controls over financial reporting, the fraud being committed in its Toxicology unit, the defective nature of its INRatio device, and the serious material risks that the

Company would face harsh regulatory scrutiny over its Medicare billing practices and alleged violations of the FCPA.

22. On August 4, 2014, the Company announced that, pursuant to its ongoing "comprehensive review of its strategy and operations" previously announced on May 5, 2014 (as part of which the Company disclosed that it was engaging an international consulting firm), Alere intended to refocus on its core business in rapid diagnostics and divest its connected health initiative business, its health management business and other non-core assets. The Company also stated that it was considering various options, including whether to pursue a sale of the entire Company.

23. On September 15, 2014, former Alere CEO Ron Zwanziger indicated to Alere that he and other former executives were interested in acquiring all of the Company's common stock at a price of $46.00 per share. On September 15, 2014, the price of Alere stock closed at $41.14 per share. The former Alere executives requested an opportunity to conduct one month of due diligence to secure financing and make a bona fide offer.

24. On September 15, 2014, Alere filed a Form 8-K with the SEC, attaching a press release in which its Chairman of the Board, Gregg J. Powers ("Powers") noted Zwanziger's proposal, but stated that the sources of any proposed financing were not identified and there was no indication that any of those sources was highly confident that the necessary funding would be available. Powers also stated that while three former senior executives who were with the Company in June made the proposal, their proposal was contingent on one month of due diligence. Powers further stated that the Board would consider any bona fide proposal that would maximize shareholder value. J.P. Morgan was identified as serving as the Company's financial advisor.

25. After Zwanziger's proposal became public, news articles stated that other suitors could come forward, and one stated that an Alere activist investor, who wanted the Company to be sold, was likely to get the sale it wanted, but that Zwanziger's proposal was thin on details. An analyst with Canaccord Genuity wrote in a note that he would not be surprised if some of the leaders in the point-of-care diagnostics space showed interest in Alere and that one or more private equity players could also be interested. Observers also mentioned industry entities such as Siemens, Abbott, Johnson & Johnson and others as possibly having interest. The Canaccord analyst stated that he believed there was more than one potential buyer in the marketplace.

26. The Company's Board of Directors and senior management subsequently declined Zwanziger's request to conduct due diligence and the proposal did not proceed. However, the Individual Defendants' efforts to sell the Company and its subsidiaries continued. On October 10, 2014, as part of its efforts at corporate restructuring, Alere completed the sale of its subsidiary, Alere Accountable Care Solutions, LLC ("ACS").

27. The Individual Defendants also cemented their leadership roles at the Company and planned to reap significant change of control benefits from any sale of Alere to a third party. On October 28, 2014, Alere announced that on October 25, 2014, its Board of Directors elected Defendant Nawana as CEO and President, and also appointed him to Alere's Board. Nawana had previously served as Alere's interim CEO and President since July 1, 2014, and prior to that, he served as Alere's Chief Operating Officer starting in December 2012. When Nawana was hired in 2012, it was, among other things, to oversee Alere's global operational functions, and his experience in complex business integrations was highlighted. In connection with being elected CEO, Nawana received a compensation package that included a base salary of $1,050,000, a cash bonus of $500,000 payable in January 2015, a target bonus for 2015 equal to 100% of his

salary, with a maximum payout of 150%, 50,000 restricted stock units, 100,000 nonqualified stock options and 150,000 performance stock units.

28. Also in October 2014, the Company implemented change of control benefits for Alere executives. Those change in control provisions stated that, in the event of a qualifying termination, named executive officers, including the Individual Defendants, would be entitled to receive, among other things, 18 months of their annual base salary, the cash component of any incentive plan award and the accelerated vesting of all outstanding unvested equity awards. Therefore, in a sale of the Company, those executives would potentially be able to receive significant monetary benefits. Specifically, under those provisions, according to filings made with the SEC, Defendant Nawana stood to gain $20.5 million, and Defendant Hinrichs stood to gain $8.7 million.

29. Alere continued the sell-off of its operations, with the eventual goal of selling the entire Company. On January 9, 2015, the Company completed the sale of its condition management, case management, wellbeing, wellness, and women's and children's health businesses, which it referred to, collectively, as its health management business. Alere sold its health management business for approximately $600 million with the stated intention to use those proceeds to pay down debt.

30. In February 2015, the Company also adopted a new compensation plan for its executives. Among other things, the compensation plan, referred to as a short-term incentive plan ("STIP") as stated in Alere's 2015 Form 10-K, was based on the achievement of two performance-based goals: a non-GAAP measure of earnings per share and a non-GAAP measure of organic growth, each for the fiscal year ended December 31, 2015.

31. In addition, on March 23, 2015, Alere announced the appointment of Defendant Hinrichs as Executive Vice President and CFO effective April 6, 2015. Alere further stated that Hinrichs' compensation would consist of an annual salary of $650,000, and participation in the 2015 STIP (whereby he could receive cash bonuses of 60% of his base salary and annual equity grants targeted at $2 million). Alere also granted Hinrichs an option to purchase 250,000 shares of Alere common stock, and 50,000 Restricted Stock Units, with each unit representing the right to receive one share of common stock. Hinrichs' offer also provided that if the price of Alere's common stock increased between the time of the announcement of his hiring and April 6, 2016, he would receive a bonus equal to the aggregate increase in the exercise price of his stock options during that period.

B. Alere Operated with Undisclosed Material Weaknesses in Its Internal Controls, But Reported Only Limited Disclosures

32. On August 8, 2016, Alere admitted to material weakness in its internal controls over financial reporting. For years prior, Alere executives were on notice of serious problems with the Company's internal controls over financial reporting, yet the Individual Defendants repeatedly falsely certified that they had created adequate internal controls over financial reporting, which had the effect of artificially inflating the market price of Alere's common stock.

33. On March 3, 2015, Alere filed with the SEC a Form NT 10-K stating that its Form 10-K for the year ended December 31, 2014 could not be filed within the prescribed time without unreasonable effort or expense. The Company attributed the delay to finalizing the Company's "accounting treatment for the tax effects of the Company's recent divestiture of its health management business on January 9, 2015."

34. On March 5, 2015, Alere filed with the SEC its Annual Report on Form 10-K for the fiscal year ended December 31, 2014 (the "2014 Form 10-K"), in which it disclosed that it

had a material weakness in internal controls, particularly related to deferred tax assets and stated that: "The material weakness related to the failure to design controls to assess the accounting for deferred tax assets which became recognizable as a result of the disposition."

35. Despite this disclosure of certain specific material weaknesses in Alere's internal controls over financial reporting, the 2014 Form 10-K was signed by Defendants Nawana and Flakne, and still contained a certification of Alere's financial statements required by SOX, signed by Defendant Nawana, attesting that the financial information contained in the Company's SEC filings was true and did not omit material facts, and that the Company's internal and disclosure controls were effective. Thus, despite the contemporaneous existence of material weaknesses in internal controls, Nawana certified, among other things, that:

> The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
>
> (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
>
> (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
>
> (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
>
> (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal

> quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting[.]

(2014 Form 10-K, Exhibit 31.1).

36. On May 28, 2015, Alere filed Amendment No. 2 on Form 10-K/A with the SEC (the "2014 Form 10-K/A") signed by, among others, Defendant Nawana. Alere disclosed in its 2014 Form 10-K/A that as a result of a material weakness identified in its 2014 Form 10-K, it had incorrectly accounted for income taxes associated with two divestitures during 2014. Furthermore, the resulting errors were deemed to be material, thus requiring a restatement of previously reported consolidated financial statements. The Company also disclosed that it needed to file an amended Form 10-Q for the three months ended September 30, 2014, and that the 2014 Form 10-K/A contained restated financial information for each of the three months ended September 30, 2014 and December 31, 2014. The 2014 Form 10-K/A also contained revised financial information for the years ended December 31, 2012 and December 31, 2013, and for each of the three months ended March 31, 2013, June 30, 2013, September 30, 2013, December 31, 2013, March 31, 2014 and June 30, 2014.

37. On November 9, 2015, Alere filed its Quarterly Report with the SEC on Form 10-Q for the fiscal quarter ended September 30, 2015 (the "2015 3Q Form 10-Q"). The Company's 2015 3Q Form 10-Q was signed by Defendant Flakne, and repeated the Company's financial results previously announced on November 4, 2015. The 2015 3Q Form 10-Q contained as Exhibits 31.1, 31.2 and 32.1 certifications pursuant to SOX, signed by Defendants Nawana and Hinrichs, substantially similar to the certifications described in ¶¶ 207-213, *supra*. Alere also disclosed in its 2015 3Q Form 10-Q, that it identified another internal control problem and

acknowledged that the Company "did not maintain a sufficient complement of resources with adequate experience and expertise in accounting for income taxes."

38. On November 13, 2015, Alere filed a Form 10-K/A, Amendment No. 3 to its 2014 Form 10-K with the SEC. Alere filed this amendment with respect to the material weakness that it had identified in the 2015 Q3 Form 10-Q. This Amendment No. 3 restated Item 9A regarding Controls and Procedures, as well as the Report of Independent Registered Public Accounting Firm that was included in the 2014 Form 10-K/A, in order to revise the previous description of the income tax material weakness that existed in its financial statements for the year ending December 31, 2014, and other related matters, such as the remediation plans. In that filing, the Company reported that it identified and corrected out-of-period errors in the quarter ending September 30, 2015 relating to U.S. taxes on foreign earnings, an additional material weakness, for the year ended December 31, 2014. However, instead of reporting this additional material weakness separately, the Company merely revised the description of the previous material weakness related to deferred tax assets. The revised description of the material weakness stated that the "Company did not maintain a sufficient complement of resources with adequate experience and expertise *in accounting for income taxes*, as a result of which our controls did not operate at a level of precision to identify errors in the calculation of tax balances resulting from dispositions and U.S. taxes on foreign earnings."

39. The 2014 10-K/A, Amendment No. 3, contained as Exhibits 31.1, 31.2 and 32.1, dated as of November 13, 2015, certifications pursuant to SOX, signed by Defendants Nawana and Hinrichs, substantially similar to the certifications described in ¶¶ 207-213, *supra*.

40. The foregoing disclosures of specific material weaknesses in Alere's internal controls were red flags to Defendants Nawana, Hinrichs and Flakne that Alere was operating

with material weaknesses in internal controls that were broader than the weaknesses that the Company disclosed.

41. In addition, a former Alere Senior Accountant in Western Europe from 2011 through 2014 (the "Senior Accountant") stated that there was a lack of internal controls at Alere. He described Alere as massive, consisting of approximately 200 entities, and he believed that the Company's financial information system could not ensure that it accurately compiled all of the necessary information. According to the Senior Accountant, revenue was typically reconciled using simply an Excel file that was linked to the Company's accounting platform, Hyperion, and the information in the file was very easy to change, thus creating opportunities for potential manipulation. For example, the Senior Accountant described one situation in which Alere needed to make an approximately $2.6 million adjustment related to internal transfer pricing in November 2013 related to fiscal year 2012. Alere's accounting firm responsible for the tax audit, PricewaterhouseCoopers ("PwC"), became aware of the deficiency and advised Alere not to take the $2.6 million adjustment. However, Alere's local financial controller in France raised the issue with Alere's corporate offices, and the decision was made to post the required adjustment. This event put Alere's corporate office on notice of a lack of proper communication between Alere entities, and a lack of internal controls by, at the latest, November 2013.

42. The Senior Accountant further stated that another Alere internal control weakness related to income tax, which was also simply handled through an Excel file. The Senior Accountant found that it was quite difficult (from a legal and fiscal perspective) for various Alere offices in different countries to transpose the tax-related figures for their locations to U.S. GAAP figures and standards because of the confusion caused by each European country's different rules and approaches for calculating income tax. As a result, it was difficult for Alere offices in

different countries to know, from a tax perspective, what was occurring in their countries, what the tax requirements were and the tax amounts they should declare.

43. A former Alere National Sales Manager in India from 2013 through early 2015 stated that Alere's operations in India used a "not very effective reporting management system" to track and report sales and other business figures, which was "very primitive."

44. A former Alere Global Vice President of Customer Experience from June 2012 through May 2014 (the "Global VP of Customer Experience"), who had worked at Alere since 2007 as the Director of Corporate Accounts, stated that it was known amongst Company employees that Alere had made more than 100 acquisitions over ten years and that the acquisitions brought into the Company different systems and reporting structures and practices for reporting revenue in various countries.

45. Alere also followed practices that led to the improper recognition of revenue. The Global VP of Customer Experience stated that at the end of a financial quarter, Alere "stuffed" its distribution channel with its products by asking distributors to buy stock of Alere products at a discount. This practice started in 2012 and the financial results that it generated did not represent true organic growth at the Company. On the contrary, this practice was utilized because employees were pressured to meet their top-line sales numbers, and channel stuffing was one way to represent that the Company was reaching its sales goals, which it in fact was not. As a result, Alere experienced a situation where distributors – who are supposed to move their Alere products on a first in, first out basis – had Alere products sitting on their shelves for as long as eight months.

C. Alere Failed to Timely Disclose That It Would Need to Recall the INRatio Device

46. For several years, Alere has been on notice of serious problems with its INRatio products and the need to fully recall them. (INRatio products include the INRatio and INRatio2 devices and the test strips used with those products.) Indeed, of all Alere products, the Company received the largest number of the most severe consumer complaints related to the INRatio devices. However, Alere improperly delayed that recall and disclosing the need for a recall until 2016.

47. INRatio is a hand-held blood coagulation monitoring system for use by patients and healthcare professionals in the management of warfarin, a commonly prescribed medication used to prevent blood clots. The INRatio device measures PT/INR, which is the patient's blood clotting time, to help ensure that patients at risk of blood clot formation are maintained within the therapeutic range with the proper dosage of oral anticoagulant therapy. Proper calibration of anti-coagulant dosage is critical. If patients take too little of the drug, they are at higher risk of suffering a stroke or other injury. If they take too much, then their blood will become too thin, heightening the risk of hemorrhage and bleed out.

48. As Alere's Global VP of Customer Service explained about INRatio, as far back as 2007, former Alere CEO Zwanziger stood up on stage in front of Alere employees and said that INRatio was "a crude device." As explained by the Global VP of Customer Service, when a customer would complain about INRatio, the standard protocol for Alere was to state that it was a "user error" – in other words, that the patient was incorrectly using the device and not that the device was defective. However, as the Global VP of Customer Service stated "nobody internally believed that was the case."

49. A former Quality Assurance ("QA") Product Support Associate at Alere from March 2014 through February 2016 (the "QA Product Support Associate"), who began at the

Company as a Quality Control Associate in February 2010 and who handled customer complaints and trouble-shooting from March 2014 through February 2016, stated that Alere needed to recall the INRatio device because "it didn't work." She had heard complaints from customers that the device would "fluctuate a lot," giving a correct result in one test and a false result in the next. This required patients to visit their doctors to ensure that their blood measurements were correct, and, when they did, the doctor found a completely different result than the one provided by the INRatio products.

50. According to the QA Product Support Associate, the complaints were "known" for years prior to the 2016 recall, and the problem was "continuous." The QA Product Support Associate stated that, among Alere's products, "by far, the most troubling was the INRatio" and that it had been a problem for at least "two years."

51. According to the QA Product Support Associate, during her tenure with the Company, the INRatio products had a higher number of "high-severity" complaints than any other product line or Alere device, a designation for a customer complaint in which an adverse event was reported. As a result, Alere needed to hire outside employees to handle the complaints and, from October 2015 until February 2016, the Company had to nearly double the QA staff needed to field complaints about the INRatio products. The QA Product Support Associate stated that the QA Senior Director knew about the problems with the INRatio products because he and the entire QA department received reports on the complaints every other week and "knew exactly what was going on."

52. Defendants were on notice of problems with INRatio since at least May 2014, when the Company issued a partial recall of the device's test strips. Specifically, in the Company's 2014 Form 10-K, Alere stated with respect to Alere's INRatio products that:

> We have encountered product issues related to our Alere INRatio systems resulting in a May 2014 recall of our Alere INRatio2 PT/INR Professional Test Strips in the United States and a December 2014 voluntary urgent medical device correction initiated with respect to our Alere INRatio and Alere INRatio2 systems to inform users not to use these systems to test patients with certain medical conditions. We have transitioned customers from the recalled Alere INRatio2 PT/INR Professional Test Strip to the Alere INRatio PT/INR Test Strip, which was not included in the recall. While it is too early to understand the full impact of the voluntary urgent medical device correction, ***we believe that our 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.*** We plan to continue our improvements to quality and regulatory compliance during 2015 and beyond.

(2014 Form 10-K at 39). (Emphasis Added).

53. In November 2015, it was reported that the institute that coordinated the study of the blood thinner Xarelto, which resulted in its FDA approval, was investigating whether the INRatio products, which were used during the Xarelto trial, had improperly distorted its results. Because the INRatio products were alleged to have been providing different results than the results obtained in a laboratory, the INRatio products' readings were likely to have led to Xarelto having a more favorable comparison to the other products in the drug trial. This information about the unreliability of the INRatio products was another fact that should have caused Defendants to disclose a reasonable possibility that a material loss relating to the INRatio products had been incurred.

54. Near the end of 2015, Alere attempted to implement software enhancements to its INRatio products to address the issue of those systems delivering results that differed from another measurement method. However, the FDA informed Alere that the information provided

did not adequately demonstrate the effectiveness of the proposed enhancements and advised Alere to submit a proposal to voluntarily remove the devices from the market.

55. In late January 2016, Defendants became aware of additional adverse information concerning the INRatio product. The precise nature of that information is not yet known to Plaintiffs because it has been redacted from the publicly available complaint recently filed by Abbott against Alere.

56. In addition, on or about February 23, 2016, *The New York Times* reported that the FDA was investigating whether the use of the INRatio products compromised the results in the Rocket AF clinical trial. The FDA was trying to determine whether the use of the INRatio products resulted in doctors giving patients the wrong dose of warfarin, causing additional bleeding, and providing an advantage to Xarelto in the comparison to warfarin. It was subsequently reported by *The New York Times* on or about March 18, 2016, that of the blood samples taken from more than 5,000 patients in the Rocket AF trial, the samples that used the INRatio products had a different reading than that obtained from a central laboratory test that was clinically significant 35% of the time.

57. Moreover, as *The New York Times* reported on March 18, 2016, in 2013, a Florida doctor, Gary Goldstein, checked the results he received from the INRatio products against those obtained from an outside laboratory, and found they did not match. Dr. Goldstein contacted Alere, but it was reported that he sensed a lack of interest from the Company. Thus, Dr. Goldstein reported the event to the FDA because of the "potential harm to patients." The article confirms the accounts of Alere's former employees discussed above. Specifically, the FDA had received more than 9,000 reports of malfunctions with the INRatio products, and more than 1,400 reports of injuries. The reported injuries were far higher than similar products on the

market. For example, market leader Roche's similar product had only 95 injury reports during the same period.

58. In its 2015 Form 10-K, issued on August 8, 2016, the Company announced that it was recording $43 million in pre-tax expenses relating to the INRatio products' withdrawal from the market, which it was taking in the fourth quarter of 2015. The fact that Alere was recording the INRatio charge in the fourth quarter of 2015 demonstrates that the charge was probable and estimable during that time period. At that time, or earlier, Defendants knew about (or recklessly disregarded) and should have disclosed: (a) the charge; as well as (b) the likely need to withdraw the INRatio products from the market upon which the charge was based, given the large number of complaints received about the INRatio products, the number of injuries reported and the continual problems that existed with their reliability and accuracy.

59. Alere's worldwide withdrawal of INRatio from the market was a withdrawal of "one of its showcase products" and Alere will forever lose the revenues associated with the sales of its INRatio products. Abbot Complaint ¶ 14. The withdrawal of INRatio will have "long-term, durable effects on Alere's earning potential,"and Alere will lose all revenues and ernings from the sale of the INRatio products.

D. Alere Failed to Disclose the Improprieties in its Toxicology Division

60. Alere was also aware that questionable practices existed in its Toxicology unit. As *The Wall Street Journal* reported during the trading day on July 27, 2016, the DOJ's criminal fraud section had recently served Alere with a subpoena seeking information about the Company's efforts to collect co-payments from patients, as well as forms submitted on their behalf to government programs such as Medicare. The DOJ was also investigating whether Alere made payments or delivered items of value to doctors who ordered the tests from Alere,

which the government considers to be illegal kickbacks. Alere's Toxicology unit, the subject of the probe, provides drug testing for employers and government bodies. That unit accounted for one quarter of the Company's $2.57 billion revenue in 2014.

61. Alere has been on notice of alleged improprieties in its Toxicology unit since at least August 2013, when Horizon Blue Cross and Blue Shield ("Horizon") filed a complaint in New Jersey Superior Court against Alere and Alere Toxicology alleging that they committed insurance fraud. Specifically, the complaint alleged that Alere and a company that it acquired, Avee Laboratories, Inc. ("Avee"), defrauded Horizon of at least $36 million by making false and fraudulent health insurance claims for unnecessary tests, in violation of New Jersey and Florida law. The complaint alleged that Alere should have been aware of Avee's improper conduct and that Alere knowingly continued that misconduct after Alere acquired Avee. For example, Horizon specifically alleged that Alere had told Horizon that, after acquiring Avee, Alere had issued new marketing materials that (unlike the prior, misleading Avee materials), were purportedly no longer false and misleading. However, Horizon alleged that, contrary to Alere's claims, the Company in fact never issued revised materials.

62. A former Medicaid Accounts Resolutions Specialist at Alere in Florida from 2010 through October 2012 (the "Medicaid Accounts Resolutions Specialist") also stated that Alere would conduct, and bill for, unnecessary toxicology screenings. For example, Alere might receive a specimen from a facility to be tested as confirmation for a specific type of drug, like opiates. In that situation, the specimen had already been tested and turned up positive for opiates and Alere only needed to confirm that original test. However, as explained by the Medicaid Accounts Resolutions Specialist, Alere would then routinely test for a panel of between seven and fourteen drugs, including THC, methamphetamine, cocaine, and bath salts, and sometimes

"on all the drugs, even if it was not requested by the facility." Alere would also re-screen the specimen, as if the initial screening had not been done and then perform the confirmation screen, and bill for all of this testing. At the time, the Medicaid Accounts Resolutions Specialist spoke to his manager about the issue, but the Medicaid Accounts Resolutions Specialist stated that "everyone was scared they were going to jail" and "Alere blamed it on Avee." After Alere sent its inflated bills to the customers who had requested the testing in the first place, a number of clients stopped using Alere, which was a "big hit on business," according to the Medicaid Accounts Resolutions Specialist.

63. Indeed, a number of high-level executives in Alere's Toxicology business recently resigned from the Company. Specifically, Alere Toxicology's CEO (John Peterson), CFO (Bobby Gardebled) and Controller (Denise Holderith) all recently left the Company during the summer of 2016. Senior Alere executives knew about, or recklessly disregarded these senior executives' departures from Alere Toxicology and the reasons for their departures.

64. A former Alere Toxicology Billing and Pricing Supervisor who worked in Alere's Florida office from March 2014 through August 2014 (the "Toxicology Billing & Pricing Supervisor") stated that while she worked there, two Medicare audits and one internal audit were happening at the same time, and based upon those audits, Alere learned that problems existed with its billing practices. In fact, the Toxicology Billing & Pricing Supervisor assisted with pulling documentation to respond to the Medicare audit, including searching for the documents that should have supported the medical necessity of the services Alere performed and for which it billed. In connection with those tasks, the Toxicology Billing & Pricing Supervisor found that physicians had not consistently documented the medical necessity for the tests Alere had performed. The audits also found that the documentation did not support the medical claims, and

that the clinics did not receive documentation of medical necessity before billing was done. During the audits, internal auditors questioned several people in Alere's Billing Department, and the Toxicology Billing & Pricing Supervisor told the auditors about observing a lack of checks and balances in verifying payment posting.

E. Alere's Undisclosed FCPA Improprieties

65. On March 15, 2016, Alere filed a Form 8-K with the SEC disclosing, *inter alia*, that on March 11, 2016, the Company had received a grand jury subpoena from the DOJ "requiring the production of documents relating to, among other things, sales, sales practices and dealings with third-parties (including distributors and foreign governmental officials) in Africa, Asia and Latin America and other matters related to the U.S. Foreign Corrupt Practices Act."

66. Alere had been on notice of alleged FCPA improprieties since at least the fall of 2013. According to a former Alere National Sales Manager in India from 2013 through early 2015, Alere's audit firm Deloitte conducted an investigation into Alere's government bidding practices in India that began in approximately late summer and early fall of 2013. The former National Sales Manager stated that the government bidding process was "highly corrupted," that Alere's policies for ensuring adherence to anti-corruption laws were not open or transparent and that most of Alere's practices in India did not match global policies.

67. The former National Sales Manager also explained that state-level governments in India purchase diagnostic products in "huge quantities" and that a potential supplier to the government needed to qualify to supply products to the government based on price. He further stated that Alere did not offer the lowest price to the government, yet the government still very often selected Alere as a provider. He explained that these transactions were facilitated by "under the table" dealings between Alere distributors and government officials.

F. February 1, 2016: Alere Announces Its Merger with Abbott

68. Without disclosing Alere's material internal control deficiencies, the need to withdraw INRatio from the market, the billing improprieties at Alere's Toxicology unit and Alere's FCPA problems, Alere embarked on a potentially highly lucrative merger with Abbott.

69. On December 10, 2015, Brian Blaser ("Blaser"), the Executive Vice President, Diagnostics Products, of Abbott, contacted Defendant Nawana to inform him that Abbott was interested in making a proposal to acquire the Company at a significant premium to its current share price.

70. On December 14, 2015, at a regularly scheduled Alere Board meeting, J.P. Morgan Securities LLC ("J.P. Morgan"), the Company's financial advisor, discussed strategic alternatives and reviewed with the Board a list of other potential strategic counterparties in the medical technology and diagnostics industry and financial sponsors, which J.P. Morgan had been preparing even prior to the Abbott contact. J.P. Morgan was authorized to contact each of the counterparties to evaluate their potential interest in a transaction with the Company, and to continue discussions with Abbott.

71. In the weeks that followed, four entities expressed interest in a potential transaction with Alere and began due diligence. By January 13, 2016, a deadline provided by J.P. Morgan, two of those companies submitted non-binding indications of interest proposing to acquire the Company for a price of $50.00 per share of Company common stock.

72. On January 11, 2016, Alere gave a presentation at a J.P. Morgan healthcare conference, and attached a copy of its presentation materials to its Form 8-K that was filed with the SEC on that date. In those materials, Alere included a summary of its financial information for the first 9 months of 2015, including its purported income which later turned out to have been

overstated by approximately 67%. Alere also included as one of four chronic care management products, the INRatio2 device with a picture of the product.

73. On January 29, 2016, Abbott proposed an acquisition at a price of $54.00 per share, and indicated that it would require as a condition to closing the full and final resolution of the matters described in a May 2012 subpoena, which the Company had received from the Office of Inspector General of the Department of Health and Human Services (the "San Diego Matter"). That subpoena sought documents relating primarily to the quality control testing and performance characteristics of Alere Triage products.

74. On January 30, 2016, Abbott revised its offer to: (a) provide all-cash consideration at a price of $56.00 per share of Company common stock; and (b) remove the previously requested closing condition related to the San Diego Matter. Later that evening of January 30, 2016, the Company and Abbott executed the Merger Agreement.

75. On February 1, 2016, the Company and Abbott issued a joint press release announcing their agreement that Abbott would pay $56.00 per common share for a total expected equity value of $5.8 billion pursuant to the terms of the Merger Agreement. In response to this news, Alere's stock price increased by $16.91 per share, or more than 45%, to close at $54.11 per share.

76. The Merger Agreement between Abbott and Alere was disclosed in, and attached as Exhibit 2.1, to a Form 8-K filed by Alere with the SEC on February 1, 2016. The Merger Agreement contained Representations and Warranties made by Alere, providing, in part, as follows:

> (a) Company SEC Documents; Undisclosed Liabilities. (a) The Company has filed with the SEC all material reports, schedules, forms, statements and other documents required to be filed by the Company with the SEC pursuant to the Securities Act or the

Exchange Act since January 1, 2014 (collectively, the "Company SEC Documents"). As of their respective effective dates (in the case of Company SEC Documents that are registration statements filed pursuant to the requirements of the Securities Act) and as of their respective SEC filing dates or, if amended prior to the date hereof, the date of the filing of such amendment, with respect to the portions that are amended (in the case of all other Company SEC Documents), ***the Company SEC Documents complied as to form in all material respects with the requirements of the Securities Act or the Exchange Act***, as the case may be, applicable to such Company SEC Documents, and ***none of the Company SEC Documents as of such respective dates*** (or, if amended prior to the date hereof, the date of the filing of such amendment, with respect to the disclosures that are amended) ***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 under which they were made, not misleading***.

(b) The consolidated financial statements of the Company (including all related notes or schedules) included or incorporated by reference in the Company SEC Documents, as of their respective dates of filing with the SEC, ***complied as to form in all material respects with the published rules and regulations of the SEC with respect thereto, have been prepared in all material respects in accordance with GAAP*** (except, in the case of unaudited quarterly statements, as permitted by Form 10-Q of the SEC or other rules and regulations of the SEC) applied on a consistent basis during the periods involved (except (i) as may be indicated in the notes thereto or (ii) as permitted by Regulation S-X) and fairly present in all material respects the consolidated financial position of the Company and its consolidated Subsidiaries as of the dates thereof and the consolidated results of their operations and cash flows for the periods shown (subject, in the case of unaudited quarterly financial statements, to normal year-end adjustments).

(c) ***Neither the Company nor any of its Subsidiaries has any liabilities of any nature (whether accrued, absolute, contingent or otherwise) that would be required under GAAP, as in effect on the date hereof, to be reflected on a consolidated balance sheet of the Company (including the notes thereto) except liabilities (i) reflected or reserved against in the consolidated balance sheet (or the notes thereto) of the Company as of September 30, 2015 (the "Balance Sheet Date") included in the Filed SEC Documents,*** (ii) incurred after the Balance Sheet Date in the

> ordinary course of business, (iii) as contemplated by this Agreement or otherwise incurred in connection with the Transactions or (iv) as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.
>
> (d) ***The Company has established and maintains disclosure controls and procedures and a system of internal controls over financial reporting (as such terms are defined in paragraphs (e) and (f), respectively, of Rule 13a-15 under the Exchange Act) as required by Rule 13a-15 under the Exchange Act. As of the date hereof, neither the Company nor, to the Company's Knowledge, the Company's independent registered public accounting firm, has identified or been made aware of "significant deficiencies" or "material weaknesses" (as defined by the Public Company Accounting Oversight Board) in the design or operation of the Company's internal controls over financial reporting which would reasonably be expected to adversely affect in any material respect the Company's ability to record, process, summarize and report financial data,*** in each case which has not been subsequently remediated. ["Knowledge" is a defined term in the Merger Agreement, which means, as to Alere, actual knowledge of certain individuals identified in the Company's Disclosure Letter.].

(Merger Agreement, Article III, Section 3.05) (emphasis added).

77. In addition, Alere represented to investors through the terms of the Merger Agreement that "there is no . . . pending or, to the [k]nowledge of the Company, threatened legal or administrative proceeding, suit, claim, investigation, arbitration or action . . . against the Company or any of its Subsidiaries . . ." that would be expected to have a material adverse effect. Merger Agreement, Section 3.07. The Company further represented that it was in compliance with "all state or federal laws, statutes, ordinances, codes, rules or regulations . . ." since January 1, 2014. In addition, Alere represented that: "Except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, the Company, each of its Subsidiaries and each of its and their directors, officers and employees and, to the Knowledge of the Company, each of its and their other agents acting on its or their behalf, is and has been since

January 1, 2014 in compliance with the Foreign Corrupt Practices Act of 1977 and any rules and regulations promulgated thereunder." (Merger Agreement, Section 3.08).

V. PARTIAL DISCLOSURES AND THE GRADUAL EMERGENCE OF THE FULL IMPACT OF THE FRAUD

A. February 26, 2016: Alere Discloses Its Inability to File Its 2015 Form 10-K

78. On February 26, 2016, after the market closed, the Company disclosed that it was unable to file its Annual Report on Form 10-K for the fiscal year ended December 31, 2015 within the prescribed time period without unreasonable effort or expense, because the Company was "conducting an analysis of certain aspects of revenue recognition in Africa and China and any potential implications on [the Company's] evaluation of internal controls over financial reporting for the year ended December 31, 2015." (Form NT 10-K filed with the SEC on February 26, 2016). The Company stated that its goal was still to file the Form 10-K within the fifteen-day extension period. The Company also disclosed that it had received a subpoena from the SEC on January 14, 2016, in connection with a previously-disclosed formal SEC investigation which requested, among other things, "additional information related to sales of products and services to end-users in Africa, as well as revenue recognition relating to sales of products and services to end-users in Africa." In addition, the Company stated that it was "conducting an analysis of certain aspects of revenue recognition in Africa and China and any potential implications on [the Company's] evaluation of internal controls over financial reporting for the year ended December 31, 2015."

79. Subsequently, on March 15, 2016, the Company filed a current report on Form 8-K with the SEC disclosing that the Company would be, again, unable to file its 2015 Form 10-K within the extension period, because it was "continuing to conduct an analysis of certain aspects of the timing of revenue recognition, more specifically, revenue cutoff, in Africa and China for

the years ended December 31, 2013, 2014 and 2015 (and each of the quarters in those annual periods)." The Form 8-K also disclosed that the Company "determined it was appropriate to expand its analysis of these aspects of the timing of revenue recognition in Africa and China to include the years ended December 31, 2013 and 2014 (and each of the quarters in those annual periods) and to determine whether a material weakness existed at December 31, 2015." Finally, the Form 8-K disclosed that on March 11, 2016, the Company had received a grand jury subpoena from the DOJ, "requiring the production of documents relating to, among other things, sales, sales practices and dealings with third-parties (including distributors and foreign governmental officials) in Africa, Asia and Latin America and other matters related to the U.S. Foreign Corrupt Practices Act."

80. Securities analysts were dismayed by the Company's disclosures. For example, in a report dated March 15, 2016, BTIG, LLC ("BTIG"), a global financial services firm, downgraded Alere from "Buy" to "Neutral" as the "DoJ Subpoena Adds Risk to Merger Agreement," "Internal Accounting Investigation May Have Expanded in Scope Regarding the Historical Timeframe," and the "Proxy Statement Continues to be on Hold Until 10-K Filing." Similarly, in a report dated March 15, 2016, Canaccord Genuity noted the significance of the DOJ subpoena, as it related to sales practices, in Asia, Africa and Latin America, that potentially made up "25% of the company's revenue," and, as a result, found that the "risk of Abbott deal closing has risen."

81. The market reacted swiftly and negatively to Alere's disclosures. Following the Company's partial disclosures concerning the DOJ subpoena and Alere's inability to timely file its 2015 Form 10-K, Alere shares plunged 8%, falling from $53.46 per share on March 14, 2016 to close at $49.32 per share on March 15, 2016 on extremely high trading volume.

B. April 20, 2016: Abbott Refuses to Publicly Commit to the Merger

82. On April 19, 2016, as subsequently disclosed by the Company on April 28, 2016 (*see* ¶ 86 below), Brian Blaser, Abbott's Executive Vice President, Diagnostics Products, and its General Counsel, Hubert Allen, informed Alere that Abbott was offering to pay Alere $30 to $50 million for Alere's expenses to mutually terminate the Merger Agreement.

83. On April 20, 2016, the CEO of Abbott, Miles D. White, during Abbott's quarterly earnings conference call, was asked "on Alere, are you reaffirming your commitment to the transaction?" In response, Abbott's CEO failed to affirm its commitment to merge with Alere, stating:

> I am going to be careful how I answer any questions about Alere, Mike, because as you know they've had delays filing their 10-K. We don't know when they'll file their proxy. We don't know when they're going to have a shareholder vote. So right now I'd say it's not appropriate for me to comment on Alere.

84. Abbott's disclosure, and Alere's silence on the issue, disappointed analysts. In a report dated April 21, 2016, Canaccord Genuity lowered its price target for Alere from $56.00 to $46.00 and wrote that: "We were surprised at Abbott's commentary (or lack thereof), and, coupled with Alere having 'no comment,' we are substantially less confident that the deal closes at the deal price of $56/share." Likewise, in a report dated April 21, 2016, Jefferies expressed skepticism for the deal, writing that: "ALR remains down sharply after ABT CEO Miles White did not reaffirm his commitment to the ALR deal when he was given the chance. The 'no comment' from ABT adds to delays in filings (10-K, proxy) and the ongoing FCPA investigation as causes of concern around the deal making it to close."

85. The market reacted negatively to these disclosures. Indeed, Alere shares plummeted 12%, falling from a closing price of $49.47 per share on April 19, 2016 to close at $43.36 per share on April 20, 2016 on extremely high trading volume.

C. April 28, 2016: Alere Announces That Abbott Wants Out Of The Merger

86. After the close of trading on April 28, 2016, in a Company press release, Alere announced certain developments relating to the pending merger with Abbott. First, Alere announced that:

> Abbott informed Alere that it has serious concerns about, among other things, the accuracy of various representations, warranties and covenants made by Alere in the parties' merger agreement. Abbott indicated that these concerns relate to the delay in filing the 2015 Form 10-K and governmental investigations previously announced by Alere.

In other words, Abbott's "serious concerns" covered the Company's recent admissions over governmental investigations and Alere's inability to timely file its 2015 Form 10-K. Second, in the same press release, Alere announced that Abbott had requested that Alere agree to terminate the Merger Agreement in return for a payment by Abbott to Alere in the range of between $30 and $50 million, an offer which Alere's Board of Directors rejected.

87. In a *Bowling Green Daily News* article dated April 29, 2016, it was reported that Abbott stated in an emailed statement that it was "awaiting access to the information it has requested from Alere relating to delays in filing its Form 10-K and the circumstances surrounding the criminal grand jury subpoena alleging violations of the Foreign Corrupt Practices Act." Abbott requested that Alere provide information on the governmental investigations and other matters, referring to its contractual rights in the Merger Agreement.

88. Analysts were shocked by this news. In a report dated April 28, 2016, Leerink compared the merger with Abbott to a "shotgun marriage." Likewise, in a report dated April 29,

2016, Canaccord Genuity lowered its price target from $46.00 to $44.00 and wrote that "Despite ALR's confidence, this latest round of developments gives us further pause."

89. The market reacted negatively to these disclosures. Indeed, Alere shares plummeted 10%, falling from a closing price of $43.50 per share on April 28, 2016 to close at $39.00 per share on April 29, 2016 on extremely high trading volume.

90. On or about June 2, 2016, *Bloomberg News* also reported that Abbott was examining Alere's books. *Bloomberg* reported that Darcy Ross, an Abbott spokeswoman, stated in an email that: "Abbott is abiding by the terms of the contract with Alere and has exercised its contractual rights to audit Alere's books and records. . . . To date, we have had a ***partial response*** from [Alere]."

D. July 11-12, 2016: Alere Withdraws INRatio

91. On or about May 26, 2016, the first of two separate class action lawsuits was filed against Alere, alleging that injuries were suffered, which were caused by the use of the INRatio products. The lawsuits were filed in California and Massachusetts, and were brought on behalf of plaintiffs and all others similarly situated who suffered injuries from the INRatio products. In addition, individuals filed direct lawsuits against Alere alleging injuries caused by the INRatio products.

92. In May 2016, Alere received a subpoena from the U.S. Attorney for the District of New Jersey, seeking documents related to the accuracy, reliability and performance of the INRatio products. The documents sought included those documents relating to Alere's interactions with the FDA.

93. On or about July 11, 2016, after the close of the market, Alere, in a press release, announced the removal of the INRatio products from the market. The Company stated that in

certain cases the blood-monitoring systems provided blood clotting time "that is ***clinically significantly lower*** than" tests done at laboratories.

94. On July 12, 2016, the Company disclosed on a Form 8-K that, in connection with the INRatio recall, Alere expected to record approximately $70-$90 million of related charges in 2016 relating to the withdrawal in the United States and related action outside the United States. The Company also stated that it expected to record an immediate non-cash impairment of $20-23 million and accelerated depreciation of approximately $33-37 million. As reported by *Bloomberg* on July 13, 2016, the FDA was not convinced that Alere had determined how to avoid erroneous test results that, in the past, were associated with three deaths.

95. On July 12, 2016, in response to the news of the INRatio withdrawal, the price of Alere's stock declined from a closing price of $39.95 per share on July 11, 2016 to a closing price of $38.61 per share on July 12, 2016, a decline of 3%.

E. July 14, 2016: Alere Announces Material Weakness in Internal Controls

96. On July 14, 2016, Alere filed a Form 8-K with the SEC, attaching a press release disclosing that it expected to conclude that ***one or more material weaknesses existed with respect to the Company's internal controls over financial reporting. As a result, those controls and procedures were not effective as of December 31, 2015, and thus, Alere planned to restate certain results***. The press release also disclosed that the Company had determined that in FY 2013, 2014 and the first three quarters of 2015, ***it incorrectly recorded the timing of recognition of certain revenue transactions***, principally in Africa and China, such as by recognizing payments when products were shipped to distributors but not yet paid for and, thus, Alere had failed to properly apply GAAP in reporting its financial results.

97. In the press release accompanying the Form 8-K filed on July 14, 2016, Alere stated that it expected that the cumulative effect of the misstatements ***would be material to the year ended December 31, 2015, and that the previously issued interim quarterly financial statements for fiscal year 2015 would be revised, along with its annual financial statements for the fiscal years ended December 31, 2013 and 2014***.

98. In the press release accompanying the July 14, 2016 Form 8-K, Alere also stated that the previously obtained consent solicitations relating to certain of the Company's notes (the "Notes") provided Alere with an extension of the deadline for delivery of certain financial information, including the 2015 Form 10-K until August 31, 2016, provided that before 5:00 p.m. New York City time on July 15, 2016 Alere: "must (i) provide certain estimated financial information for fiscal year 2015 and the first quarter of 2016; and (ii) pay or cause to be paid to the consenting holders of the Notes a further cash payment equal to $5.00 for each $1,000 aggregate principal amount of such holders' Notes (the 'Third Extension Fee')." Alere stated that it issued this press release to provide the estimated financial information required by the consent solicitations, and that the Company would pay or cause to be paid the Third Extension Fee.

F. July 20, 2016: Abbott Again Refuses to Publicly Commit to the Merger

99. On July 20, 2016, Abbott conducted an analyst conference call in connection with its second quarter of 2016 financial results. Among other things, Abbott CEO White stated, regarding the Merger with Alere, that: "From our perspective there's been no change. . . . They [*i.e.,* Alere] still haven't filed a 10-K. Our access to information has been limited." While Abbott had received some financial information from Alere, White stated that a fair amount of the requested information still had not been received from the Company. Regarding Alere's

recent announcements on February 26, 2016 and March 15, 2016 about its 2015 Form 10-K, *supra* ¶¶ 74-75, White stated: "The announcement that they put out was not that forthcoming and I certainly wouldn't share the optimism that one of their analysts shared." White further stated about the Merger: "Whether it all works out the way originally planned or not I don't know. . . . We cannot make a prediction about the Alere deal."

G. July 27, 2016: Alere Receives Criminal Subpoena Tied to Toxicology Unit

100. On July 27, 2016, Alere disclosed that it had received an additional federal subpoena, now served by the DOJ Criminal Fraud Unit, regarding the Company's toxicology business, requesting records relating to Medicare, Medicaid and Tricare billings from 2010 at the Company's pain management testing lab in Austin, Texas. Alere further disclosed that it had received this subpoena on July 1, 2016, seeking patient billing records. According to an article in *The Wall Street Journal*, the subpoena requested "information about Alere's efforts to collect copayments from patients, as well as forms submitted on their behalf to government programs such as Medicare." In addition, *The Wall Street Journal* reported that the DOJ was investigating whether Alere made payments or delivered items of value to doctors who ordered tests, which would be considered illegal kickbacks.

101. Alere's Toxicology unit, which is the subject of the DOJ investigation, provides drug-testing for employers and government entities. In 2014, the Toxicology unit accounted for approximately one-quarter of the Company's $2.57 billion in revenue.

102. Once again, analysts were dismayed by yet another negative disclosure by the Company. For example, in a report dated July 27, 2016, Jefferies wrote that the disclosure added "to the seemingly endless string of bad news for ALR."

103. The market reacted swiftly and negatively to these disclosures. Indeed, Alere shares plunged 29%, falling from a closing price of $44.06 per share on July 26, 2016 to close at $31.47 per share on July 27, 2016, on extremely high trading volume.

H. August 8, 2016: Alere Finally Files Its 2015 Form 10-K

104. On August 8, 2016, Alere filed its 2015 Form 10-K, approximately five months after its original due date. Among other things, the Company reported 2015 revenue of $2.46 billion, a net loss of $13 million and non-GAAP adjusted EBITDA of $499 million, which was below Alere's estimate of $505-$520 million. Alere's revenue of $623 million for the fourth quarter of 2015 was also below consensus estimates of $627.8 million and decreased 6.6% from the fourth quarter of 2014. Each of the Company's six reported segments had a decrease in revenue during the fourth quarter of 2015 as compared to the fourth quarter of 2014, and Alere also had a decrease in revenue for the entire year of 2015 as compared to 2014.

105. In addition, the 2015 Form 10-K disclosed that the Company had incorrectly reported the revenue for certain fiscal periods, including the first three quarters of 2015, and thus revised its consolidated financial information. Alere's revisions reflect material changes to reported income (loss) from continuing operations. As the table below shows, ***these revisions resulted in decreases in previous-reported income from continuing operations of 67% for the nine months ending September 30, 2015.*** In addition, the revision to the third quarter of 2015 was so significant that the previously reported income from continuing operations was revised to a loss.

Amounts in thousands	**Quarter Ended**			
Income (loss) from continuing operations	**9/30/2015**	**6/30/2015**	**3/31/2015**	**Nine Months Ended**

				9/30/2015
As Previously Reported	$ 5,501	$ 20,263	$ (7,549)	$ 18,215
Revision Adjustment	$ (7,884)	$ (5,493)	$ 1,200	$ (12,177)
As Revised	$ (2,383)	$ 14,770	$ (6,349)	$ 6,038
Impact of Revision Adjustments on Previously Reported Figures	**-143.3%**	**-27.1%**	**15.9%**	**-66.9%**

(2015 Form 10-K at 85-87).

106. Moreover, as demonstrated in the table below, Alere's initially reported net revenue results for the second quarter of 2015 represented that Alere had *exceeded* analyst expectations, while Alere's revisions in the 2015 Form 10-K stated that the Company did not, in fact, meet such expectations:

Quarter Ended	**Analyst Expectations (as reported by Bloomberg LP on 8/4/2015)**	**Initially Reported Revenue (as reported in 2015 Form 10-Q, filed on 8/6/2015)**	**Revised Revenue (as reported in 2015 Form 10-K, filed on 8/8/2016)**
6/30/2015	$ 627,000	$ 629,156	$ 623,371

107. The Company's 2015 Form 10-K included a further disclosure that Alere had material weakness in its internal controls, stating that:

> [W]e also concluded that we had material weaknesses in internal controls over revenue recognition as further described in Item 9A "Controls and Procedures" in this Annual Report on Form 10-K. We also concluded that the material weakness in internal controls over accounting for income taxes that existed at December 31, 2014 had not been remediated as of December 31, 2015 and, therefore, continued to be a material weakness as of that date.

(2015 Form 10-K at 2-3).

108. The 2015 Form 10-K further stated that:

> We have identified material weaknesses in our internal control over financial reporting as of December 31, 2014 and 2015, which have not been remediated, and these or other material weaknesses could impair our ability to report accurate financial information in a timely manner and/or increase the risk of future errors, which could adversely affect our business, results of operations, cash flows and financial condition.

(2015 Form 10-K at 23).

109. Describing the particular material weaknesses regarding revenue recognition, Alere stated in its 2015 Form 10-K:

> [M]anagement concluded that we had the following material weaknesses related to revenue recognition: (i) we did not maintain a sufficient complement of resources at our subsidiaries with appropriate knowledge, experience and training to ensure proper application of US GAAP in determining revenue recognition, (ii) we also did not maintain effective controls over information and communications as it relates to revenue recognition at our subsidiaries (specifically, we did not implement and reinforce an adequate process for internally communicating nonstandard terms and conditions between our subsidiaries' commercial operations and finance groups and between our subsidiaries' finance groups and our corporate accounting group), (iii) we did not design effective controls over the review of terms of purchase orders and customer contracts, including amendments to contracts, to ensure proper application of US GAAP in determining revenue

> recognition and (iv) we did not design effective controls to ensure that revenue would not be recognized until title and risk of loss had passed to our customers.

(2015 Form 10-K at 23).

110. In light of the foregoing admissions, in the 2015 Form 10-K, the Company set forth the procedures it would follow to remediate its internal control deficiencies relating to its revenue recognition policies and reporting, including hiring additional personnel, reorganizing operations, enhancing the review process of contracts and purchase orders, creating and implementing formal global processes regarding nonstandard arrangements, formalizing revenue recognition training and expanding internal audit testing of controls. (2015 Form 10-K at 91).

111. Significantly, Alere has stated that its remediation process to cure its internal control deficiencies is still ongoing and the Company has not been able to determine whether these material weaknesses have been remediated. (2015 Form 10-K at 91).

112. Alere also stated in its 2015 Form 10-K under the Company's "Risk Factors" that due to the ongoing remediation of its material weaknesses, it could not provide reasonable assurance that its financial reporting can be relied upon. Alere effectively informed its investors that it was incapable of issuing reliable financial statements. (2015 Form 10-K at 24).

113. PwC, the Company's outside auditor, performed an audit of the effectiveness of the Company's internal controls over financial reporting as of December 31, 2015. PwC's audit report condemned Defendants' disregard for internal controls, noting that "the Company did not maintain, in all material respects, effective internal control over financial reporting." (2015 Form 10-K at F-2).

114. In the 2015 Form 10-K, the Company also reported that its withdrawal of its INRatio products would have a negative impact on the Company's fourth quarter 2015 financial results. Specifically, the Company reported that:

> Due to the fact that the circumstances giving rise to the voluntary withdrawal [of the INRatio products] in the United States and related action outside the U.S. existed as of December 31, 2015, certain charges incurred in connection with the withdrawal have been recorded in 2015. Specifically, we recorded a charge of approximately $38 million in the year ending December 31, 2015, of which, approximately $18 million is attributable to the impairment of certain inventory of our INRatio and INRatio2 products; approximately $3 million is related to the impairment of production equipment; and, approximately $16 million is related to the estimated costs of removing our INRatio and INRatio2 from the market, including: notifications to users, return and disposals costs and other related amounts. Additionally, our decision to withdraw the INRatio and INRatio2 PT/INR Monitoring Systems impacted the useful life assumptions of certain tangible and intangible assets. As a result of this change in estimates, we recorded approximately $4 million of accelerated amortization of intangible assets and approximately $1 million of accelerated depreciation of tangible assets in the year ending December 31, 2015. Finally, during fiscal year 2016 we expect to incur approximately $16 million of accelerated amortization, approximately $3 million of accelerated depreciation, and $2 million of other onetime cash expenditures related to this matter.

(2015 Form 10-K at 53-54).

115. Alere's 2015 Form 10-K also revealed the existence of other investigations, including one by the U.S. Attorney in Tennessee in July 2016, which concerned the possible submission for reimbursement of improper Medicare and Medicaid claims. Alere further stated that it was in the process of responding to Civil Investigative Demands, or CIDs, requesting patient and billing records and records related to interactions with third parties.

116. On the same day it filed the 2015 Form 10-K, the Company issued a press release, stating, among other things, that:

> During the fourth quarter of 2015, the Company recorded $43 million in pre-tax expenses ($30 million after tax) related to its previously announced voluntary INRatio market withdrawal. On a non-GAAP basis, the Company reported Non-GAAP adjusted EBITDA of $95 million in the fourth quarter of 2015, compared to $127 million in the prior year period.
>
> Alere expected to record approximately $70-90 million of charges relating to this voluntary withdrawal in 2016. Due to the fact that ***the condition that led to the voluntary withdrawal existed as of December 31, 2015***, certain of these charges incurred in connection with the recall are being recorded in 2015 rather than 2016. Specifically, the Company recorded $43 million in pre-tax expenses ($30 million after tax) in the fourth quarter of 2015 related to its previously announced voluntary INRatio market withdrawal. Of this amount, approximately $17 million will ultimately be settled in cash and is, therefore, included in non-GAAP adjusted EBITDA for both the quarter and full year ended December 31, 2015.

117. Regarding its restatement, Alere stated as follows in the August 8 press release:

> Most notably, the Company recognized additional income tax expense of $8 million in 2015 (nine months YTD) and a reduction in income tax expense of $7 million in 2014 related to the timing of recognition of certain tax-specific items. These tax-related revisions resulted in a decrease of $0.09 in basic and diluted earnings per share in 2015 (nine months YTD) and an increase of $0.07 in basic and diluted earnings per share in 2014.

118. On August 8, 2016, after Alere filed its 2015 Form 10-K, Abbott issued a statement, revealing, in part, that Alere's filing "does not eliminate Abbott's concerns about its business controls and practices given the ***litany of issues that have come to light*** since our agreement was announced." The Abbott press release further stated that Alere had failed to provide Abbott with an adequate explanation for the extended filing delay and refused to provide Abbott with detailed and relevant information on several outstanding issues, and that Abbott was still waiting to see Alere's financial results for the first half of 2016.

I. August 10, 2016: Abbott Details the Material Negative Developments Related to the Potential Merger

119. On August 10, 2016, Abbott further publicly stated that Alere had withheld information from Abbott that made it impossible to know if or when the Merger would close. Abbott compiled a list of "several key developments" that were impacting the potential Merger Agreement. In Abbott's words:

> Several key developments have occurred with respect to Alere since the date of the Alere merger agreement, including three separate investigations by the U.S. Department of Justice (two of which are criminal investigations), a delay in the filing of Alere's required SEC reports, management's disclosure of unremediated material weaknesses over financial reporting, and a product recall following notice from the U.S. Food and Drug Administration. Abbott has requested information from Alere relating to these and other matters, but ***Alere has failed to provide requested information relating to certain key topics***, and Abbott continues to wait for such information. Abbott is unable to predict when it will be able to complete its review or the outcome of the review and cannot predict at this time when or whether the conditions to the Alere acquisition will be satisfied. On January 30, 2016, Abbott entered into a merger agreement with Alere. Following the date of the Alere merger agreement, several key developments occurred with respect to Alere, ***none of which Abbott was aware of when it executed the Alere merger agreement***. These developments include, among other things:
>
> • a criminal investigation by the U.S. Department of Justice relating to potential violations by Alere of the U.S. Foreign Corrupt Practices Act in Africa, Asia and Latin America;
>
> • a criminal investigation by the U.S. Department of Justice's Fraud Section relating to billing practices of Alere for U.S. government insurance programs, including Medicare, Medicaid and Tricare;
>
> • an investigation by the U.S. Department of Justice relating to accuracy, reliability and performance of Alere's INRatio® products;
>
> • an over-five-month delay in the filing of Alere's Annual Report on Form 10-K for 2015; an ongoing delay in the filing of Alere's Quarterly Report on Form 10-Q for the first quarter of 2016; and a notice by Alere that it does not expect to file its Quarterly Report on Form 10-Q for the second quarter of 2016 by its due date;
>
> • a disclosure by Alere and its auditors that a material weakness in Alere's internal control over revenue recognition existed as of December 31, 2015 and that such material weakness has not been remediated;

• a disclosure by Alere and its auditors that the material weakness in Alere's internal control over the accounting for income taxes, ***which existed as of December 31, 2014***, has not been remediated and continued to exist as of December 31, 2015;

• a disclosure by Alere that it cannot estimate when such material weaknesses will be remediated, and that its initiatives to remediate such material weaknesses may not be successful;

• a notice of non-compliance by the NYSE as a result of Alere's failure to timely file its SEC reports, noting that Alere could potentially risk its listing status as a result of such non-compliance;

• a potential default under Alere's credit agreement and senior notes as a result of Alere's failure to timely file its SEC reports, which remains unresolved because Alere has not yet filed its Quarterly Report on Form 10-Q for the first quarter of 2016, for which Alere obtained, after the payment of a fee, a waiver until August 18, 2016 for the credit agreement and until August 31, 2016 for the senior notes; and

• a recall of Alere's INRatio® products within the United States and Canada following notice by the U.S. Food and Drug Administration.

In light of these significant developments and pursuant to its rights under the Alere merger agreement, Abbott has sought on numerous occasions information from Alere relating to these matters and its internal controls, compliance with law and disclosure controls. Although Alere has provided some information to Abbott, ***Alere has denied Abbott the access to which it is entitled under the Alere merger agreement for certain key topics, including the events surrounding Alere's delayed financial statements, Alere's internal controls, and significant legal compliance matters***. Abbott continues to insist that Alere produce such information, consistent with Alere's obligations under the Alere merger agreement. Abbott is unable to predict at this time when it will be able to complete its review or the outcome of this review. ***In light of the above, Abbott cannot predict at this time whether the Alere acquisition will occur on a timely basis, or at all***.

120. On August 10, 2016, Sadif Investment Analytics ("Sadif"), a European research firm, issued a negative analyst report on Alere, stating that it "is a below average quality company with a negative outlook." Sadif's prior report in June 2016 had rated Alere as average. Its new rating of Alere, issued in September 2016, was risky.

J. August 17, 2016: Alere Files Its Belated Form 10-Q for Q1 2016

121. On August 17, 2016, Alere filed with the SEC its Form 10-Q for the first quarter of 2016 ("2016 1Q Form 10-Q") and a Form 8-K, to which it attached a press release announcing it first quarter 2016 financial results. In those filings, Alere reported that its revenue for the first quarter of 2016 was $578 million, which was a 6% decrease from the prior year first quarter and disclosed that the Company had experienced a net loss from continuing operations during the first quarter of 2016 of $10 million or $0.18 per basic and diluted share.

122. Alere also included a chart in its press release, comparing revenue in the following categories for the first quarter of 2016 with the first quarter of 2015: Cardiometabolic Disease, Infectious Disease, Toxicology, Other, Consumer Diagnostics and License and Royalty. ***In each of the six categories listed, revenue had declined.***

123. Alere further stated that as of March 31, 2016, the Company's disclosure controls and procedures were not effective. The Company reiterated identical material weaknesses and an identical plan for remediation relating to revenue recognition and income taxes, as in its 2015 Form 10-K at ¶¶ 103-105, *supra*. (2016 1Q Form 10-Q at 46-47).

K. <u>August 25, 2016: Alere Sues Abbott to Force the Merger</u>

124. On August 25, 2016, Alere filed a complaint against Abbott in Delaware Chancery Court. *See Alere Inc., v. Abbot Laboratories*, C.A. No. 12691-VCG (Del. Ch. Aug. 31, 2016 ("*Alere*"). The next day, on August 26, 2016, Alere issued a statement that the lawsuit seeks to compel Abbott to obtain the necessary antitrust approvals to complete the transaction. Glossing over the material negative facts that had been unearthed about Alere since the announcement of the Merger, Alere claimed that Abbott was simply experiencing buyer's remorse and wanted to extricate itself from the Merger Agreement based on Abbott's subsequent agreement to buy St. Jude Medical, Inc. ("St. Jude") which was publicly announced on April 28, 2016. In other

words, according to Alere, Abbott was severely delaying (and attempting to back out of) its acquisition of Alere because it would be extremely difficult for Abbott to acquire both Alere and St. Jude at the same time.

125. However, a review of the timeline of the Abbott-St. Jude's transaction reveals that Alere's claim is meritless. Indeed, Abbott was having significant discussions to purchase St. Jude's well before Abbott executed the Merger Agreement with Alere. By December 15, 2015, Abbott's CEO had already expressed an interest in a potential business combination to St. Jude's then-incoming CEO Michael T. Rousseau, which occurred ***before*** Abbott and Alere began negotiations about a possible transaction. By February 2016, Abbott's financial advisor had provided a possible indicative purchase price to St. Jude's financial advisor, and by the end of February, Abbott and St. Jude's had entered into a confidentiality agreement and due diligence had begun. By March 15, 2016, a transaction with an indicative value of $85.00 per St. Jude's share was proposed and Abbott's in-depth due diligence was commencing. Abbott and St. Jude reached an agreement on April 27, 2016 at a value of approximately $85.00 per St. Jude's share.

126. Alere filed a Motion for Expedited Proceedings with the Delaware Chancery Court on August 31, 2016. In opposing that motion, Abbott referred to Alere's complaint against Abbott as "nothing but a publicity stunt" and called Alere's lawsuit, and demand for expedited proceedings, frivolous. Abbott also stated that Alere filed its lawsuit "to ***divert public attention*** from the drumbeat of regulatory problems, product recalls, criminal subpoenas, investigations, and control failures that have plagued Alere since the parties signed the merger agreement." (Emphasis added). Abbott further contended that any purported delay in Abbott's submitting information to antitrust authorities was caused by Alere's ***inability to "get its act together" to report accurate financial information, which Abbott stated was the result of Alere's severe***

material weaknesses in its internal controls over financial reporting. Abbott stated that Alere had not been forthcoming with information sought by Abbott as to Alere's financial issues, including the documents and data that Abbott needed from Alere to understand the Company's accounting errors and internal control problems. *See Alere*, Defendant's Opposition to Plaintiff's Motion For Expedited Proceedings ("Def. Opp'n") at 2-3 (emphasis added).

127. Included in Abbott's filing with the Delaware Chancery Court was a previously undisclosed e-mail from a whistleblower (Alere India's Director of Finance), stating that Alere was interfering with Abbott's attempts to investigate possible legal violations by Alere in India by coaching witnesses to provide false information, retaliating against those who refused, and even sending Alere's head of finance in India on an unjustified "long leave" to make him unavailable for interviews by Abbott. The whistleblower's e-mail stated that:

> I believe you guys are looking for me, whereas company management is saying I am not available, which is wrong, I am very much available but not allowed to come to office (They suspended me with pay). They have done this so that ***the truth will not come out in front of Abbott leadership***.

Alere, Def. Opp'n, at 9 (emphasis added).

L. September 6, 2016: Alere Files Its Belated Form 10-Q for Q2 2016

128. On September 6, 2016, Alere filed its Form 10-Q for the second quarter of 2016 with the SEC ("2016 2Q Form 10-Q"). It also filed a Form 8-K, to which it attached a press release announcing its second quarter 2016 financial results. In those filings, Alere reported that: (a) its revenue for the second quarter of 2016 was $611 million, which was a 2% decrease from the prior year second quarter; and (b) the Company had experienced a net loss from continuing operations during the second quarter of 2016 of $35 million or $0.46 per basic and diluted share,

compared to net income of $15 million or $0.11 per basic and diluted share in the prior year second quarter.

129. Alere also included a chart in its press release, comparing revenue in the following categories for the second quarter of 2016 with the second quarter of 2015: Cardiometabolic Disease, Infectious Disease, Toxicology, Other, Consumer Diagnostics and License and Royalty. In four of the six categories listed, revenue declined, and a fifth category was relatively unchanged.

130. Alere further stated that as of June 30, 2016, the Company's disclosure controls and procedures were not effective. The Company reiterated identical material weaknesses related to revenue recognition, the failure to design and maintain effective controls, and an identical plan for remediation relating to revenue recognition and income taxes, as in its 2015 Form 10-K at ¶¶ 103-105, *supra*. (2016 2Q Form 10-Q at 56-57).

M. November 3 and 15, 2016: Abbott Sues Alere for Breach of Contract and Alere Agrees to Turn Over Previously-Withheld Documents

131. On November 3, 2016, Abbott filed a complaint in the Delaware Court of Chancery alleging breach of contract against Alere. *See Abbott Laboratories v. Alere Inc.*, CA 12872 (the "Breach of Contract Action"). Abbott alleged that Alere had refused to provide Abbott with access to financial and business information as required by the Merger Agreement. Specifically, Abbott alleged that it had sought, and Alere had failed to provide it with, a number of different categories of critical documents, including: internal accounting records and other documents needed to assess Alere's compliance with the FCPA; Medicare and Medicaid claims detail required to evaluate Alere's compliance with government health care laws; and information regarding Alere's payments to physicians necessary to understand Alere's

compliance with the Anti-Kickback Statute and Stark Law. According to Abbott, Alere had "simply ignored many of Abbott's requests," and Abbott sought prompt access to those materials.

132. On November 15, 2016, just a week after Abbott's allegations became public, Abbott and Alere agreed to settle Abbott's Breach of Contract Action. Specifically, as *Bloomberg* reported that day, only after Abbott had filed suit against Alere did Alere agree that it would turn over to Abbott "files about bribery probes of [Alere's] foreign operations and U.S. billing practices." As Abbott later alleged, however, as of Abbott's December 7, 2016 lawsuit against Alere, Alere still had not provided these documents to Abbott.

N. November 4, 2016: Alere Announces that the Centers for Medicare & Medicaid Services Revoked Arriva Medical's Medicare Enrollment

133. On November 4, 2016, in its Form 10-Q filed with the SEC for the third fiscal quarter of 2016 ("2016 3Q Form 10-Q") signed by Jonathan Wygant, Alere's CAO and Corporate Controller, the Company disclosed that it had received a letter from CMS stating that CMS was revoking the Medicare enrollment for Alere's subsidiary, Arriva Medical. Specifically, the Company disclosed that:

> On October 12, 2016, our subsidiary, Arriva Medical, LLC, or Arriva, which is our durable medical equipment, or DME, supply business that specializes in the furnishing of diabetic testing supplies via mail order, received a notice, dated October 5, 2016, that its Medicare enrollment will be revoked by CMS, based on CMS assertion that, ***over a five year period, Arriva had allegedly submitted claims for 211 deceased patients*** (even if the products were appropriately ordered in advance of the patients death).

2016 3Q Form 10-Q (emphasis added).

134. In the same Form 10-Q, the Company also disclosed that, on November 2, 2016, CMS had denied Alere's appeal of Arriva Medical's revocation, and the revocation was effective as of November 4, 2016, the date of the Form 10-Q filing. Furthermore, the Company revealed in its 2016 3Q Form 10-Q, the severe consequences of the revocation:

> Unless and until the enrollment is reactivated, Arriva will be ineligible for reimbursement for any products or services furnished on or after November 4, 2016 . . . ***There can be no guarantee that Arriva's Medicare enrollment will be reinstated***, that it will be reinstated retroactively, or that we will be reimbursed by Medicare for any diabetes testing supplies supplied to customers on or after November 4, 2016. ***Further, if our appeal is not successful, Arriva will be barred from re-applying for enrollment in the Medicare program for at least three years***. The Medicare revocation would also prevent Arriva from being able to be reimbursed for any Medicaid covered products or services. ***If we are not successful in getting Arriva's Medicare enrollment reinstated, our cardiometabolic business may be adversely affected***. Our results of operations for the nine-month period ended September 30, 2016, included approximately $88 million in revenue attributable to Arriva.

2016 3Q Form 10-Q at 46 (emphasis added)

135. Prior to CMS' October 2016 revocation of Arriva's Medicare enrollment, Arriva had a long, recidivist history of violating Medicare provisions and was the subject of numerous investigations concerning such misconduct.

136. For example, in March 2012, Arriva Medical acquired the Tennessee-based company AmMed Direct LLC ("AmMed"). Prior to the acquisition, AmMed was subject to a *qui tam* action filed by the DOJ and the State of Tennessee in connection with AmMed's submitting false claims to Medicare for diabetes testing supplies between September 2008 and January 2010 in violation of the Federal False Claims Act. Specifically, in *United States ex. rel. v. AmMed Direct LLC*, filed in the U.S. District Court for the Middle District of Tennessee (the "Qui Tam Action"), the DOJ and Tennessee alleged that AmMed widely advertised free products in order to induce Medicare beneficiaries to contact AmMed or its hired telemarketing firm. Once AmMed confirmed that a beneficiary was covered by Medicare, AmMed representatives improperly attempted to sell the beneficiary supplies that would be paid for by Medicare. Contrary to AmMed's alleged misconduct, Medicare rules prohibit medical businesses such as AmMed from making unsolicited telephone contact with beneficiaries to sell them their

products, unless specific exceptions apply. The DOJ and Tennessee further alleged that, as a result of AmMed's improper marketing, many Medicare beneficiaries who called AmMed to receive the advertised products returned their medical supplies to AmMed. AmMed, however, failed to timely refund the money to Medicare or Tennessee's agency. Rather, AmMed allowed the unpaid refunds to accrue from September 2006 until January 2010.

137. The Qui Tam Action settled in April 2012, one month after Arriva Medical acquired AmMed, with AmMed paying $18 million to the United States and Tennessee.

138. In addition, in Alere's 2014 Form 10-K, dated March 5, 2015, Alere disclosed that Arriva Medical was in the process of responding to a CID from the U.S. Attorney for the Middle District of Tennessee in connection with an investigation of possible ***improper claims submitted to Medicare and Medicaid.*** In connection with this investigation, the U.S. Attorney sought patient and billing records. This investigation has been underway since at least March 5, 2015, when Alere first disclosed it, through November 4, 2016, when the Company filed its 2016 3Q Form 10-Q. Defendants have thus been on notice of significant compliance issues at Arriva Medical since, at the latest, March 5, 2015.

139. The market reacted swiftly and negatively to the November 2016 news of Arriva's Medicare enrollment revocation and the above-described news that Abbott was suing Alere. As a result of this news, Alere's stock plummeted by approximately 16%, to close at a price of $36.10 per share on November 4, 2016, down $6.76 from its opening price that day of $42.86 per share.

O. December 7, 2016: Abbott Sues Alere to Terminate the Merger

140. On December 7, 2016, Abbott filed suit to terminate its $5.8 billion purchase of Alere, citing setbacks since the deal was signed that Abbott said have significantly eroded the value of the Company. *See* Abbott Complaint.

141. At the time Abbott filed its complaint it issued a press release stating that:

> In the 10 months following the Jan. 30, 2016, signing of the agreement, Alere has suffered a series of damaging business developments, including the government eliminating the billing privileges of a substantial Alere division, the permanent recall of an important product platform, multiple new government subpoenas, including two new criminal subpoenas, and a five-month delay in filing its 10K coupled with admissions of internal control failures requiring restatement of its 2013-2015 financials.
>
> "Alere is no longer the company Abbott agreed to buy 10 months ago," said Scott Stoffel, divisional vice president of external communications, Abbott. "These numerous negative developments are unprecedented and are not isolated incidents brought on by chance. We have attempted to secure details and information to assess these issues for months, and Alere has blocked every attempt. This damage to Alere's business can only be the result of a systemic failure of internal controls, which combined with the lack of transparency, led us to filing this complaint."
>
> Under terms of the merger agreement, Abbott may terminate the transaction if adverse events materially change Alere's long-term prospects. Abbott filed its complaint seeking termination in the Delaware Court of Chancery, citing these events among others as material adverse event

142. On December 13, 2016, a redacted version of Abbott's complaint was made publicly available. Abbott's core claim is that it should be allowed to terminate the Merger Agreement because of Alere's subsequent disclosure of multiple increasingly serious problems, individually and collectively amounting to material adverse effects under the terms of the Merger Agreement. Abbott Complaint ¶ 1. These events include the investigation and resulting delay in the filing of Alere's financial statements which "were never before disclosed to . . . the public," the permanent recall of the INRatio products, multiple government subpoenas, including two criminal ones, and Arriva Medical being barred from the Medicare program. *Id.* ¶ 3

143. Abbott further states that Alere suffers from a previously undisclosed "fundamental lack of controls throughout the company" ranging from financial reporting to product quality to legal compliance adversely affecting the Company's business operations. *Id.* ¶

4. Abbott alleges that its efforts to obtain visibility into the nature and scope of Alere's internal control deficiencies has been met "with obfuscation and concealment" by Alere and the refusal to provide certain critical information. *Id.* ¶ 2. According to Abbott, "Alere continually act[s] like a company with something to hide." *Id.* ¶ 5.

144. The market reacted swiftly and negatively to the news that Abbott had brought this most recent suit to end the Merger with Alere. As a result of this news, Alere's stock fell by approximately 7.6%, to close at a price of $36.67 per share on December 7, 2016, down $3.01 from its opening price that day of $39.68 per share.

VI. ALERE'S ACCOUNTING VIOLATIONS

A. Provisions Regarding Financial Reporting

145. GAAP are the official accounting standards of the Financial Accounting Standards Board ("FASB"). The SEC has adopted these standards, which require the financial statements of filers to adhere to them. The FASB has codified GAAP into a structure called the Accounting Standards Codification ("ASC"), which is the framework for financial reporting for all public filers.

146. SEC Regulation S-X states that financial statements filed with the SEC that are not prepared and presented in accordance with GAAP "…will be presumed to be misleading or inaccurate, despite footnote of other disclosures...." (17 C.F.R. § 210.4-01(a)(1)). Regulation S-X requires that interim financial statements must also comply with GAAP, with the exception that interim financial statements need not include disclosure that would be duplicative of disclosures accompanying annual financial statements. (17 C.F.R. § 210.10-01(a)). Violations of GAAP, therefore, equate to violations of SEC Regulations.

147. The conceptual framework underlying financial accounting and reporting, especially the rules that comprise the accrual-based accounting required by the standards adopted by the SEC (i.e., GAAP), are set forth, among other places, in Statements of Financial Accounting Concepts ("FASCONs") promulgated by the FASB.

148. FASCON No. 8, Conceptual Framework for Financial Reporting - Chapter 1, The Objective of General Purpose Financial Reporting, and Chapter 3, Qualitative Characteristics of Useful Financial Information ("FASCON 8"), specifically states that "[t]he objective of general purpose financial reporting is to provide financial information about the reporting entity that is useful to existing and potential investors, lenders, and other creditors in making decisions about providing resources to the entity." (FASCON 8, OB2).

149. During the Class Period, the Company's financial statements did not comply with the concepts established by the FASB, and specifically did not faithfully represent the transactions it purported to represent. Accordingly, the Company failed to provide reliable and accurate financial information to its investors, lenders, creditors and other market participants. Furthermore, the Company failed to provide reliable and accurate financial information to its investors, lenders, creditors and other market participants based on its specific violations of the accounting principles discussed below.

B. Revenue

150. GAAP provides a series of rules for when and how to recognize revenue. GAAP states that in order for revenue to be recognized, it must be "realized or realizable" and "earned." (FASB Accounting Standards Codification ("ASC") 605, *Revenue Recognition* ("ASC 605"), -10-25-1).

151. Referencing FASCON 5, *Recognition and Measurement in Financial Statements of Business Enterprises* ("FASCON 5"), ASC 605 states, specifically, the following, in relevant part:

> Revenue and gains are realized when products (goods or services), merchandise, or other assets are exchanged for cash or claims to cash. That paragraph states that revenue and gains are realizable when related assets received or held are readily convertible to known amounts of cash or claims to cash.

ASC 605-10-25-1.

152. GAAP, ASC 605-15-25-1 specifically, also provides rules that must be followed in order to recognize revenue when a Company sells its product but gives the buyer the right to return the product. Revenue from sales transactions, including a right of return, shall be recognized at the time of sale only if all of the following conditions are met:

a. The seller's price to the buyer is substantially fixed or determinable at the date of sale;
b. The buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product. If the buyer does not pay at time of sale and the buyer's obligation to pay is contractually or implicitly excused until the buyer resells the product, then this condition is not met;
c. The buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product;
d. The buyer acquiring the product for resale has economic substance apart from that provided by the seller…;
e. The seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer; and
f. The amount of future returns can be reasonably estimated.

ASC 605-15-25-1.

153. The SEC, in Staff Accounting Bulletin ("SAB") No. 104 (codified into Topic 13), also provides that revenue generally is realized or realizable and earned when all of the following criteria are met:

- Persuasive evidence of an arrangement exists;
- Delivery has occurred or services have been rendered;

- The seller's price to the buyer is fixed or determinable; and
- Collectability is reasonably assured.

Further, the SEC specifically sets forth criteria that must be met in order to recognize revenue when delivery has not occurred. These criteria include:

1. The risks of ownership must have passed to the buyer;

2. The customer must have made a fixed commitment to purchase the goods, preferably in written documentation;

3. The buyer, not the seller, must request that the transaction be on a bill and hold basis. The buyer must have a substantial business purpose for ordering the goods on a bill and hold basis;

4. There must be a fixed schedule for delivery of the goods. The date for delivery must be reasonable and must be consistent with the buyer's business purpose (*e.g.*, storage periods are customary in the industry);

5. The seller must not have retained any specific performance obligations such that the earning process is not complete;

6. The ordered goods must have been segregated from the seller's inventory and not be subject to being used to fill other orders; and

7. The equipment [product] must be complete and ready for shipment.

154. The above listed conditions are the important conceptual criteria that should be used in evaluating any revenue transaction. This listing is not intended as a checklist. In some circumstances, a transaction may meet all factors listed above but not meet the requirements for revenue recognition. The SEC has also noted that in applying the above criteria to a purported

bill and hold sale, the individuals responsible for the preparation and filing of financial statements also should consider the following factors:

> 1. The date by which the seller expects payment, and whether the seller has modified its normal billing and credit terms for this buyer;[20]
>
> 2. The seller's past experiences with and pattern of bill and hold transactions;
>
> 3. Whether the buyer has the expected risk of loss in the event of a decline in the market value of goods;
>
> 4. Whether the seller's custodial risks are insurable and insured; and
>
> 5. Whether extended procedures are necessary in order to assure that there are no exceptions to the buyer's commitment to accept and pay for the goods sold (*i.e.*, that the business reasons for the bill and hold have not introduced a contingency to the buyer's commitment).

(Topic 13, Revenue Recognition, footnotes omitted).

155. Specific to delivery of the product and passage of title, the SEC has commented that situations may exist where title to delivered products passes to a buyer, but the substance of the transaction is that of a consignment or a financing. The SEC has commented that certain characteristics of a transaction preclude revenue recognition even if title to the product has passed to the buyer. One such situation includes the following:

> The buyer has the right to return the product and:
>
> > (a) the buyer does not pay the seller at the time of sale, and the buyer is not obligated to pay the seller at a specified date or dates;
> >
> > (b) the buyer does not pay the seller at the time of sale but rather is obligated to pay at a specified date or dates, and the buyer's obligation to pay is contractually or implicitly

> excused until the buyer resells the product or subsequently consumes or uses the product;
>
> (c) the buyer's obligation to the seller would be changed (*e.g.*, the seller would forgive the obligation or grant a refund) in the event of theft or physical destruction or damage of the product;
>
> (d) the buyer acquiring the product for resale does not have economic substance apart from that provided by the seller; or
>
> (e) the seller has significant obligations for future performance to directly bring about resale of the product by the buyer.
>
> (Topic 13, Revenue Recognition, footnotes omitted).

156. The Company's own revenue recognition policy required that before revenue could be recorded, it meet four of the most basic "bright-line" conditions for recording revenue. If any condition fails to be satisfied, revenue recognition must be delayed until the period in which the final condition is met. As stated in Alere's 2014 Form 10-K (filed on March 5, 2015), 2014 Form 10-K/A (filed on May 28, 2015), and 2015 Form 10-K (filed on August 8, 2016), below is the Company's "Summary of Significant Accounting Policies" as it relates to its revenue recognition policies:

> Revenue Recognition
>
> We primarily recognize revenue when the following four basic criteria have been met: (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the fee is fixed or determinable and (4) collection is reasonably assured.
>
> ***The majority of our revenue is derived from product sales. We recognize revenue upon transfer of the title and risk of loss of the products to third-party customers, less a reserve for estimated product returns and allowances.*** Determination of the reserve for estimated product returns and allowances is based on our management's analyses and judgments regarding certain conditions.

> Should future changes in conditions prove management's conclusions and judgments on previous analyses to be incorrect, revenue recognized for any reporting period could be adversely affected.

2015 Form 10-K at F-24; 2014 Form 10-K at F-17; 2014 Form 10-K/A at 61-62 (emphasis added).

157. If any condition fails to be satisfied, revenue recognition must be delayed until the period in which the final condition is met.

158. The Company's stated (but violated) revenue recognition policy was consistent with GAAP, as indicated above. Alere violated its revenue recognition policies throughout the Class Period by failing to appropriately account for: (1) transactions where the product was shipped to the distributor, but the Company retained title in the products until the distributor paid for the products in full or the distributor was not obligated to pay the Company until the products were sold through to the end-user; (2) bill and hold transactions; and (3) other transactions where all contractual criteria for title and risk of loss passing to the customer had not been met.

159. Accordingly, Alere recognized revenue during the Class Period prior to it being realized or realizable and/or earned in violation of GAAP and its own stated revenue recognition policies.

C. Return Allowance

160. With respect to a sales returns allowance, GAAP specifies that if revenue is recognized because the conditions ASC 605-15-25-1 are met, any costs or losses that may be expected in connection with any returns shall be accrued in accordance with ASC 450, *Contingencies*, (ASC 605-10-25-1). ASC 450 establishes that an estimated loss from a loss contingency shall be accrued by a charge to income if both of the following conditions are met:

a. Information available before the financial statements are issued or are available to be issued indicates that it is probable that an asset had been impaired or a liability had been incurred at the date of the financial statements; and

b. The amount of loss can be reasonably estimated.

161. During the Class Period, Alere also failed to comply with ASC 605 and ASC 450, by not establishing an appropriate returns allowance with respect to revenue recorded in Alere's Indian subsidiary.

D. Materiality

162. FASCON 8 specifies that: "Information is material if omitting it or misstating it could influence decisions that users make on the basis of financial information about a specific reporting entity." (FASCON 8, QC-11). FASCON 8 further states that, "[M]ateriality is an entity-specific aspect of relevance based on the nature or magnitude, or both, of the items to which the information relates in the context of an individual entity's financial report." (FASCON 8, QC-11). Materiality, therefore, requires both quantitative and qualitative consideration.

163. The SEC's view on materiality reiterates the necessity of evaluating both quantitative and qualitative factors when assessing an item's materiality. SAB No. 99 has been codified into Topic 1: Financial Statements, Section M, Materiality.

164. SAB No. 99 also provides that when management or the independent auditor expects (based, for example, on a pattern of market performance) that a known misstatement may result in a significant positive or negative market reaction, that expected reaction should be taken into account when considering whether a misstatement is material.

165. In addition, Codification of Staff Accounting Bulletins, Topic 1, Section M specifies additional qualitative considerations that should be taken into account when assessing materiality, including, but not limited to, the following:

- Whether the misstatement masks a change in earnings or other trends;
- Whether the misstatement hides a failure to meet analysts' consensus expectations for the enterprise; and
- Whether the misstatement changes a loss into income or vice versa.

(Codification of Staff Accounting Bulletins, Topic 1, Section M).

166. Here, Alere's restated results for the first nine months of 2015 ***resulted in a decrease in previously reported income from continuing operations of approximately 67%.*** In addition, its revision as to the third quarter of 2015 resulted in a loss where previously it had reported income. Moreover, Alere's reported net revenue for the second quarter of 2015 initially had exceeded analyst expectations, but its restated results did not meet such expectations. These are all factors supporting the materiality of Alere's misstatements.

167. Alere did not disclose in its 2014 Form 10-K/A or its 2015 Form 10-Q for the first, second and third quarters that it had a material weakness in internal controls regarding revenue. Alere's failure to maintain effective internal control over financial reporting due to material weaknesses related to revenue recognition and accounting for income taxes, and accordingly, the resulting revisions to its annual and quarterly financial statements during the Class Period, were material.

168. Alere cited the newly-reported material weaknesses in its 2015 Form 10-K as having caused the errors in its accounting for recognizing revenue in the consolidated financial statements for the years 2013 and 2014, and each of the interim periods in 2014 and 2015. The nature of these material weaknesses did not substantively change from the beginning to the end of the Class Period and were in existence throughout the Class Period.

169. The material weaknesses set forth in Alere's 2015 Form 10-K, noted above, were of such magnitude and uncertainty that as of September 6, 2016, when Alere filed its Q2 2016 Form 10-Q, the Company supplemented its description of the aforementioned material

weaknesses. ***Specifically, Alere acknowledged that it could provide no guidance as to when the material weaknesses would be remediated, or what additional impact these material weaknesses may have had in prior periods.***

170. Abbott has publicly stated that ***the material weaknesses in Alere's internal controls were "[s]o severe … that Alere's 2013 and 2014 financial statements … needed to be corrected," and that, "[a]s a result, Abbott could not rely on Alere's financial data -- and could not submit it as true and accurate to government antitrust authorities around the world."*** *Alere*, Def. Opp'n, at 2 (emphasis added).

171. Abbott has also stated that, "Alere has refused, even to this day, to hand over the documents and data Abbott needs to understand Alere's accounting errors and internal control problems." *Id.* at 8.

VII. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS

172. Defendants' statements about the Company's business and operations were materially false and misleading and/or omitted material facts necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading. These statements were false and misleading and/or failed to disclose, among other things, that: (1) the Company's reported financial statements for each of the first three quarters of 2015 and for fiscal year 2014 improperly recognized and reported revenue in violation of GAAP; (2) the Company had material weaknesses in internal controls over financial reporting, including such weaknesses relating to the recognition of revenue in 2014, and each of the interim periods in 2015, resulting in material errors in its reported financial statements and the need to restate them; (3) the Company's INRatio products were defective and Alere needed to withdraw those products from the market and disclose a related loss contingency; (4) the SOX certifications were

false and did not disclose the Company's failure to properly recognize revenue, in violation of GAAP, and the material weaknesses in its internal controls; (5) the Company engaged in improper activities in its Toxicology unit regarding billing and other practices, and improper actions by its overseas divisions to win business, which were contrary to Alere's statements that it might be subject to legal risks when those risks had already come to pass; and (6) the Company's Arriva Medical subsidiary submitted numerous improper Medicare claims on behalf of deceased beneficiaries.

A. Alere Restatements of Previously Reported Financial Results

173. In the 2015 Form 10-K, the Company admitted violating GAAP in connection with its recognition and reporting of revenue for fiscal year 2014, as well as each of the first three quarters of 2015, and admitted that its previously reported financial statements were materially false and misleading by restating those results.

174. In its 2014 Form 10-K/A, filed with the SEC on May 28, 2015, Alere reported, among other things, 2014 net revenue as $2.589 billion, gross profit as $1.219 billion, a loss from continuing operations as $176 million or $2.38 per basic and diluted common share, and a net loss available to common stockholders of $59 million or $0.71 per basic and diluted common share. The 2014 Form 10-K/A was signed by, among others, Defendant Nawana. The 2014 Form 10-K/A contained as Exhibits 31.1, 31.2 and 32.1 certifications pursuant to SOX, signed by Defendants Nawana and Hinrichs, identical in all material respects to the certifications described in ¶¶ 207-213 below.

175. As Defendants admitted in the 2015 Form 10-K in connection with Alere's restatement of its financial statements, the 2014 Form 10-K/A was materially false and misleading because of errors in applying GAAP regarding the timing of revenue recognition.

Because of the failure to follow GAAP, the numbers reported in the 2014 Form 10-K/A required the following restatement: net revenue was changed from $2.589 billion to $2.575 billion; gross profit was revised from $1.219 billion to $1.212 billion; the loss from continuing operations was changed from $176 million or $2.38 per basic and diluted common share to a loss of $171.8 million or $2.33 per basic and diluted common share; and the net loss available to common stockholders was revised from $59 million to $54.8 million or from a loss of $0.71 to $0.66 per basic and diluted common share.

176. In its 2015 1Q 10-Q, filed with the SEC on May 28, 2015, Alere reported, among other things, 2015 1Q net revenue of $608.2 million, gross profit of $292.0 million, a loss from continuing operations of $7.5 million or $0.15 per basic and diluted common share, and net income available to common stockholders of $203.9 million or $2.42 per basic and diluted common share. The 2015 1Q Form 10-Q was signed by Defendant Flakne. The 2015 1Q 10-Q contained as Exhibits 31.1, 31.2 and 32.1 certifications pursuant to SOX, signed by Defendants Nawana and Hinrichs, identical in all material respects to the certifications described in ¶¶ 207-213 below.

177. The 2015 Form 10-K in connection with Alere's restatement of its financial statements, the 2015 1Q Form 10-Q was materially false and misleading because of errors in applying GAAP regarding the timing of revenue recognition. Because of the failure to follow GAAP, the numbers reported in the 2015 1Q Form 10-Q required the following restatement: net revenue was changed from $608.2 million to $612.9 million; gross profit was revised from $292.0 million to $295.2 million; a loss from continuing operations was revised from $7.5 million or $0.15 per basic and diluted common share to a loss of $6.3 million or $0.14 per basic and diluted common share; and net income available to common stockholders was revised from

$203.9 million to $205.1 million or from $2.42 to $2.43 per basic and diluted common share. 2015 Form 10-K at 86.

178. In its 2015 2Q Form 10-Q, filed with the SEC on August 6, 2015, Alere reported, among other things, 2015 2Q net revenue as $629.2 million, gross profit as $292.6 million, income from continuing operations as $20.3 million or $0.17 per basic and diluted common share, and net income available to common stockholders of $14.6 million or $0.17 per basic and diluted common share. The 2015 2Q Form 10-Q was signed by Defendant Flakne. The 2015 2Q Form 10-Q contained as Exhibits 31.1, 31.2 and 32.1 certifications pursuant to SOX, signed by Defendants Nawana and Hinrichs, identical in all material respects to the certifications described in ¶¶ 207-213 below.

179. The 2015 2Q Form 10-Q was materially false and misleading because of errors in applying GAAP regarding the timing of revenue recognition. Because of the failure to follow GAAP, the numbers reported in the 2015 2Q Form 10-Q required the following restatement: net revenue was changed from $629.2 million to $623.4 million; gross profit was revised from $292.6 million to $287.3 million; income from continuing operations was revised from $20.3 million or $0.17 per basic and diluted common share to income of $14.8 million or $0.11 per basic and diluted common share; and net income available to common stockholders was revised from $14.6 million to $9.1 million or from $0.17 to $0.11 per basic and diluted common share. 2015 Form 10-K at 86.

180. In its 2015 3Q Form 10-Q, filed with the SEC on November 9, 2015, Alere reported, among other things, 2015 3Q net revenue as $602 million, gross profit as $275 million, income from continuing operations as $5.5 million or $0.00 per basic and diluted common share, and net income available to common stockholders of $195,000 or $0.00 per basic and diluted

common share. The 2015 3Q Form 10-Q was signed by Defendant Flakne. The 2015 3Q Form 10-Q contained as Exhibits 31.1, 31.2 and 32.1 certifications pursuant to SOX, signed by Defendants Nawana and Hinrichs, identical in all material respects to the certifications described in ¶¶ 207-213 below.

181. The Defendants' 2015 3Q Form 10-Q was materially false and misleading because of errors in the applying GAAP regarding the timing of revenue recognition. Because of the failure to follow GAAP, the numbers reported in the 2015 3Q Form 10-Q required the following restatement: net revenue amount was changed from $602 million to $603.8 million; gross profit was revised from $275 million to $277 million; income from continuing operations was revised from $5.5 million or $0.00 per basic and diluted common share to a loss of $2.4 million or $0.9 per basic and diluted common share; and net income available to common stockholders was revised from $195,000 to a net loss of $7.7 million or from $0.00 to a loss of $0.09 per basic and diluted common share. 2015 Form 10-K at 85.

B. Alere's Undisclosed Violation of Its Internal Accounting Policies

182. Defendants' statements concerning Alere's revenue recognition policy (**¶** 157, *supra*) were materially false and misleading because they misrepresented, and failed to disclose, that Alere violated its own public stated internal accounting policy. Specifically, as Alere stated in its 2015 Form 10-K, under the terms of certain sales contracts in Africa, (i) Alere had "retained title in the products until the distributor paid for the products in full;" (ii) "the distributor was not obligated to pay [Alere] until the products were sold through to the end-user;"' and (iii) the "title and risk of loss [had not] pass[ed] to the customer."

C. Alere's Failure to Disclose a Loss Contingency Regarding the INRatio Products

183. As discussed above, ASC 450 states that an estimated loss from a loss contingency shall be accrued by a charge to income if it is probable a liability has been incurred as of the date of the financial statements and the amount of loss can be reasonably estimated. (ASC 450-20-25). ASC 450 further states that disclosure of a contingency shall be made if there is at least a reasonable possibility that a loss or an additional loss may have been incurred and either of the following conditions exists:

a. An accrual is not made for a loss contingency because it is not probable that an asset had been impaired or a liability had been incurred and/or the amount of loss cannot be estimated;
b. An exposure to loss exists in excess of the amount accrued.

(ASC 450-20-50).

184. When such situations exist, ASC 450 requires that the following information be disclosed:

a. The nature of the contingency; and
b. An estimate of the possible loss or range of loss or a statement that such an estimate cannot be made.

(ASC 450-20-50).

185. In addition to the reporting guidance provided in ASC 450, the SEC provides guidance and examples of material events that must be filed on Form 8-K within four business days to satisfy obligations under SEC rules. One of the material events that requires a filing of a Form 8-K is Material Impairments. In addition to disclosure of "Material Impairments," the SEC provides that a public company may disclose any other event that is important to security holders.

186. The disclosures in the 2015 Form 10-K, plus the Company's announcement of a voluntary withdrawal of INRatio products in July 2016, were the first time that Alere explicitly

notified investors, as well as the SEC, that due to the ineffectiveness of the Company's INRatio products, a material charge would be recognized, or that it was reasonably possible that a material charge would be recognized and, accordingly, would have a material impact to the Company's financial statements. Yet, the Company was aware that it was reasonably possible it would have to withdraw INRatio products as early as the end of 2014 and no later than the end of 2015`.

187. Specifically, at the end of 2014, the Company launched an investigation into the INRatio Products to address this matter, which ultimately led to the aforementioned withdrawal of the products in July of 2016. In its 2015 Form 10-K, the Company reported the following regarding this investigation and its result:

> Over the course of the past two years, Alere invested in the research and development of software Enhancements intended to address the potential, in certain cases, of the system to deliver a result that differs from that of another measurement method.
>
> We submitted the software enhancements to the FDA at the end of 2015. The FDA notified us that it believes the company's studies do not adequately demonstrate the effectiveness of the software modification and advised us to submit a proposed plan to voluntarily remove the INRatio device from the market.
>
> In light of this input from the FDA and our business considerations, in July 2016 we determined to voluntarily remove the INRatio systems from the market.

2015 Form 10-K at F-95.

188. Accordingly, Alere was aware of the ineffective nature of the INRatio products by, at the latest, December 2014. At that time, Alere informed INRatio users of concerns with its INRatio products and reported these concerns to the FDA.

189. Between the December 2014 voluntary recall and the press release in July of 2016 that described the withdrawal of the INRatio products, the Company failed to meet its reporting obligations under ASC 450 and SEC guidelines, by failing to provide information through Forms 8-K, Forms 10-Q and Forms 10-K describing the material charge that was, at minimum, reasonably possible due to concerns with the effectiveness of its INRatio products and that improvements to these products would not be accepted by the FDA.

190. Specifically, the Company was aware, throughout 2015, that there was at least a reasonable possibility that a material loss had been incurred relating to its INRatio products, but it chose not to disclose this information until mid-2016.

191. Alere's failure to disclose any relevant loss contingency information regarding the Company's financial exposure with respect to its INRatio products, as well as the steps taken by the Company to improve the products, from December 2014 to July 2016, indicates that the Company did not meet the aforementioned ASC 450 and SEC Form 8-K reporting requirements.

D. Alere Fails to Disclose Material Adverse Facts Relating to its Arriva Medical Subsidiary

192. Arriva Medical is a wholly-owned subsidiary of Alere which, among other things, operates as a major, national mail order supplier of diabetic testing supplies, including blood glucose monitors, test strips, lancets, lancing devices and control solutions, as well as other related medical supplies in the U.S. Arriva Medical, which generates $117 million in annual revenue and $24 million of EBITDA, represents approximately 4.6% of Alere's business by revenue. The products supplied by Arriva Medical are usually covered by Medicare, Medicaid and other third-party payers.

193. A key component of Arriva Medical's business relates to it being one of the few suppliers of diabetic testing supplies under the Medicare National Mail Order Competitive Bid

Program for Diabetes Testing Supplies. In connection with those services, Arriva Medical also submits claims for reimbursement from Medicare and Medicaid.

1. Arriva Medical Operates in a Stringent Regulatory Setting Imposing Severe Consequences for Filings on Behalf of Deceased Patients

194. Arriva Medical operates in a stringent regulatory environment, imposing severe consequences for filings made on behalf of deceased patients. Thus, the federal regulation governing revocation of Medicare enrollment explicitly states that "CMS may revoke a currently enrolled provider or supplier's Medicare Billing Privileges" for "[a]buse of billing privileges." 42 C.F.R. 424.535(a)(8). Such billing abuses include situations where "[t]he provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service" because of instances including, but not limited to, "[w]here the beneficiary is deceased." 42 C.F.R. 424.535(a)(8)(i)(A).

195. Revocation of a provider's or supplier's Medicare enrollment causes a "provider's or supplier's billing privilege [to be] revoked [and] any provider agreement in effect at the time of revocation is terminated." 42 C.F.R. 424.535(b). Once the Medicare billing privilege is revoked, the participant is "barred from participating in the Medicare program from the date of the revocation until the end of the re-enrollment bar." 42 C.F.R. 424.535(c). The "re-enrollment bar begins 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation." 42 C.F.R. 424.535(c)(1).

196. The preamble to the section of the Code of Federal Regulations governing revocation of Medicare enrollment states that revocation is appropriate when a provider or supplier engages in a pattern of improper billing practices, with as few as ***three violations*** sufficient to constitute an abusive pattern. In this regard, the preamble states:

> This revocation authority is not intended to be used for isolated occurrences or accidental billing errors. Rather, this basis for revocation is directed at providers and suppliers who are engaging in a pattern of improper billing . . . We believe that it is both appropriate and necessary that we have the ability to revoke billing privileges when services could not have been furnished by a provider or supplier. ***We recognize the impact that this revocation has, and a revocation will not be issued unless sufficient evidence demonstrates abusive billing patterns. Accordingly, we will not revoke billing privileges under § 424.535(a)(8) unless there are multiple instances, at least three, where abusive billing practices have taken place*** . . . In conclusion, we believe that providers and suppliers are responsible for the claims they submit or the claims submitted on their behalf. We believe that it is essential that providers and suppliers take the necessary steps to ensure they are billing appropriately for services furnished to Medicare beneficiaries.

73 Fed. Reg. 36,448, 36,455 (June 27, 2008) (emphasis added).

197. Accordingly, the Department of Health and Human Services, Departmental Appeals Board ("DHHS") has repeatedly upheld decisions by Administrative Law Judges confirming the revocation by CMS of a provider's or supplier's Medicare enrollment and billing privileges in cases where such provider or supplier submitted as few as three claims on behalf of deceased patients.

198. The DHHS recently upheld the three-year revocation of the Medicare enrollment of Florida neurologist, John DeCerce, for submitting claims for "35 services allegedly rendered to eight individual beneficiaries who were, in fact, deceased on the alleged service dates." *See John Decerce, M.D., (Ptans: 27276x, 27276z),* DAB No. CR4568 (2016) (Apr. 4, 2016). DHHS noted there were at least "three or more instances" of "claims of services allegedly rendered to persons who were deceased on the service dates," and that "[t]hree or more of such claims is defined to be a pattern." *See id.* Similarly, the DHHS upheld an Administrative Law Judge's decision to revoke Medicare enrollment and billing privileges of Florida podiatrist, Patrick Brueggeman, for a period of three years based upon his submission of "33 claims for services provided to 16 beneficiaries after the dates of their death." *See* Patrick Brueggeman, D.P.M.,

DAB. No. 2725 (Jul. 26, 2016). A data analysis performed by CMS showed that Brueggeman billed for services provided to 16 different beneficiaries who were deceased at the alleged time of service, and that the claims submitted to Medicare "actually identified *deceased* Medicare beneficiaries." *See id.* In reaching its decision, the DHHS went so far as to note that, "even ***one claim*** for reimbursement for services to beneficiaries who were deceased is a sufficient basis for CMS to revoke participation and billing status." *See Med-Care Diabetic and Med. Supplies, Inc., (Ptan: 1289360001; Npi: 1619978434),* DAB No. CR4615 (2016) (May 20, 2016).

199. Therefore, making even a single claim on behalf of a deceased patient is a sufficient basis for CMS to revoke participation and billing status. Three claims on behalf of deceased patient(s) constitutes an abusive pattern of improper billing practices.

2. Alere Fails to Disclose That Arriva Medical Filed Claims on Behalf of Deceased Patients over a Multi-Year Period

200. On March 5, 2015, in Alere's Form 10-K filed with the SEC, and again on May 28, 2015 in a Form 10-K/A filed with the SEC, Alere disclosed that Arriva Medical was being investigated for possibly submitting false claims to Medicare and Medicaid by stating that:

> Through our subsidiary **Arriva Medical, we are a major, national mail order supplier of diabetic testing supplies**, including blood glucose monitors, test strips, lancets, lancing devices, and control solutions, as well as other related medical supplies in the U.S. **These products are usually covered by Medicare, Medicaid and other third-party payers**.
>
> Arriva Medical, which is **our mail order diabetes testing product supply business, primarily sells products which are covered by Medicare, Medicaid and other third-party payers.** Our major competitors for the sale of these products are large retail pharmacies, such as Walmart, Walgreens and CVS, independent pharmacies and a small number of mail order suppliers. Competition for **reimbursed diabetes testing supplies, which represent the majority of our business**, changed significantly in 2013 as a result of CMS' decision, based on a competitive bidding process, to reimburse only 18 selected suppliers willing to accept a fixed lowered reimbursement rate. **As a result of the competitive bidding process, Arriva Medical was awarded a national mail-order contract**.

> Our subsidiary, Arriva Medical, LLC, or Arriva, is also in the process of responding to a Civil Investigative Demand, or CID, from the United States Attorney for the Middle District of Tennessee **in connection with an investigation of possible improper claims submitted to Medicare and Medicaid**.
>
> 2014 Form 10-K/A at 6, 10, 34, F-58; 2014 Form 10-K at 6, 10, 33, F-49 (Emphasis added).

201. In Alere's Forms 10-Q filed with the SEC on August 6, 2015, November 9, 2015, August 17, 2016 and September 6, 2016, as well as in Alere's 2014 Form 10-K/A (dated November 13, 2015), Defendants made the following disclosure:

> Our subsidiary, Arriva Medical, LLC, or Arriva, is also in the process of responding to a Civil Investigative Demand, or CID, from the United States Attorney for the Middle District of Tennessee in connection with an **investigation of possible improper claims submitted to Medicare and Medicaid**. The CID requests patient and billing records. Both investigations are in preliminary stages, and we cannot predict what effect, if any, the investigations, or any resulting claims, could have on Alere or its subsidiaries.
>
> (2015 2Q Form 10-Q at 24; 2015 3Q Form 10-Q at 23; 2016 2Q Form 10-Q at 23; 2015 Form 10-K/A dated November 13, 2015, at F-58 (Emphasis added).

202. In Alere's 2015 Form 10-K dated August 8, 2016, Defendants made the following additional disclosure:

> We and our subsidiary, **Arriva Medical, LLC, are also in the process of responding to Civil Investigative Demands, or CIDs, the most recent CID which was received in July 2016, from the United States Attorney for the Middle District of Tennessee in connection with an investigation of possible improper claims submitted to Medicare and Medicaid**. The CIDs request patient and billing records and records related to interactions with third parties. We are cooperating with the investigation of the United States Attorney for the Middle District of Tennessee and are providing documents responsive to the CIDs. We cannot predict what effect, if any, these investigations, or any resulting claims, could have on Alere or its subsidiaries.
>
> Our businesses are subject to extensive and frequently changing federal, state, local and foreign laws and regulations. Changes in applicable laws, changes in the interpretation or application of such laws, or any failure to comply with existing or future laws, regulations or standards could have a material adverse effect on

> our results of operations, financial condition, business and prospects. From time to time, we have been subject to inquiries, investigations and enforcement actions by governmental authorities alleging that we have not fully complied with our legal and regulatory obligations, some of which have not yet been resolved.

2015 Form 10-K at 7, 12, 46, F-57 (Emphasis added).

203. These statements were materially false and misleading because they failed to disclose that over a multi-year period Arriva Medical had submitted at least 211 claims to CMS on behalf of deceased patients. Defendants knew or recklessly disregarded these facts because they knew of the importance of complying with the relevant regulations concerning the submission of such improper claims and the pendency of the government investigation requiring the Company to add extra focus on the relevant facts, the existence of serious internal control deficiencies that prevented the remediation of these problems, and Arriva's history of being investigated and scrutinized by regulators.

3. Alere Also Failed to Disclose That CMS Had Shut Off Arriva Medical's Access to a Key CMS System

204. In addition, as alleged above (*see* ¶ 201), Alere represented that Arriva Medical was an authorized service provider to CMS. A similar representation was made in the Company's 2015 Form 10-K filed with the SEC on August 8, 2016, which stated, in relevant part, that:

> **Arriva Medical, which is our mail-order diabetes testing product supply business, primarily sells products which are covered by Medicare, Medicaid and other third-party payers.** Our major competitors for the sale of these products are large retail pharmacies, such as Walmart, Walgreens and CVS, independent pharmacies and a small number of mail-order suppliers. Competition for reimbursed diabetes testing supplies, which represent the majority of our business in this field, changed significantly in 2013 as a result of the decision by the Centers for Medicare & Medicaid Services, or CMS, to utilize a competitive bidding process. Based on the most recent bidding process, CMS will reimburse only nine selected suppliers willing to accept a fixed lowered reimbursement rate for the period from July 2016 to December 2018. **As a result of the most recent**

> **competitive bidding process, Arriva Medical was awarded a national mail-order contract.**

2015 Form 10-K at 12 (Emphasis added)

205. Defendants failed to update the disclosure made in the 2015 Form 10-K and failed to disclose in the 2015 Form 10-K that in August 2015, CMS unilaterally shut off access to the HIPAA Eligibility Tracking System ("HETS"), which is the CMS system used to determine Medicaid beneficiary eligibility, including dates of death. Arriva Medical was, instead, only allowed to run eligibility checks one time per month per beneficiary. This impaired Arriva Medical's ability to insure against making claims on behalf of deceased patients, given that: (i) updates to HETS are not made in sufficient time to allow suppliers to identify deceased patients prior to billing for reorders of covered medical supplies; (ii) Alere has no face-to-face contact with beneficiaries or their caregivers because of its status as a mail order supplier; and (iii) Arriva Medical services beneficiaries with chronic conditions who require regular reorders of covered products.

E. The SOX Certifications Were Materially False and Misleading

206. SOX, among other things, established provisions related to internal controls over financial reporting, with an overall purpose "to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles." (Exchange Act, 17 C.F.R. § 240.13a-13(f) (2007)).

207. Section 404 of SOX requires publicly-traded companies, annually, to provide a report on internal controls prepared by their management and attested to by their independent auditors. Additionally, SOX requires management to: (1) acknowledge its responsibility for the

adequacy of the company's internal control structure and procedures for financial reporting; and (2) assess the effectiveness of the internal controls over financial reporting.

208. SOX also requires that management evaluate any change in the company's internal controls over financial reporting that occurred during a fiscal quarter that has materially affected, or is reasonably likely to materially affect, the company's internal controls over financial reporting. Material changes are required to be disclosed.

209. Management is not permitted to conclude that the company's internal controls over financial reporting is effective if any material weaknesses are identified, and management must disclose such material weaknesses.

210. The Company's 2014 Form 10-K/A filed with the SEC on May 28, 2015, contained certifications pursuant to SOX, signed by Defendants Nawana and Hinrichs, who certified:

1. I have reviewed this annual report on Form 10-K of Alere Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-l 5(f) and l 5d-l 5(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others

within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

2014 10-K/A, Exhibits 31.1 and 31.2.

211. Likewise, the 2014 10-K/A contained the following certifications pursuant to SOX, signed by Defendants Nawana and Hinrichs:

> Each of the undersigned officers of Alere Inc. (the "Company") hereby certifies, to his knowledge, that the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013

> (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company. This certification is being furnished as an exhibit to the Report pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section. This certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing, except to the extent that the Company specifically incorporates this certification by reference.

2014 10-K/A, Exhibit 32.1.

212. As alleged above, Defendants Nawana and Hinrichs each signed substantially similar certifications as the one in the above paragraph, which were included in Alere's filing with the SEC of its 2015 1Q Form 10-Q on May 28, 2015, its 2015 2Q Form 10-Q on August 6, 2015 and its 2015 3Q Form 10-Q on November 9, 2015. Each of these certifications was materially false and misleading because:

- The respective quarterly and annual SEC filings *did* contain untrue statements of a material fact and omitted to state material facts necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the relevant periods, as described in ¶¶ 173-206 above;

- The respective quarterly and annual SEC filings *did* contain financial statements, and other financial information, that did not fairly present in all material respects the financial condition, results of operations and cash flows of Alere, with respect to the relevant periods, as described in ¶¶ 173-206 above;

- The certifying officers referenced in the respective quarterly and annual SEC filings *did not* design, or cause to be designed, disclosure controls and procedures to ensure that material information relating to Alere and its consolidated subsidiaries was made known to such officers with respect to

the relevant periods, as described in ¶¶ 173-206 above;

- The certifying officers referenced in the respective quarterly and annual SEC filings *did not* design, or cause to be designed, internal control over financial reporting to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, with respect to the relevant periods, as described in ¶¶ 173-206 above;

- The certifying officers referenced in the respective quarterly and annual SEC filings *did not* properly evaluate the effectiveness of Alere's disclosure controls and procedures, and thus *did not* present in the respective SEC filings, accurate conclusions about the effectiveness of the disclosure controls and procedures, as of the end of each relevant period, as described in ¶¶ 173-206 above;

- The certifying officers *did not* disclose in the respective SEC filings all changes in Alere's internal control over financial reporting that occurred during Alere's most recent fiscal quarter that materially affected, or were reasonably likely to materially affect, Alere's internal control over financial reporting, as described in ¶¶ 173-206 above;

- The certifying officers *did not* disclose all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting, which were reasonably likely to adversely affect Alere's ability to record, process, summarize and report financial information, as described in ¶¶ 173-206 above; and

- The certifying officers referenced in the respective quarterly and annual SEC filings *did not* ensure that the SEC filings were fully compliant with the requirements of Sections 13(a) and 15(d) of the Exchange Act, nor did they ensure that the information contained in the SEC filings fairly presented, in all material respects, the financial condition and results of operations of the Company, as described in ¶¶ 173-206 above.

Accordingly, each of the foregoing certifications was signed recklessly and without factual basis by the respective Defendants.

F. Alere's Risk Disclosures Omitted Material Facts

213. On March 15, 2016, Alere disclosed that it received a grand jury subpoena from the DOJ requiring the production of documents relating to, *inter alia,* sales practices overseas and other matters related to the FCPA.

214. As alleged above, since at least the fall of 2013, Alere was aware of improprieties by its facilities in India, including bribery of government officials to win business. Such activities would be violations of the FCPA.

215. On July 27, 2016, Alere disclosed that it received a subpoena from the DOJ Criminal Fraud Unit regarding the Company's toxicology business, requesting documents relating to Medicare, Medicaid and Tricare billings from 2010, reportedly about collecting copayments from patients. It was also reported that the DOJ was investing illegal kickbacks made by Alere.

216. As alleged above, billing improprieties had been ongoing at Alere's toxicology unit for years. These improper practices were occurring at more than one toxicology unit and in 2013, Alere was sued because of false health insurance claims for unnecessary tests in violation of New Jersey and Florida law.

217. Alere stated in its 2014 Form 10-K/A that certain laws applied to its business, including that:

> We are also subject to laws regulating fraud and abuse in the healthcare industry, including anti-kickback and false claim laws. We are also subject to a number of legal requirements relating to our international operations, including the U.S. Foreign Corrupt Practices Act and the U.K. Bribery Act, which generally prohibit engaging in certain activities to obtain or retain
> business or to influence a person working in an official capacity.
>
> * * *
>
> We are subject to laws regulating fraud and abuse in the healthcare industry, including anti-kickback and false claims laws. The Federal Anti-Kickback Statute prohibits persons from knowingly and willfully

> soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Many states have also adopted laws similar to the Anti-Kickback Statute.
>
> * * *
>
> Other laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, or are for items or services that were not provided as claimed. These laws may also be triggered by failure to return identified overpayments to a payer.
>
> * * *
>
> [A]ny failure to comply with existing or future laws, regulations or standards could have a material adverse effect on our results of operations, financial condition, business and prospects.

218. Alere also stated in the 2014 Form 10-K/A that there were certain risk factors that applied to its business, including the following (emphasis omitted):

> • We could incur additional legal compliance costs associated with our global operations and could become subject to legal penalties if we do not comply with certain regulations.
>
> * * *
>
> • Our business is subject to substantial regulatory oversight and our failure to comply with applicable regulations may result in significant costs or, in certain circumstances, the suspension or withdrawal of previously obtained clearances or approvals.
>
> * * *
>
> • We are subject to healthcare fraud and abuse regulations that could result in significant liability, require us to change our business practices and restrict our operations in the future.
>
> * * *
>
> • Billing and payment for healthcare services are highly regulated, and

> the failure to comply with applicable laws and regulations can result in civil or criminal sanctions, including exclusion from federal and state healthcare programs.

219. The above statements in Alere's 2014 Form 10-K/A were materially false and misleading because Alere omitted to disclose the improprieties in its toxicology unit and the alleged bribery of government officials in India which were not merely risks, but had already occurred.

G. The Merger Agreement Was Materially False and Misleading

220. The Merger Agreement between Abbott and Alere was disclosed in, and attached as Exhibit 2.1 to, a Form 8-K filed by Alere with the SEC on February 1, 2016. The Merger Agreement contained Representations and Warranties by Alere, providing, in part, as follows:

> (a) Company SEC Documents; Undisclosed Liabilities. (a) The Company has filed with the SEC all material reports, schedules, forms, statements and other documents required to be filed by the Company with the SEC pursuant to the Securities Act or the Exchange Act since January 1, 2014 (collectively, the "Company SEC Documents"). As of their respective effective dates (in the case of Company SEC Documents that are registration statements filed pursuant to the requirements of the Securities Act) and as of their respective SEC filing dates or, if amended prior to the date hereof, the date of the filing of such amendment, with respect to the portions that are amended (in the case of all other Company SEC Documents), ***the Company SEC Documents complied as to form in all material respects with the requirements of the Securities Act or the Exchange Act***, as the case may be, applicable to such Company SEC Documents, and ***none of the Company SEC Documents as of such respective dates*** (or, if amended prior to the date hereof, the date of the filing of such amendment, with respect to the disclosures that are amended) ***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 under which they were made, not misleading***.
>
> (b) The consolidated financial statements of the Company (including all related notes or schedules) included or incorporated by reference in the Company SEC Documents, as of their

respective dates of filing with the SEC, ***complied as to form in all material respects with the published rules and regulations of the SEC with respect thereto, have been prepared in all material respects in accordance with GAAP*** (except, in the case of unaudited quarterly statements, as permitted by Form 10-Q of the SEC or other rules and regulations of the SEC) applied on a consistent basis during the periods involved (except (i) as may be indicated in the notes thereto or (ii) as permitted by Regulation S-X) and fairly present in all material respects the consolidated financial position of the Company and its consolidated Subsidiaries as of the dates thereof and the consolidated results of their operations and cash flows for the periods shown (subject, in the case of unaudited quarterly financial statements, to normal year-end adjustments).

(c) ***Neither the Company nor any of its Subsidiaries has any liabilities of any nature (whether accrued, absolute, contingent or otherwise) that would be required under GAAP, as in effect on the date hereof, to be reflected on a consolidated balance sheet of the Company (including the notes thereto) except liabilities (i) reflected or reserved against in the consolidated balance sheet (or the notes thereto) of the Company as of September 30, 2015 (the "Balance Sheet Date") included in the Filed SEC Documents,*** (ii) incurred after the Balance Sheet Date in the ordinary course of business, (iii) as contemplated by this Agreement or otherwise incurred in connection with the Transactions or (iv) as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(d) ***The Company has established and maintains disclosure controls and procedures and a system of internal controls over financial reporting (as such terms are defined in paragraphs (e) and (f), respectively, of Rule 13a-15 under the Exchange Act) as required by Rule 13a-15 under the Exchange Act. As of the date hereof, neither the Company nor, to the Company's Knowledge, the Company's independent registered public accounting firm, has identified or been made aware of "significant deficiencies" or "material weaknesses" (as defined by the Public Company Accounting Oversight Board) in the design or operation of the Company's internal controls over financial reporting which would reasonably be expected to adversely affect in any material respect the Company's ability to record, process, summarize and report financial data,*** in each case which has not been subsequently remediated. ["Knowledge" is a defined term in the

> Merger Agreement, which means, as to Alere, actual knowledge of certain individuals identified in the Company's Disclosure Letter.].

Merger Agreement, Article III, Section 3.05 (Emphasis Added).

221. In addition, Alere represented to investors through the terms of the Merger Agreement that "there is no . . . pending or, to the [k]nowledge of the Company, threatened legal or administrative proceeding, suit, claim, investigation, arbitration or action . . . against the Company or any of its Subsidiaries . . ." that would be expected to have a material adverse effect. Merger Agreement, Section 3.07. The Company further represented that it was in compliance with "all state or federal laws, statutes, ordinances, codes, rules or regulations . . ." since January 1, 2014. In addition, Alere represented that: "Except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, the Company, each of its Subsidiaries and each of its and their directors, officers and employees and, to the Knowledge of the Company, each of its and their other agents acting on its or their behalf, is and has been since January 1, 2014 in compliance with the Foreign Corrupt Practices Act of 1977 and any rules and regulations promulgated thereunder." Merger Agreement, Section 3.08.

222. The above statements from the Merger Agreement were materially false and misleading because, among other things: Alere's SEC filings did not comply with all the requirements of the Exchange Act and did contain untrue statements of material facts; its financial statements did not comply with GAAP in all material respects; and its disclosure controls and procedures had material weaknesses.

223. In addition, contrary to its statements in the Merger Agreement, Alere had not complied with all laws and its undisclosed actions concerning foreign officials were giving rise to an FCPA investigation, and Alere was denied access to HETS, impairing Arriva Medical's

ability to insure against making claims on behalf of deceased patients, which would result in its Medicare enrollment being revoked.

H. Defendants' Material Omissions That Rendered Their Statements Materially False and Misleading

224. The foregoing statements, described in paragraph 221 above, were also materially false and misleading for their failure to disclose other material, non-public facts whose non-disclosure rendered the Defendants' statements materially misleading. During the Class Period, the Defendants failed to disclose the material adverse facts below that were in existence at the time each of the foregoing materially false and misleading statements was made, the disclosure of which would have led to declines in Alere's stock price at an earlier date.

225. The disclosures Alere should have made include the following:

- That facts existed raising the likelihood of a criminal investigation of Alere by the DOJ relating to potential violations of the FCPA in Africa, Asia and Latin America subjected Alere to criminal charges;
- That facts existed raising the likelihood of a criminal investigation of Alere by the DOJ's Fraud Section relating to billing practices of Alere for U.S. government insurance programs, including Medicare, Medicaid and Tricare;
- That the problems with its INRatio products required Alere to disclose that a charge was required in 2015 and that it would need to withdraw those products from the market;
- That a material weakness in Alere's internal controls over revenue recognition existed, which would result in the restatement of Alere's financial statements for the year 2014 and the first three quarters of 2015; that the material weakness in Alere's internal controls over the accounting for income taxes, ***which existed as of December 31, 2014***, has not been remediated and continued to exist as of December 31, 2015; and
- That facts existed raising the likelihood of an investigation of Alere by the DOJ relating to the accuracy, reliability and performance of the INRatio products; and

- That facts existed raising the material likelihood that CMS would revoke Arriva Medical's Medicare enrollment.

VIII. ADDITIONAL ALLEGATIONS OF SCIENTER

226. Defendants acted with scienter in that Defendants Nawana, Hinrichs and Flakne (and accordingly Alere) knew or recklessly disregarded that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and knowingly or recklessly participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws.

227. First, Defendants have admitted that the material weaknesses plaguing the Company's internal controls over financial reporting during the Class Period were so severe and pervasive that the Company did not know whether its current or future financial statements could be relied upon. In addition to the previously-disclosed material weakness concerning specifically income taxes, in the Company's 2015 Form 10-K filed on August 8, 2016, the Company admitted that it ***also suffered from an additional four material weaknesses***, stating that:

> (i) we did not maintain a sufficient complement of resources at our subsidiaries with appropriate knowledge, experience and training to ensure proper application of US GAAP in determining revenue recognition, (ii) we also did not maintain effective controls over information and communications as it relates to revenue recognition at our subsidiaries (specifically, we did not implement and reinforce an adequate process for internally communicating nonstandard terms and conditions between our subsidiaries commercial operations and finance groups and between our subsidiaries finance groups and our corporate accounting group), (iii) we did not design effective controls over the review of terms of purchase orders and customer contracts, including amendments to contracts, to ensure proper application of US GAAP in determining revenue recognition and (iv) we did not design effective controls to ensure that

> revenue would not be recognized until title and risk of loss had passed to our customers.

2015 Form 10-K at 90.

228. As a result of these egregious material weaknesses in internal controls, some of which had gone knowingly or recklessly unremediated since at least December 31, 2014, the Company admitted it could not accurately represent its current or future financial statements and that the Company was forced to restate its financial statements for fiscal year ended December 30, 2014, as well as for the first three fiscal quarters of 2015.

229. Second, Defendants' Class Period admissions of certain material weaknesses in the Company's internal controls, prior to the August 8, 2016 disclosure, put Defendants on notice that the Company was at risk of suffering from additional, widespread and more serious material weaknesses in internal controls, causing the Company's financial results during the Class Period to be misstated. For example, Defendants admitted to the following specific material weaknesses in internal controls throughout the Class Period, without disclosing the full and widespread nature of the Company's material weaknesses in internal controls:

- In in its 2014 Form 10-K filed with the SEC on March 5, 2015, Alere disclosed it suffered from a material weakness in internal controls related to deferred tax assets and specifically that: "The material weakness related to the failure to design controls to assess the accounting for deferred tax assets which became recognizable as a result of the disposition." Moreover, in the 2014 Form 10-K, Alere further stated regarding internal controls: "The effectiveness of our internal control over financial reporting is subject to various inherent limitations, including cost limitations, judgments used in decision making, assumptions about the likelihood of future events, the soundness of our systems, the possibility of human error and the risk of fraud" and that "there can be no assurance ***that any system of or internal control over financial reporting will be successful in preventing all errors or fraud or in making all material information known in a timely manner to the appropriate levels of management.***"

- In its 2014 Form 10-K/A filed on May 28, 2015, Alere ***admitted that as result of a material weakness identified in its 2014 Form 10-K, it had incorrectly accounted for income taxes associated with two divestitures during 2014 and that the resulting errors were deemed to be material***, thus requiring a restatement of previously-reported consolidated financial statements.

- In the Company's 2015 third quarter Form 10-Q, filed on November 9, 2015, Alere admitted that it had identified ***another internal control problem*** and acknowledged that the Company "***did not maintain a sufficient complement of resources with adequate experience and expertise in accounting for income taxes***."

- In the Company's Form 10-K/A, Amendment No. 3, filed with the SEC on November 13, 2015, the Company ***once again expanded the scope of the material weaknesses plaguing its internal controls*** when it admitted that it had identified out-of-period errors in the third fiscal quarter of 2015 relating to U.S. taxes on foreign earnings, which affected the Company for the year ended December 31, 2014. However, instead of reporting this additional material weakness separately, the Company merely revised the description of the previous material weaknesses related to deferred tax assets such that the "***Company did not maintain a sufficient complement of resources with adequate experience in accounting for income taxes as a result of which our controls did not operate at a level of precision to identify errors in the calculation of tax balances resulting from dispositions and U.S. taxes on foreign earnings***."

230. Given the Company's troubled and recidivist history of inadequate internal controls, known by Defendants throughout 2015, Defendants were on notice that additional material weaknesses were likely to exist, rendering the Company's financial statements unreliable and misstated.

231. Similarly, numerous former Alere employees have stated that the Company failed to maintain adequate internal controls over financial reporting during the Class Period. For example, the Senior Accountant described above stated that Alere's internal controls were inadequate for the following reasons:

a) The Company was massive, consisting of approximately 200 entities, and, as such, the Company's financial information system, as it was

implemented, could not ensure that it accurately compiled all of the necessary information;

b) Because Alere's revenue was typically reconciled using simply an Excel file that was linked to the Company's accounting platform, the information in the file was very easy to change, thus creating opportunities for potential manipulation; and

c) As a result of the $2.6 million adjustment related to internal transfer pricing made in November 2013, Alere's accounting firm responsible for the tax audit, PricewaterhouseCoopers, became aware of the deficiency and advised Alere not to take the $2.6 million adjustment – an event which put Alere's corporate office on notice of a lack of proper communication between Alere entities and a lack of internal controls by, at the latest, November 2013.

232. Likewise, the Alere National Sales Manager discussed above confirmed that Alere's operations in India, likely subject to the DOJ's grand jury subpoena related to the FCPA, did "not [maintain a] very effective reporting management system" to track and report sales and other business figures and that the system "needed to be updated" because it was "very primitive."

233. Third, despite the contemporaneous existence and partial disclosure of material weaknesses in Alere's internal controls, Defendants, Nawana, Hinrichs and Flakne signed the Company's materially false and misleading Class Period SEC filings, and Defendants Nawana and Hinrichs signed the accompanying SOX certifications, falsely attesting that the financial information contained in the Company's SEC filings were true, did not omit material facts and that the Company's internal controls and disclosure controls were effective. In these certifications, Defendants specifically represented that they personally designed and implemented adequate internal controls over financial reporting. Either the Defendants who signed the certifications made knowingly false statements in the certifications, or they acted in reckless disregard of the truth – that Alere had massive undisclosed material weaknesses in its

internal controls. As Abbott alleged in its complaint, Alere had systemic company-wide failures of internal controls, and it was an "absence of internal controls" that caused the problems to arise. Abbott Complaint ¶¶ 2, 11.

234. Fourth, the timing of the Company's disclosures of its material weaknesses in its internal controls is suspicious and supports a strong inference of Defendants' scienter. For example, on February 1, 2016, Alere announced its Merger with Abbott, and shortly thereafter began announcing problems. For example, as late as January 16, 2016, during an Alere Healthcare Conference hosted by J.P. Morgan (the same firm Alere hired to advise it as part of its corporate sell-off), Defendant Nawana reassured investors that "we look forward to reporting our full Q4 2015 results around mid-February." These are the same results that the Company later in fact, took months to report and which came in 6% below analyst expectations. Then, within days, on February 26, 2016, Alere announced that it was unable to timely file its 2015 Form 10-K because the Company was "conducting an analysis of certain aspects of revenue recognition in Africa and China and any potential implications on [the Company's] evaluation of internal controls over financial reporting for the year ended December 31, 2015." Given that, throughout the Class Period, Alere was plagued by undisclosed material weaknesses in its internal controls, Defendants were on notice or recklessly disregarded at a much earlier time the existence of the material weaknesses in internal controls that led to the delayed filing of the 2015 Form 10-K.

235. Fifth, the Company has restated its financial results for the fiscal year ended December 31, 2014 and the first three fiscal quarters of 2015, and the collective magnitude and extent of these restatements, supports a strong inference of Defendants' scienter. Specifically, in the 2015 Form 10-K, the Company admitted violating GAAP in connection with its recognition and reporting of revenue for fiscal year 2014, as well as each of the first three quarters of 2015

and admitted that its previously-reported financial statements were materially false and misleading by restating those results. The 2014 Form 10-K/A was materially false and misleading because of Alere's errors in applying GAAP regarding the timing of revenue recognition.

236. Sixth, in the wake of the Company's restated financial results, the Company announced that it was under a number of governmental investigations, which put Defendants on notice of these and other related issues concerning the Company's material weaknesses in internal controls and Alere's misstated financial results. For example:

- On March 5, 2015, Alere disclosed that on December 10, 2014 the Company and its subsidiary, Avee Laboratories Inc., received subpoenas from the U.S. Attorney for the District of New Jersey seeking marketing and other documents relating to billing and marketing practices concerning the Company's toxicology testing;

- On November 29, 2015, Alere announced that on August 28, 2015 it had received a subpoena from the SEC, which indicated it was conducting a formal investigation of Alere, concerning the Company's restatement and its sales practices in Africa;

- On February 26, 2016, Alere announced that on January 14, 2016 it had received another subpoena from the SEC, seeking information relating to sales of products and services to end-users in Africa, as well as revenue recognition concerning these issues;

- On March 15, 2016, Alere disclosed that on March 11, 2016 it had received a criminal subpoena from the DOJ regarding issues relating to the FCPA, amongst other things, the Company's sales practices in Africa, Asia, and Latin America;

- On July 11, 2016, Alere announced that it was initiating a voluntary withdrawal of its INRatio Product;

- On August 8, 2016, the Company announced that in May 2016, the U.S. Attorney's Office for the District of New Jersey issued a subpoena to Alere seeking information relating to the safety, accuracy, and reliability of its INRatio product;

- On July 27, 2016, Alere announced that on July 1, 2016, it had received another criminal subpoena from the DOJ seeking records related to Medicare, Medicaid and Tricare billings dating back years to 2010 for specific patient samples tested at the Company's Austin, Texas toxicology laboratory; and

- Also on August 8, 2016, Alere announced that in July 2016, it had received Civil Investigative Demands from the U.S. Attorney's Office for the Middle District of Tennessee in connection with an investigation of possible improper claims submitted by Alere to Medicare and Medicaid.

237. Moreover, given the heightened regulatory scrutiny the Company was under from the beginning of the Class Period, Defendants knew or should have known about the continuing risk of ***additional*** material weaknesses in internal controls, which indeed existed at Alere and were disclosed later in the Class Period. For example, on August 28, 2015, Alere received a subpoena from the SEC concerning the Company's restatement to its financial statements, including deferred taxes, the initial subject of the first-announced material weakness, highlighting the additional scrutiny Alere continues to be under concerning its internal controls over financial reporting.

238. Additionally, analysts' responses to the Company's announcements of the governmental investigations it was under, supports the materiality of these investigations and underscores Defendants' strong inference of scienter. For example, in a report dated November 9, 2015, BTIG described the SEC subpoena concerning Alere's restated financials for tax treatment as a "new material issue." Likewise, on November 10, 2015, Jefferies stated that the SEC subpoena concerning Alere's restated financials regarding tax treatment was a "[B]ody [B]low" to the Company and noted the risk the subpoena caused, stating that:

> The tax issue is more difficult to wall off … the company noted that it has material weaknesses in the calculation of tax balances resulting from dispositions and U.S. taxes on foreign earnings … The restated tax financials show the divestitures resulted in a number of changes including deferred tax benefits. The extent that material reporting weaknesses

resulted in errors in these and other calculations is difficult to know given the limited details.

239. When on, February 26, 2016, Alere disclosed that the SEC had served yet another subpoena on the Company concerning its revenue recognition, the source of the Company's restatement, analysts took note once again. For example, in a report dated February 28, 2016, an analyst wrote that: "Alere disclosed they received a second subpoena from the SEC (on January 14, 2016) related to its previously disclosed subpoena focusing on Alere's Africa business and associated revenue recognition practices in Africa."

240. Seventh, after the announcement of the merger with Abbott, Alere intentionally concealed its true financial condition, its internal control weaknesses and other material adverse facts from Abbott. For example:

a) In an email dated April 29, 2016, an Abbott spokesman wrote that: "Abbott is awaiting access to the information it has requested from Alere relating to delays in filing its form 10-K and the circumstances surrounding the criminal grand jury subpoena alleging violations of the Foreign Corrupt Practices Act";

b) On or about June 2, 2016, *Bloomberg News* reported that Abbott was examining Alere's books. Bloomberg reported that Darcy Ross, an Abbott spokeswoman, had stated in an email that: "Abbott is abiding by the terms of the contract with Alere and has exercised its contractual rights to audit Alere's books and records … To date, we have had a ***partial response*** from [Alere]";

c) In a filing with the SEC dated August 9, 2016, Abbott stated that "Abbott has requested information from Alere relating to [the US government's investigations, Alere's material weaknesses in internal controls, the delays in Alere's filing its SEC reports, and the INRatio Product recall], but ***Alere had failed to provide requested information relating to certain key topics***, and Abbott continues to wait for such information";

d) After the merger was announced, Alere withheld from Abbott documents concerning files about bribery probes of its foreign operations and U.S. billing practices that Alere agreed to disclose to Abbott only after Abbott needed to file litigation against Alere; and

e) Even after purportedly agreeing to produce documents to Abbott about the various government investigations, Alere backtracked and has again refused to produce those documents. As Abbott has stated, "Alere continually act[s] like a company with something to hide." Abbott Complaint ¶ 5.

241. In opposing Alere's Motion for Expedited Proceedings to move the merger with Abbott forward, filed with the Delaware Chancery Court on August 31, 2016, Abbott contended that any purported delay in Abbott's submitting information to antitrust authorities as part of the merger was in fact caused by Alere's inability to report accurate financial information. Abbott stated that that was the result of Alere's own severe material weaknesses in its internal controls over financial reporting. Abbott also stated that Alere had not been forthcoming to Abbott with information sought by Abbott as to Alere's financial state, including the documents and data that Abbott needed from Alere to understand the Company's accounting errors and internal control problems. For example, Abbott maintained that:

> Alere rebuffed Abbott's attempts to obtain transparency into the circumstances surrounding the delay of Alere's 2015 financials and its lack of adequate financial controls. ***For months, Alere refused Abbott's request to review critical financial information and transaction data, and failed to provide updates regarding the magnitude of the impact of its years of accounting errors*** so that—until Alere finally filed its belated 10-K—the possibility of a restatement of Alere's prior financials remained looming. Despite its contractual obligation to provide Abbott this information, ***Alere has refused, even to this day, to hand over the documents and data Abbott needs to understand Alere's accounting errors and internal control problems***. The point merits emphasis: Alere not only was months behind in its obligations to disclose its financial condition to the investing public, but ***kept Abbott in the dark as well, notwithstanding Abbott's continual requests for information***.
>
> ***These actions are part of a concerted effort to thwart Abbott's access to information***. That is not just Abbott's view. Indeed, Abbott recently received correspondence from a whistleblower alleging that Alere has interfered with Abbott's attempt to investigate possible legal violations in India by ***coaching witnesses to provide false information, retaliating***

> ***against those who refuse, and even sending Alere's head of finance in India on an unjustified "long leave" to make him unavailable for interview by Abbott***.

Alere, Def. Opp'n at 8 (emphasis added).

242. Included in Abbott's filing with the Delaware Chancery Court was a previously undisclosed email from a whistleblower (Alere India's Director of Finance), stating that Alere was, as discussed above, interfering with Abbott's attempts to investigate possible legal violations. The whistleblower's email stated that:

> I believe you guys are looking for me, whereas company management is saying I am not available, which is wrong, I am very much available but not allowed to come to office (They suspended me with pay). They have done this ***so that the truth will not come out in front of Abbott leadership***.

Alere, Def. Opp'n at 9 (emphasis added).

243. This email supports a strong inference that Alere executives have withheld from investors, including Abbott, material, negative information about the Company.

244. Eighth, the Individual Defendants Hinrichs and Nawana have admitted their personal familiarity with the Company's systems and processes. Indeed, on the Company's November 5, 2015 conference call with investors, Hinrichs acknowledged (with Nawana present on the call) that Hinrichs personally understood that, "the company has been run for a long time as a series of smaller entities that rolled up, and so therefore the information flow was sometimes scattered. We are in the process, as Namal and I have talked about, of converting to more of a global view and a global enterprise view of things." Along those lines, Hinrichs stated that "a couple months ago," the Company had "instituted a monthly financial review with all the executives and all the finance leadership that probes much more deeply into the monthly results and what that means for the forecast." As part of these monthly financial reviews, the Company's material weaknesses in internal controls should have been apparent to all of the

senior executives who participated in them. Indeed, Hinrichs claimed that he and Nawana were having "weekly calls" with "go-to market leaders in the regions" and that they were both "staying tightly abreast of what's happening in each of those regions." However, as Hinrichs further admitted on November 5, 2015 (although the whole truth of this admission was not yet plain to investors absent the Company's subsequent disclosures): "[N]ot having great harmonized systems is an excuse that should not be an excuse."

245. Ninth, as discussed above (at ¶ 183), Alere's accounting misstatement was a violation of an internal Alere accounting policy on revenue recognition.

246. Tenth, as discussed above (at ¶ 206), Alere was denied access to HETS in August 2015, impairing Arriva Medical's ability to insure against making claims on behalf of deceased patients, and jeopardizing its Medicare enrollment status.

247. Eleventh, as discussed above, Alere continually hid materially adverse information from Abbott and from its shareholders, including files about bribery probes and of Alere's foreign operations and U.S. billing practices, and failing to disclose prior to the Merger vote that Arriva's Medicare eligibility was revoked.

IX. CLASS ACTION ALLEGATIONS

248. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all those who purchased Alere's securities between May 28, 2015 and December 7, 2016, inclusive and who were damaged thereby. Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

249. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Alere's securities were actively traded on the New York Stock Exchange. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Millions of Alere shares were traded publicly during the Class Period on the NYSE. As of August 4, 2016, Alere had 86,734,565 shares of common stock outstanding. Record owners and other members of the Class may be identified from records maintained by Alere or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

250. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

251. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

252. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations and prospects of Alere;

(c) whether Defendants acted with scienter; and

(d) to what extent the members of the Class have sustained damages and the proper measure of damages.

253. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

X. LOSS CAUSATION

254. Defendants' wrongful conduct, as alleged herein, directly and proximately caused Plaintiffs and the Class to suffer substantial losses. During the Class Period, Plaintiffs and the Class purchased Alere securities at artificially inflated prices and were damaged thereby when the price of Alere securities declined when the truth was revealed. The price of Alere securities significantly declined (causing investors to suffer losses) when Defendants' misrepresentations, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, and/or the risks that had been fraudulently concealed by the Defendants materialized.

255. Specifically, Defendants' materially false and misleading statements and omissions misrepresented, *inter alia*, the Company's improper reporting of revenue under GAAP, the efficacy of the Company's internal controls over financial reporting, Alere's misconduct in its toxicology division, the Company's failure to timely recognize recall charges in connection with its INRatio products, and that the Company's likelihood of non-compliance with the FCPA.

When those misrepresentations and omissions were corrected and the risks concealed by them materialized, investors suffered losses as the price of Alere securities declined. As a result of the disclosure of the truth of Defendants' fraud, Alere's common stock price declined approximately 34%, plummeting from a Class Period high closing price of $55.39 per share on August 13, 2015 to close at $36.67 per share on December 7, 2016, the final day of the Class Period.

256. The disclosures that corrected the market prices to reduce the artificial inflation caused by Defendants' materially false and misleading statements and omissions are detailed below and summarized in the following chart, which identifies each corrective disclosure event and the price declines in Alere common stock resulting from the event:

Date*	**Corrective Event**	**Closing Stock Price**	**Stock Price Change**
03/15/2016	Alere announced that on March 11, 2016, it had received a grand jury subpoena from the 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. Alere also announced that it would be unable to file its 2015 Form 10-K within the previously-granted extension period (March 15, 2016), as it was continuing to investigate certain aspects of the timing of revenue recognition, specifically revenue cut-off, in Africa and China for 2013, 2014, and 2015 (and each quarter in those fiscal years).	$49.32	**-8%**

Date*	**Corrective Event**	**Closing Stock Price**	**Stock Price Change**
04/20/2016	During Abbott Laboratories' earnings conference call, Abbott CEO Miles D. White declined to affirm his company's commitment to the merger with Alere, stating, in relevant part that Alere has "had delays filing their 10-K. We don't know when they'll file their proxy. We don't know when they're going to have a shareholder vote. So right now I'd say it's not appropriate for me to comment on Alere."	$43.36	**-12%**
04/28/2016-04/29/2016 (**04/29/2016**)	After the close of trading on April 28, 2016, Alere announced: (i) that it had rejected Abbott's request to terminate the pending acquisition in exchange for between $30 and $50 million; and (ii) that Abbott had said it had "serious concerns" about the accuracy of Alere's financial condition in connection with Alere's delayed filing of its 2015 10-K and the government's investigations into the Company.	$39.00	**-10%**
7/12/2016	On July 12, 2016, in a Form 8-K dated that day, the Company disclosed the withdrawal of the INRatio products and stated that, at that time, Alere expected to record approximately $70-$90 million of related charges in 2016 relating to the withdrawal in the United States and related action outside the United States. In that same Form 8-K, the Company also stated that it expected to record an immediate non-cash impairment of $20-23 million and accelerated depreciation of approximately $33-37 million.	$38.61	**-3%**

Date*	**Corrective Event**	**Closing Stock Price**	**Stock Price Change**
07/27/2016-	*The Wall Street Journal* published an article disclosing that the DOJ's criminal fraud section had previously sent Alere a subpoena seeking patient-billing records and documents concerning government billing practices, specifically "information about Alere's efforts to collect copayments from patients, as well as forms submitted on their behalf to government programs such as Medicare." In addition, *The Wall Street Journal* reported that the DOJ was investigating whether Alere made payments or delivered items of value to doctors who ordered tests, conduct which the government considers to be illegal kickbacks.	$31.47	**-29%**
11/4/2016	On November 3, 2016, after the close of trading, it was revealed that Abbott had filed suit against Alere to compel Alere to produce documents that Alere had withheld from Abbott. In addition, on November 4, 2016, in a Form 10-Q for the third fiscal quarter of 2016, the Company disclosed that Arriva Medical had received a notice from CMS on October 5, 2016 revoking Arriva Medical's Medicare enrollment, because CMS had determined that, over a five-year period, Arriva Medical had submitted claims for reimbursement for 211 patients who were previously deceased. The revocation was effective as of November 4, 2016.	$36.10	**-16%**
12/7/2016	On December 7, 2016, Abbott filed suit against Alere to prevent the completion of the Merger.	$36.67	**-7.6%**
**Date of stock price drop in parentheses*			

257. Accordingly, as a result of their purchases of Alere's publicly traded common stock during the Class Period, Plaintiffs and other members of the Class suffered economic loss and damages.

XI. APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)

258. The market for Alere's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Alere's securities traded at artificially inflated prices during the Class Period. On August 13, 2015, the Company's stock closed at a Class Period high of $55.39 per share. Lead Plaintiffs and the other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Alere's securities and market information relating to Alere, and have been damaged thereby.

259. During the Class Period, the artificial inflation of Alere's stock was caused by the material misrepresentations and/or omissions particularized in this Complaint, causing the damages sustained by Plaintiffs and the other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Alere's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Alere and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when the truth was disclosed, negatively affected the value of the Company stock. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiffs and the other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

260. At all relevant times, the market for Alere's securities was an efficient market for the following reasons, among others:

(a) Alere stock met the requirements for listing, and was listed and actively traded on the NYSE, a highly efficient and automated market;

(b) As a regulated issuer, Alere filed periodic public reports with the SEC and/or the NYSE;

(c) Alere regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Alere was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

261. As a result of the foregoing, the market for Alere's securities promptly digested current information regarding Alere from all publicly available sources and reflected such information in Alere's stock price. Under these circumstances, all purchasers of Alere's securities during the Class Period suffered similar injury through their purchase of Alere's securities at artificially inflated prices and a presumption of reliance applies.

262. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are grounded on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information identified above, positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the material undisclosed facts, including

the severe undisclosed material weaknesses in the Company's internal controls, and the severe consequences of possible criminal proceedings against the Company for either its Toxicology unit's violations or its violations of the FCPA, and the Medicare billing violations by Arriva Medical, as set forth above, that requirement is satisfied.

XII. NO SAFE HARBOR

263. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Alere who knew that the statement was false when made.

COUNT I

Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

264. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

265. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and the other Class members, as alleged herein; and (ii) cause Plaintiffs and the other members of the Class to purchase Alere's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

266. Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Alere's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

267. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Alere's financial well-being, operations and prospects, as specified herein.

268. These Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Alere's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Alere and its business,

operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

269. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these Defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, products, projections and/or reports; (iii) each of these Defendants enjoyed significant personal contact and familiarity with the other Defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times, including communications with governmental and regulatory agencies; and (iv) each of these Defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

270. The Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Alere's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated

by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

271. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Alere's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired Alere's securities during the Class Period at artificially high prices and were damaged thereby.

272. At the time of said misrepresentations and/or omissions, Plaintiffs and the other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding the problems that Alere was experiencing, which were not disclosed by Defendants, Plaintiffs and the other members of the Class would not have purchased or otherwise acquired their Alere securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

273. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

274. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

COUNT II

Violation of Section 20(a) of The Exchange Act Against the Individual Defendants

275. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

276. The Individual Defendants acted as controlling persons of Alere within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

277. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to

control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

278. As set forth above, Alere and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: January 4, 2017

By their attorneys,

/s/Adam M Stewart

Edward F. Haber (BBO#215620)
ehaber@shulaw.com
Adam M. Stewart (BBO#661090)
astewart@shulaw.com
SHAPIRO HABER & URMY LLP
Seaport East
Two Seaport Lane
Boston, MA 02210
(617) 439-3939

Plaintiffs' Liaison Counsel

ABRAHAM, FRUCHTER & TWERSKY, LLP
Jeffrey S. Abraham (admitted *pro hac vice*)
jabraham@aftlaw.com
Lawrence D. Levit (admitted *pro hac vice*)
llevit@aftlaw.com
One Penn Plaza, Suite 2805
New York, New York 10119
(212) 279-5050
(212) 279-3655 (fax)

Plaintiffs' Lead Counsel

BERNSTEIN LITOWITZ BERGER & GROSSMANN LLP
Gerald H. Silk
Adam H. Wierzbowski
1251 Avenue of the Americas
New York, NY 10020
Tel.: (212) 554-1400
Fax: (212) 554-1444

Member of Plaintiffs' Executive Committee

ENTWISTLE & CAPPUCCI LLP
Vincent R. Cappucci
Robert N. Cappucci
Heather Sertial
299 Park Avenue, 20th Floor
New York, NY 10171
Telephone: (212) 894-7200
Fax: (212) 894-7272

Member of Plaintiffs' Executive Committee

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) on January 4, 2017.

/s/ Adam M. Stewart
Adam M. Stewart